



# Modernising the FSANZ Act

## Draft Regulatory Impact Statement

10 March 2021

# Contents

List of acronyms used in this report .....	2
1 Executive Summary .....	3
2 Background and context.....	15
3 The problems to solve .....	19
3.1 The Terms of Reference have called for a focus on inconsistencies with 'best practice' .....	19
3.2 Policy Problem 1   In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer .....	25
3.3 Policy Problem 2   Legislation does not enable a strong, resilient and agile food regulation system.....	35
3.4 Policy Problem 3   Current arrangements undermine the power of a single, joint food standards system.....	40
4 Rationale for government action .....	47
5 Options to address the Policy Problems .....	49
5.1 Option 1   Retain the status quo.....	50
5.2 Option 2   Modernise the Act to make it agile, resilient and fit-for-purpose.....	50
5.3 Option 3   Build on FSANZ's role to reinforce the bi-national nature of the joint food standards system .....	64
6 Impacts of reform options .....	69
6.1 Impacts of Option 1   Retain the status quo .....	69
6.2 Impacts of Option 2   Modernise the Act to make it agile, resilient and fit-for-purpose.....	74
6.3 Impacts of Option 3   Build on FSANZ's role to reinforce the bi-national nature of the joint food standards system .....	103
7 Discussion questions .....	122
8 Next steps .....	125
Appendix A Terms of Reference .....	126
Appendix B FSANZ Act Review Steering Committee members .....	128
Appendix C Review consultation plan .....	129
Appendix D Impact analysis assumptions .....	130
D.1 Assumptions underpinning other quantitative analysis .....	132
Appendix E Summary of comparable international food regulatory systems.....	134

## List of acronyms used in this report

ACCC – Australian Competition and Consumer Commission  
AMSA – Australian Maritime Safety Authority  
APEC – Asia-Pacific Economic Cooperation  
EU – European Union  
FDA – The United States of America’s Food and Drug Administration  
FRA – The Australia-New Zealand Food Regulation Agreement  
FRSC – Food Regulation Sub-Committee  
FSANZ – Food Standards Australia New Zealand  
FSCF – APEC Food Safety Cooperation Forum  
FSMA – The United States of America’s Food Safety Modernisation Act 2011  
GRAS pathways – Generally Recognised As Safe pathways  
ISFR – Implementation Subcommittee for Food Regulation  
JIFSAN – Joint Institute for Food Safety and Applied Nutrition  
MAS – Monetary Authority of Singapore  
MOU – Memorandum of Understanding  
MPI – New Zealand Ministry of Primary Industries  
NZFSSRC – New Zealand Food Safety Science and Research Centre  
SFCRs – Safe Food for Canadians Regulations (2018)  
SLA – Service Level Agreement  
RIS – Regulatory Impact Statement  
ToR – Terms of Reference  
UK – United Kingdom  
US – The United States of America

# 1 Executive Summary

Access to adequate food is a basic human right.<sup>1</sup>

While ensuring a safe food supply is a significant challenge in some parts of the world, people living in Australia and New Zealand can be confident in the quality and safety of the food they eat – even if they are unaware of the significant regulatory efforts exerted to achieve this.

The joint Australia-New Zealand food standards system has an excellent reputation for safety, which also underpins the industry's economic prosperity. The 2019 *State of the Industry Report* published by the Australian Food and Grocery Council found that the food and grocery sector (alone) injected AUD \$122.1 billion into the economy in 2017/18 and representing 32% of all manufacturing jobs.<sup>2</sup> Likewise, New Zealand's position is strong, with food and beverage exports in 2018 valued at NZD \$29 billion, accounting for 43% of New Zealand's total exports.<sup>3</sup>

The food industry is slated as a core driver of Australia and New Zealand's economic recovery post the COVID19 pandemic. Its success is contingent on Australia and New Zealand's continued reputation for high quality and safe food and both qualities in part owe their strength to the effectiveness of the joint food standards system. Food regulation is also an important lever in the growing need to shape population dietary and consumption trends, which are in turn associated with heightened risk of morbidity and mortality.

The *Food Standards Australia New Zealand Act 1991* (the Act) is one of several foundational instruments that make up the joint food standards 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 has been in place for almost 30 years, with few amendments over that time. Yet, in the same period, the food industry has evolved radically, with new technologies, more globalised supply chains, and shifting dietary patterns constantly pushing innovation and reshaping consumer expectations. Public health issues, such as changing consumption patterns, have increased concerns about chronic conditions relating to diet (such as obesity).

Many stakeholders have been quick to stipulate that the Australia-New Zealand joint food standards system is not broken; and FSANZ delivers a highly valued service to the community. They observed that there are many elements of the current scheme that should be preserved, including FSANZ's independence, bi-national nature, and scientific approach.

However, there is also evidence that the regulatory framework has struggled to keep pace with the changing landscape, which has challenged FSANZ to deliver efficient and effective regulation and minimise regulatory burden across the system.

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.

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<sup>1</sup> Attorney General Department 2020, available at: <<https://www.ag.gov.au/rights-and-protections/human-rights-and-anti-discrimination/human-rights-scrutiny/public-sector-guidance-sheets/right-adequate-standard-living-including-food-water-and-housing#what-is-the-right-to-an-adequate-standard-of-living>>

<sup>2</sup> Australian Food and Grocery Council 2020, *AFGC 2019 State of the Industry*, available at: <<https://www.afgc.org.au/download/afgc-2019-state-of-the-industry>>

<sup>3</sup> Ministry of Business, Innovation & Employment 2018, *Emerging growth opportunities in New Zealand Food & Beverage*, available at: <<https://www.mbie.govt.nz/dmsdocument/2209-emerging-growth-opportunities-nz-food-beverage-pdf>>

The Australian Government Department of Health (Department of Health) is leading the Review in partnership with the 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).

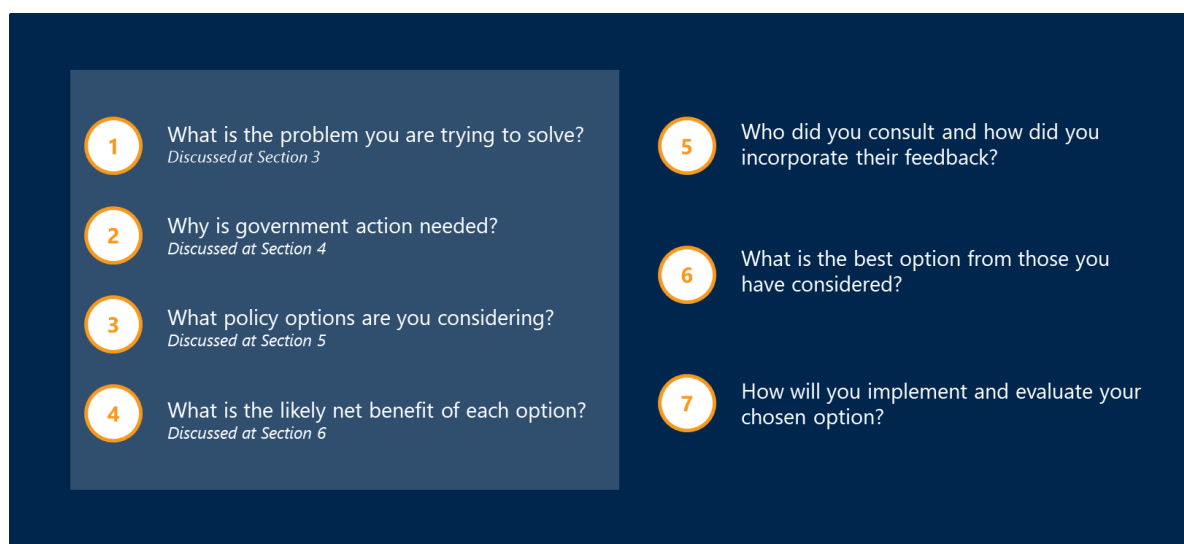
The ToR call for the Review to examine the Act and FSANZ's operations, with several key areas being called out for specific consideration. At this time, there is an opportunity to consider how legislative and operational changes can assist FSANZ to deliver its current statutory functions efficiently and effectively, 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 has involved extensive public consultation (see Appendix C), including the distribution of a scoping paper that attracted 92 written responses from a broad range of stakeholders across Australia and New Zealand. The scoping paper was aimed at confirming the most salient policy problems had been identified and sought feedback on some early 'reform ideas'. This draft RIS presents more developed reform opportunities, and invites feedback to specifically characterise the impact of key changes to inform a decision about which is the preferred option moving forward.

Specific discussion questions have been included for consideration, and feedback will be collected until Tuesday 18 May 2021 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.

The structure of this document is informed by the Australian Government Guide to Regulatory Impact Analysis, which sets out seven key questions that government must ask itself before seeking regulatory change. As shown in Figure 1, the draft RIS seeks to answer the first four questions only – the final three questions will be answered as part of the final RIS and informed by consultation on the draft RIS (see section 0 for next steps).

**Figure 1 | The seven guiding questions of regulatory impact analysis**



## The problems to solve

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 an ongoing case for regulation, where 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.

The legislative scheme is dated however, and there is evidence that its effectiveness is diminishing. This draft RIS calls out three broad Policy Problems to this effect:

- **Policy Problem 1 | The Act does not support efficient and effective regulation and is burdensome to administer in its current form.** Many of the legislative provisions inhibit risk-based and proportionate regulatory activities which create inefficiencies and delays in the system. FSANZ, governments, industry and consumer and public health groups all attract unnecessary costs attributable to the current framework.
- **Policy Problem 2 | Legislation does not enable a strong, resilient, and agile joint food standards system.** The Act currently reinforces a piecemeal and reactive regulatory focus to creating and amending food standards which does not support optimal population health or economic outcomes. Moreover, there is limited collaboration and integration of effort across the regulatory system; the wealth of expertise about food safety and food composition is distributed across many stakeholders and could be more effectively coordinated to deliver value to the joint food standards system and support Australian and New Zealand food businesses to maintain and enhance their competitive advantage in international markets.
- **Policy Problem 3 | Current arrangements undermine the power of a single, joint food standards system.** In its current form, the Act does not fully capitalise on a joint Australian and New Zealand system. The Act limits FSANZ's power to assist in food recalls and incidents and provides no formal remit for FSANZ to extend Australia and New Zealand's influence on the international stage. The current model results in inconsistent interpretation of food standards across jurisdictions and variable uptake of best regulator practice.

## Rationale for government action

Australian and New Zealand governments (at all levels) play a vital role in regulating food standards, including by providing a regulatory framework for how foods can enter the Australian and New Zealand markets. These roles are broadly understood and endorsed by all stakeholder groups consulted as part of the Review. Notwithstanding different views about the relative priority of different regulatory objectives, the role for government in ensuring a safe food supply that protects consumers, enables informed decisions and promotes economic opportunities for food businesses is broadly accepted.

## Options for reform and criteria to assess net benefit

### Guidance note

While this draft RIS presents three broad options for consideration, stakeholders are not being asked to consider the value of each option as an immutable package. Rather, feedback on this draft RIS will inform the combination of components that make up the 'preferred option' when developing the final RIS. For example, to reflect stakeholder feedback, the final RIS might identify Option 3 as the preferred option, where Option 3 encapsulates only two components of reform, rather than the three currently described. Each of those components might look slightly different to how they are presented in this document.

Finally, please note that the options presented for consultation are done so without prejudice; they do not represent any form of agreed position from any government in Australia or New Zealand.

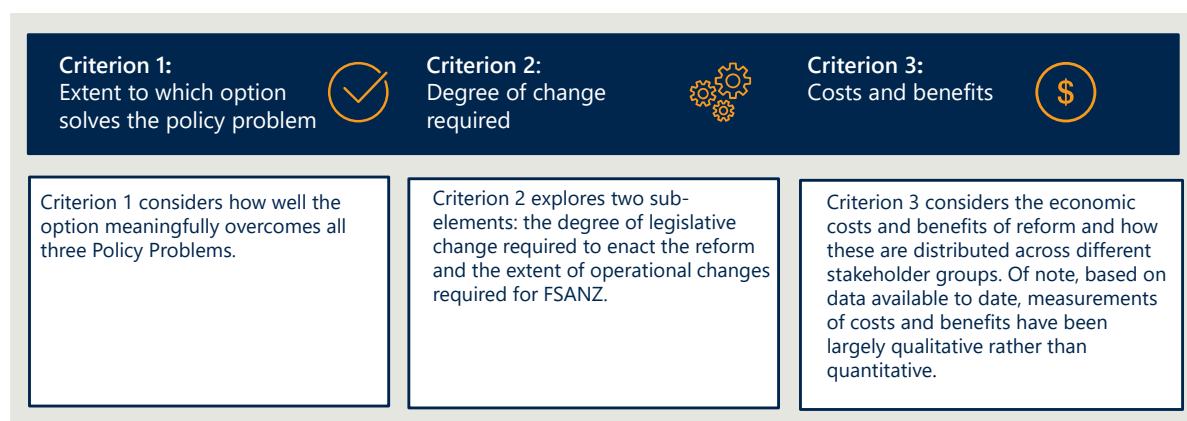
Three options to address the Policy Problems have been identified below.

The preferred option for reforming the Act will ultimately be identified in the final RIS, based on an assessment of each option against three evaluation criteria (Figure 2). Specifically, the final RIS will

conclude the overall net benefit of each option, and how key costs and benefits are distributed across key stakeholder groups.

This draft RIS *commences* this analysis and summarises the available research, data and consultation outputs. It does not attempt to calculate a net benefit for each option, or to describe in absolute terms how the costs and benefits are distributed across stakeholder groups -this information will be developed by incorporating feedback received on this draft RIS.

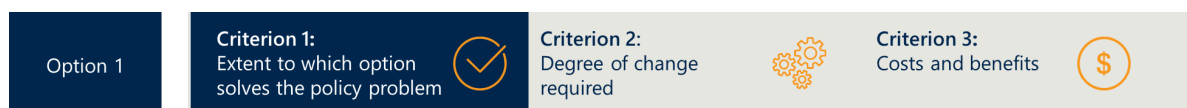
**Figure 2 | Three evaluation criteria are used in this report<sup>4</sup>**



The reform ideas expressed as part of each Option and a summary of the initial assessment and associated commentary is detailed below.

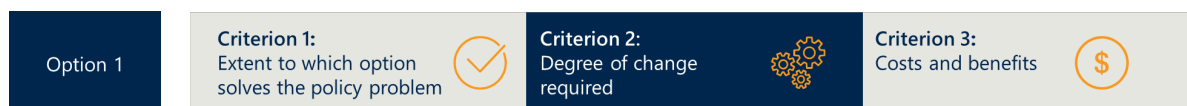
## Option 1 | Retain the status quo

This option suggests no changes to the Act or FSANZ's associated operations.






The Act is not fundamentally flawed or ill-equipped to deal with the market failures it is designed to address. Nonetheless, Option 1 does not meaningfully address any of the policy problems identified. Specifically:

- The Act would remain inefficient to administer
- The Act, in its current form, does not optimally support a strong, resilient and agile regulatory system
- Current arrangements will continue to undermine the power of a single, joint food standards system.



As no changes are proposed, no change is required. However, stakeholders would see this as a missed opportunity to update the Act so that it is future focused.

<sup>4</sup> Criterion 1 considers how well the option meaningfully overcomes all three Policy Problems. By tying this to the Policy Problems, this includes an exploration of how well the option supports efficient and risk-proportionate regulation; whether it improves or detracts from Trans-Tasman consistency; how it changes the relationships between the different players in the food regulatory ecosystem; and whether it is likely to facilitate trade while protecting health and safety; among other matters. This approach draws on input provided by stakeholders, particularly New Zealand Government stakeholders.

Option 1	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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The status quo represents the existing regulatory scheme and regulatory burden already faced by stakeholders.

For **industry**, the process of lodging applications to amend food standards imposes a burden of approximately AUD \$1.08 million (NZD \$1.16 million) per annum. Importantly, this cost is currently borne by a small number of stakeholders (for example, only 21 applications were lodged in 2019-2020). Stakeholders have reported that the costs associated with the application process is a real barrier to many small and medium businesses seeking variations to food standards - this is particularly problematic, as the burden associated with complying with food standards (which is out of scope for this Review) is significant and shared across food businesses of all sizes.

Beyond the costs of preparing an application, delay costs can be substantial for industry. For example, one business reported lost revenue of AUD \$130,000 (NZD \$139,100) for every month their application took to be approved (in addition to the USD \$40 million that had already been spent on research and development). This particular application took 11 months to finalise - based on the number of other low risk (level 1 and 2) applications FSANZ received that year (and assuming for the point of illustration that each application is similarly delayed and incur a similar delay cost), the current legislative framework represents up to AUD \$21.5 million (NZD \$23.0 million) per year in opportunity costs alone.

While these costs are significant, a benefit of the current approach is that it is well known and well understood by industry and provides a competitive edge to Australian and New Zealand businesses due to the high reputation for quality and safety.

For **governments**, this option represents moderate administrative costs associated with monitoring and enforcing food standards. For governments, although the status quo is not broken and has delivered good public health and trade outcomes over many years, evidence suggests that the system is strained.

For **consumers**, this option limits the range of products available to them (due to deterrent effect), however delivers sustained assurance around the quality and safety of the joint food standards system.

For **FSANZ**, Option 1 represents substantial operational costs to administer an outdated and inflexible Act. FSANZ is currently funded for approximately AUD \$20 million (NZD \$21.4 million) per annum, AUD \$0.54 million (NZD \$0.578 million) of which is used to administer the general procedure processes. Total funding for FSANZ over the next ten years is estimated at AUD \$200 million (NZD \$214 million). At this stage we have identified no benefits for FSANZ from this Option.

## Option 2 | Modernise the Act, make it agile, resilient and fit-for-purpose

Option 2 seeks to modernise the Act to make it agile, resilient and fit-for-purpose. This includes creating a framework premised on data-driven, intelligence led decision-making and better integration between system stakeholders. It comprises six key components of change:

- Component 1 | Clarify objectives and functions and reflect these in the Act
- Component 2 | Facilitate risk-based approaches to developing or amending food regulatory measures
- Component 3 | Build in flexibility to create bespoke regulatory sandboxes<sup>5</sup>




<sup>5</sup> A regulatory sandbox generally refers to a regulatory "safe space" that creates an environment for businesses to test products with less risk of being "punished" by the regulator for non-compliance. In return, regulators require applicants to incorporate appropriate safeguards to insulate the market from risks of their innovative business. It typically involves a framework set up by a regulator to allow pilot testing of innovations by private firms in a controlled environment (e.g. exemptions, allowances, time-bound exceptions etc.) overseen by regulators.



- Component 4 | Position FSANZ as the engine of food safety intelligence, equipped to drive forward-looking regulation
- Component 5 | Foster new approaches to working with other agencies, with a focus on intelligence-sharing
- Component 6 | Streamline FSANZ's governance and operations.

Option 2 would involve significant changes to the legislation and FSANZ's operations, including enhancing FSANZ's intelligence-gathering and coordination functions, and streamlining its internal governance arrangements.

Of note, both Options 2 and 3 propose to change or expand the functions of FSANZ – other components of the legislation not considered within these options would remain unchanged.




Option 2	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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Option 2 solves the first and second policy problems, but not the third:

- It would result in a modern, fit-for-purpose regulatory framework
- A strong, resilient and agile food regulation system; however, it would not substantially overcome current impediments to strengthen the bi-national nature of the joint food standards system.




An overview of how Option 2 addresses Policy Problems 1 and 2 is shown at Figure 3.

Figure 3 | Impact of Option 2 on Policy Problem 1 and 2

FROM...	➤	TO...
<b>POLICY PROBLEM 1</b>		
In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer	➤	The Act is fit for purpose and underpins efficient and effective regulation
The objectives and current functions of FSANZ are not clear	➤	Objectives and functions are clarified, including a clear authorising environment for FSANZ to lead key functions related to public health and safety
Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible	➤	Processes and decision-making arrangements to amend food standards are reconceived to support more flexible and risk-proportionate approaches
Elements of FSANZ's operations are inefficient	➤	FSANZ's operations are streamlined through changes to FSANZ's legislated governance and investments in business solutions
<b>POLICY PROBLEM 2</b>		
Legislation does not enable a strong, resilient and agile food regulatory system	➤	The Act supports an agile, resilient and collaborative food regulatory system
Statutory timeframes and resourcing constraints within FSANZ reinforce a piecemeal and reactive regulatory focus	➤	FSANZ is positioned as the engine of food safety intelligence, enabled to drive forward-looking regulation
Food safety and quality no longer guarantee a competitive advantage for Australian and New Zealand food businesses	➤	FSANZ successfully keeps pace with changing consumer expectations and can better leverage food regulatory measures to reflect these
There is limited collaboration and integration of effort across the regulatory system	➤	FSANZ collaborates with Food Ministers' Meeting, governments and others to drive intelligence-led decisions and quality research and policy work
<div> <div>Option 2</div> <div> <b>Criterion 1:</b> Extent to which option solves the policy problem            </div> <div> <b>Criterion 2:</b> Degree of change required            </div> <div> <b>Criterion 3:</b> Costs and benefits            </div> </div>		

There are a mix of 'quick wins' and more substantial legislative and operational changes embodied in Option 2. It would require a significantly new approach to developing or varying food standards or introducing foods to the market via other mechanisms. While these changes would require some operational adaptations for both FSANZ and industry, these could be achieved relatively easily.

This Option also imagines FSANZ in a more expanded role, as the centre of intelligence collection, collation and communication. This reform would represent a fairly significant effort for FSANZ to stand up a new function and change the way that FSANZ works with the governments, industry, and expert bodies.

Option 2	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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There are an extensive count of costs and benefits associated with the six components of Option 2.

For **industry**, there are some initial and ongoing compliance and substantive costs associated with transitioning to new arrangements to develop and vary food standards.

However, benefits include an AUD \$4.190 million (NZD \$4.483 million) reduction in the regulatory burden over 10-years associated with more risk-proportionate processes to vary food standards; improved competitive advantage from more credible claims about sustainability; with higher profits and improved consumer surplus as a result. A growth in innovation of 1% from approaches such as regulatory sandboxes equate to AUD \$3.5 million (NZD \$3.745 million) in exports, as per research from Swinburne University.<sup>6</sup>

For **governments**, there would be (currently unquantified) adjustment costs, compliance and enforcement costs associated with enforcing regulatory sandboxes and enforcing compliance for products that come to market through a lighter-touch, industry self-certified pathway.

Conversely, the benefits would include improved system and government agriculture policy alignment (including with the whole-of-government policy to increase the value of Australia's agricultural industry to AUD \$100 billion by 2030<sup>7</sup>), greater efficiency and timeliness on progress related to Ministers' strategic priorities and more effective regulation.

For **consumers**, costs include marginal increases in the risk of adverse health outcomes attributable to a more risk-proportionate assessment of products and changes to food standards (with the exception of the self-certified pathway where risks may be elevated).

Identified benefits include increased confidence in sustainability and safety of food, enhanced choice, improved access to information.

For **FSANZ**, this option would present some one-off establishment costs to set up new processes and arrangements and ongoing operational costs associated with these new arrangements. Streamlined governance arrangements could result in a reduction in administrative costs of AUD \$1.2 million (NZD \$1.3 million) over 10 years.

Benefits for FSANZ would be significant. There would be improved role clarity, operational agility and flexibility and improved efficiency through new pathways to change food standards delivering additional capacity savings of 24,000 hours (AUD \$1.755 million or NZD \$1.878 million) over 10-years.

### Option 3 | Build on FSANZ's role to reinforce the bi-national nature of the joint food standards system

Option 3 includes all of the reform ideas set out in Option 2, plus an additional three components of change. Compared to Option 2, Option 3 seeks to further amend the Act to give FSANZ broader statutory functions, aimed at reinforcing the bi-national nature of the joint food standards system. This includes reducing as much as possible the known tensions and inconsistencies that exist in the enforcement of food standards and building collective capability across the jurisdictions by promoting innovative and best practice regulation in the joint food standards system.

Option 3 includes all of the components set out in Option 2, *plus*:

- Component 1 | Provide for FSANZ to coordinate food incident and food recall responses, on its own initiative
- Component 2 | Provide for FSANZ to give greater guidance on food standards
- Component 3 | Position FSANZ to take on an enforcement role

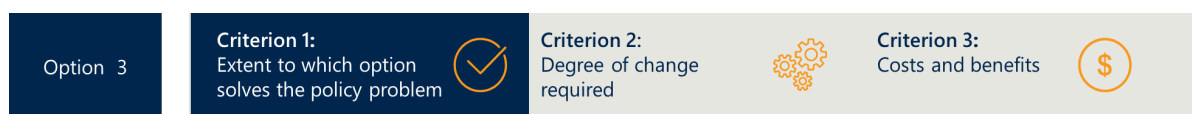
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<sup>6</sup> Swinburne University estimates that innovation within the food manufacturing sector in Australia is responsible for approximately AUD \$350 million in annual exports, AUD \$1.88 billion in annual business turnover, and 4,572 additional jobs created per annum. Note this report is not publicly available.

<sup>7</sup> Delivering Ag2030 (2020), Australian Department of Agriculture Water and the Environment. Available at: <https://www.agriculture.gov.au/sites/default/files/documents/delivering-ag2030.pdf>.

- Component 4 | Clarify legislation so FSANZ can extend Australia and New Zealand’s influence on the international stage.

Option 3 would involve an expansion in FSANZ’s operations, through a greater role in relation to enforcement guidance and/or activities.



Option 3 could solve all three Policy Problems. It would result in:

- A modern, fit-for-purpose regulatory framework
- A strong, resilient and agile food regulation system; and
- Greater consistency across Australia and New Zealand.

Figure 4 outlines how Option 3 would modernise FSANZ to address all three policy problems.

Figure 4 | Impact of Option 3 on Policy Problem 1, 2 and 3

FROM...		>	TO...			
POLICY PROBLEM 1						
In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer		➤	The Act is fit for purpose and underpins efficient and effective regulation			
The objectives and current functions of FSANZ are not clear		➤	Objectives and functions are clarified, including a clear authorising environment for FSANZ to lead key functions related to public health and safety			
Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible		➤	Processes and decision-making arrangements to amend food standards are reconceived to support more flexible and risk-proportionate approaches			
Elements of FSANZ's operations are inefficient		➤	FSANZ's operations are streamlined through changes to FSANZ's legislated governance and investments in business solutions			
POLICY PROBLEM 2						
Legislation does not enable a strong, resilient and agile food regulatory system		➤	The Act supports an agile, resilient and collaborative food regulatory system			
Statutory timeframes and resourcing constraints within FSANZ reinforce a piecemeal and reactive regulatory focus		➤	FSANZ is positioned as an engine of food safety intelligence, positioned to drive forward-looking regulation			
Food safety and quality no longer guarantee a competitive advantage for Australian and New Zealand food businesses		➤	FSANZ successfully keeps pace with changing consumer expectations and can better leverage food regulatory measures to reflect these			
There is limited collaboration and integration of effort across the regulatory system		➤	FSANZ collaborates with Food Ministers' Meeting, governments and others to drive intelligence-led decisions and quality research and policy work			
POLICY PROBLEM 3						
Current arrangements undermine the power of a single, joint food system		➤	Arrangements reinforce the bi-national nature of the food system			
FSANZ is limited in its power to assist in food incidents and food recalls		➤	FSANZ has the statutory power it needs to respond in an efficient and timely way to food incidents and food recalls			
Inconsistent interpretation and enforcement of food standards is an enduring issue for the system		➤	FSANZ provides greater guidance on food standards to reduce confusion for businesses and promote consistent, best practice enforcement			
FSANZ has no legislative remit to extend Australia and New Zealand's influence on the international stage		➤	FSANZ can full extend Australia and New Zealand's influence over food standard setting and support greater international trade opportunities			
Option 3	Criterion 1: Extent to which option solves the policy problem	✔	Criterion 2: Degree of change required	⚙️	Criterion 3: Costs and benefits	💰

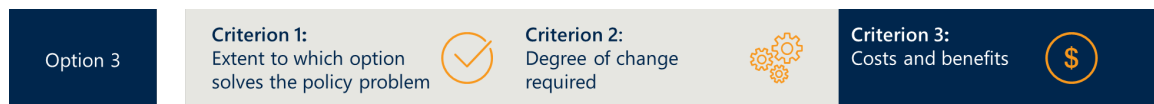
Implementation of this option will come with significant change. It includes all of the effort required to implement Option 2 and requires additional legislative changes, most significantly to position FSANZ to give interpretive advice and take on enforcement responsibilities.

While there are some components of change in Option 3 that simply formalises or extends on work that FSANZ is already doing (such as its role in food incidents and food recalls, or representing Australia and New Zealand as the standard setting body for the joint food standards system on the world stage), there are other changes that require a significant operational change for FSANZ (such as taking on regulatory activities), which would also have flow on operational changes for governments, and industry.

There is particular complexity around the establishment of a bi-national regulator which would also be challenging to implement, with little precedent for such a model existing. Positioning FSANZ as an enforcement agency would require negotiation between Australia and New Zealand under the Food Treaty and amendments to the Food Regulation Agreement, the Food Treaty and other related legislation in Australian states and territories and New Zealand. While it may create efficiencies and foster a more united approach to the regulation of food standards and the protection of population health and safety across the two countries, there are also serious risks of inefficiencies, duplication or delays where the proposed institutional arrangements replace pockets where the current arrangements are highly functional.

The value of positioning FSANZ to take on these functions on behalf of both countries is a particular point of consultation in this draft RIS.

Stakeholders have indicated they value the bi-national nature of the system and welcome ideas about how to further strengthen this approach. However, many stakeholders have also voiced reservations about how FSANZ will maintain its science-focus and independence in the context of a much broader statutory remit. Some stakeholders indicated significant concern about referring powers to the Australian Government and losing the ability to tailor the legislative framework governing monitoring and enforcement at a jurisdictional level.



For **industry**, there would be some compliance costs associated with understanding how to work with a new regulatory model, particularly if enforcement arrangements changed. On the other hand, there may be significant savings associated with more consistent interpretation and enforcement of food standards, and recognition of existing quality assurance complemented by (rather than duplicated by) government-initiated inspections and audits.

For **governments**, this Option would necessitate some upfront establishment costs, such as those associated with referring powers to the Australian Government to enable FSANZ to initiative food recalls and incident responses; or take on enforcement responsibilities. Ongoing operational costs for FSANZ as a result of this change would likely need to be passed on to Australian and New Zealand Governments.

In terms of benefits, changes to enforcement arrangement would potentially release capacity at the state, territory and New Zealand level, which could be then focused on progressing other work. Expanding FSANZ's work with key international trading partners will also likely end Australia and New Zealand's influence and open up new economic opportunities and strategic partnerships relating to food.

For **consumers**, this Option would not present any substantive costs. Benefits include increased confidence in the joint food standards system attributable to more timely detection and response to food contaminations or other incidents.

For **FSANZ**, this option would present some one-off establishment costs to set up new processes and arrangements, potentially including taking on new resources and building capability to deliver a regulatory function (including a communication campaign of approximately AUD \$200,000 to \$800,000 or NZD



\$214,000 to \$856,000). Ongoing operational costs associated with these new arrangements would include a sustained, higher employee count.

Benefits are likely to include increased ability to take immediate action to food incidents resulting in a safer joint food standards system, greater influence interpretation of food standards, a more unified, bi-lateral system and greater influence on how to approach food standards harmonisation.

## 2 Background and context

Food impacts every person every day of their lives.

Across Australia and New Zealand, tens of thousands of businesses create the supply chain of processors, manufacturers, distributors, and vendors, feeding a bi-national population of more than 30 million people (as well as a much broader export market).

Data from 2016 indicates that more than 230,000 Australians work in agricultural production<sup>8</sup>, and countless more work in the manufacture, supply, and sale of food and food-related products. Food production is particularly important in regional areas, where 82% of the food production workforce is located.<sup>9</sup> In New Zealand, the food and beverage sector accounted for 46% of all goods and services exports, making it by far the most important part of the country's trade economy.<sup>10</sup>

The availability of quality, safe food is something that most Australians and New Zealanders take for granted, yet it is a highly sophisticated regulatory system that creates this sense of security.

As shown in Figure 5, the regulatory system is made up of legislation, intergovernmental agreements and treaties, and involves every layer of government across Australia and New Zealand.

The *Food Standards Australia New Zealand Act 1991* (the Act) is one of the foundational instruments that make up the joint food standards system. It is empowered by the *Australian Food Regulation Agreement* (FRA), the *Joint Food Standards Treaty between Australia and New Zealand*, and various jurisdictional food Acts. It authorises Food Standards Australia New Zealand (FSANZ) to set and amend food standards, regulating how foods can enter the market in Australia and New Zealand, among other functions.

Of particular note:

- **The Australia and New Zealand Food Ministers' Meeting (previously the Ministerial Forum on Food Regulation (the Forum<sup>11</sup>))** is the body that sets the policy direction for the joint food standards system. It is comprised of ministers from all Australian and New Zealand jurisdictions. The Food Ministers' Meeting is established by the Food Regulation Agreement (FRA).<sup>12</sup>
- **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 Food Ministers' Meeting to progress key objectives for the joint food standards system. FSANZ is primarily funded through an Australian 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.
- **FSANZ is further supported by the National Measurement Institute (NMI).** This expert body supports FSANZ through laboratory services to check the implementation of the Food Code; research and

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<sup>8</sup> Binks B, Stenekes N, Kruger H, Kancans R, Snapshot of Australia's Agricultural Workforce (2016), The Australian Bureau of Agricultural and Resource Economics and Sciences (ABARES). Available at: <https://www.agriculture.gov.au/abares/products/insights/snapshot-of-australias-agricultural-workforce>

<sup>9</sup> Ibid.

<sup>10</sup> Growing the food and beverage sector, New Zealand Ministry of Business, Innovation, and Employment. Available at: <https://www.mbie.govt.nz/business-and-employment/economic-development/growing-the-food-and-beverage-sector/>

<sup>11</sup> As part of the response to the Review of the Former COAG Councils and Ministerial Forums (also known as the Conran Review), it was agreed in October 2020 that the Forum would be known as the 'Food Ministers' Meeting'. This change came into effect from February 2021.

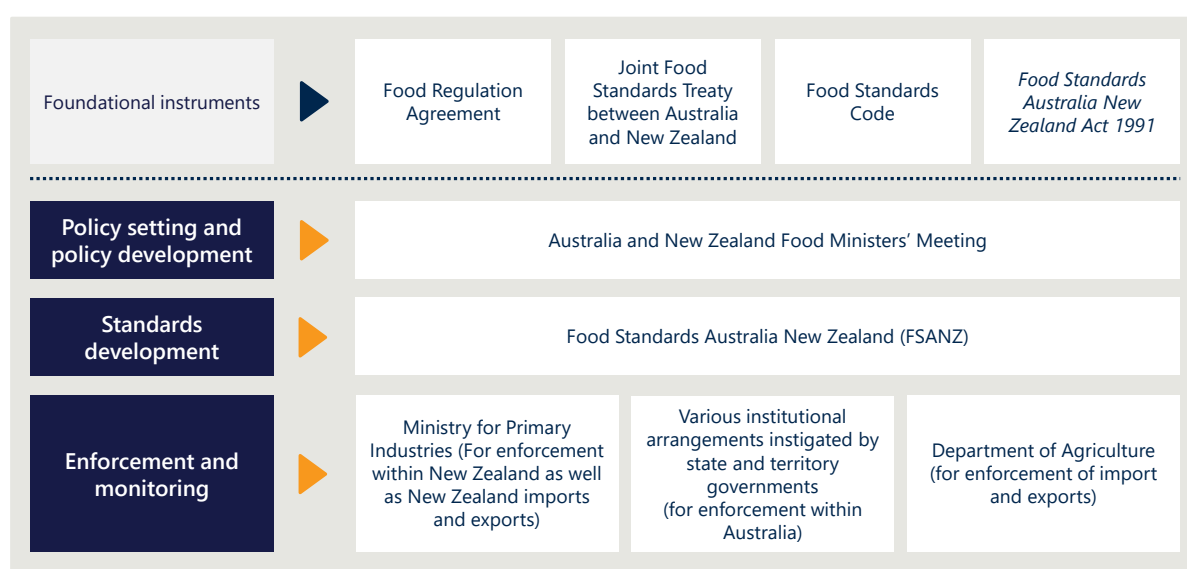
<sup>12</sup> The Food Ministers' Meeting's role, authorising environment, configuration and operations were considered as part of the Review of the COAG Councils and Ministerial Forums Report delivered to the Australian National Cabinet in October 2020.

development; industry and laboratory sector education; and expertise and advice on niche areas of Food Code guidance (for example for allergens). The NMI also contributes to crisis incident responses, particularly in cases of chemical and microbiological contamination.

- **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 the Ministry for Primary Industries (MPI).

The *Trans-Tasman Mutual Recognition Arrangement* (TTMRA) is a critical part of the background to the joint food standards system. The TTMRA is an agreement between the Australian Government, State and Territory Governments, and the Government of New Zealand which provides that, with a few exceptions, a good (including food products) that may be legally sold in Australia may be sold in New Zealand and vis versa. Note that the TTMRA gives jurisdictions the right to ban unilaterally, for 12 months, the sale of goods in their jurisdiction for health, safety or environmental reasons. Before the Temporary Exemption expires, the COAG Council responsible for the affected good is required to determine whether a particular standard should apply to the good, and if so, the appropriate standard.

**Figure 5 | Overview of the joint food standards system**

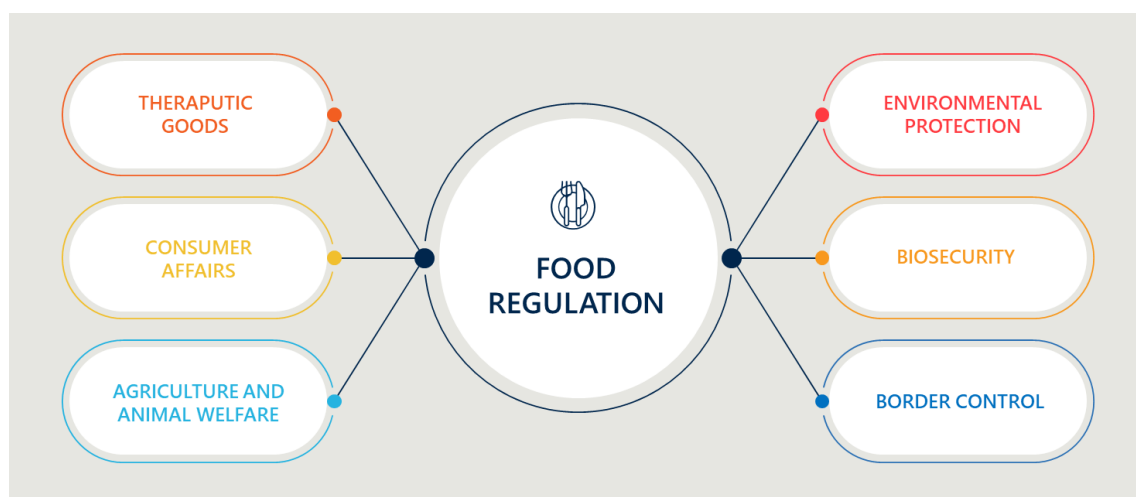


### **Food businesses must comply with multiple regulatory schemes.**

The Act is designed to protect health and safety (discussed further at section 3.1.4). Market actors make applications to FSANZ to change food standards in response to new innovations or interests in bringing foreign products to the Australian and New Zealand markets (note that only a small portion of these market actors possess the resources required to support these applications). Importantly, the Act works in parallel to a number of other regulatory schemes that provide other assurances related to food (Figure 6). Collectively, this represents a significant burden placed on industry. The implication of this complicated regulatory landscape is a constant need for Governments to streamline regulation to minimise impediments (while still achieving the objectives of regulation) and simultaneously respond to changes in the food industry.

This web of interconnected regulatory systems can also be confusing for consumers. For many, it is unclear who to contact if they become aware of a food-related issue, or what avenues exist for addressing food product related problems.

Figure 6 | Food regulation and a selection of key intersecting regulatory schemes



### The Act is almost 30 years old

The Act was written at a point in time where preventing foodborne illness or injury was the focal point of regulation. In the early 1990s, supply chains were far less globalised, and there were fewer large, national, or multi-national companies with sophisticated food safety processes in place. In this context, robust pre-market approvals helped to ensure that the food sold in Australia and New Zealand was safe to eat.

Over the last 30 years, however, there have been significant shifts in the food industry, including changing 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 multinational food market combined with new technologies has seen innovation excel at a pace never seen before. At the same time, new challenges have arisen, such as the need to maintain food security, and to respond to food crime and other issues.

### This review is an exciting opportunity for modernisation

In November 2019, the Food Ministers' Meeting (then the Forum) agreed on an ambitious plan to reform the regulatory system to ensure it remains strong, robust and agile into the future.

Reviewing the Act is a critical input to this work, and the Terms of Reference for the Review (see Appendix A) are suitably broad. They call for an examination of the Act and FSANZ's associated operations and responsibilities, with several key areas being called out for specific consideration.

This is an opportunity to consider how the Act can be modernised to work most effectively within a more mature and integrated joint food standards system. This includes exploring a transition to outcomes-based legislation, administered in a risk-based and proportionate manner.

While contained to a review of the Act, there is also an opportunity at hand to consider how the Act and FSANZ as a regulatory body can best contribute to the success of the overall scheme, for example, by supporting data-driven, intelligence-led<sup>13</sup> decisions across the regulatory landscape.

The Australian Government requires regulatory or legislative changes to be subject to a Regulatory Impact Statement (RIS) which confirms that regulation is the most appropriate approach to addressing a Policy Problem and to ensure that the benefits of proposed regulatory changes outweigh the costs. Similarly, New Zealand is committed to modernisation of key regulatory systems to support innovation, increase efficiency, and remove complexity while managing risk.

<sup>13</sup> The term 'intelligence' in this context refers to insights arising from food safety and composition data.

When considering regulatory burden, there is an important distinction to note between burden incurred under the Act and that of specific food standards; in the context of the Act, regulatory burden relates to the *processes* for changing food standards. There is a separate concept of burden associated with the actual contents of food standards, and while this is something FSANZ must systematically consider in its work, it is out of scope for this review.

While stakeholders across the board have (to date) been unanimous in their support for maintaining a high bar for safety and quality of food products produced or sold in Australia or New Zealand, the regulatory burden of the current approach is significant.

The need for minimising regulatory burden is well recognised across Australia and New Zealand's joint food standards system. For example, the Australian Institute of Food Science and Technology and RDS Partners released a report in early 2021 which made 11 recommendations to expand the growth potential of Australia's food manufacturing sector.<sup>14</sup> Four of these recommendations spoke directly about reducing regulatory burden and promoting innovation. KPMG's 2014 *Competitive Alternatives Study* found that regulatory burdens were a key contributor for the fact that the cost of doing business in the Australian agri-food manufacturing sector is higher than all comparable mature countries, including North America and Europe. In turn, Business New Zealand has identified complying with regulatory burdens one of the key barriers to growth in industry.<sup>15</sup> This is particularly the case for small businesses, who comprise a large proportion of food related industry.<sup>16</sup>

Although stakeholders have shown a degree of impatience for change there have also been clear words of caution:

- **Population health and safety should never be compromised.** The Review should not seek to make any recommendations that would reduce the quality and safety standards imposed on foods, which protect consumers and also create a reputation for excellence that give food businesses a competitive edge on the export market.
- **The joint nature of the regulatory scheme should not be weakened.** Stakeholders lauded the value of a joint food standards system. This has been recognised as a key strength, by Australian and New Zealand stakeholders alike, which delivers mutual economic and social benefits, through common food standards, joint policy development and a single food market. The joint food standards 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. Where FSANZ currently have several Australia-only functions, stakeholders felt the Review should seek to strengthen consistency across the Tasman, rather than reduce it.
- **FSANZ's independence and science-based approach is a key strength to maintain.** Stakeholders valued FSANZ as a credible, independent body with considerable technical and scientific expertise. Many stakeholders have observed that the rigorous scientific approach that FSANZ takes to its roles and functions plays a vital role in instilling confidence in the development and review of food standards, and in the joint food standards system more generally.
- **Multiple viewpoints should be considered.** Stakeholder interest in this Review has been high; and the feedback generated to date has given rich insight into the priorities and conflicts that exist with the system. To ensure balanced consideration of these viewpoints, this document specifically draws out the regulatory impact for four key stakeholder groups: FSANZ; Governments (Australian, New Zealand and state and territory); industry; and consumer and public health.

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<sup>14</sup> AIFST & RDS Partners, "Exploring the growth potential of Australia's food manufacturing sector: A new narrative for Australia's agri-food system" January 2021

<sup>15</sup> Regulation perspectives, Business New Zealand. ISSN 1177-293X. Available at: [https://www.businessnz.org.nz/\\_data/assets/pdf\\_file/0008/89504/Regulation-Perspectives.pdf](https://www.businessnz.org.nz/_data/assets/pdf_file/0008/89504/Regulation-Perspectives.pdf)

<sup>16</sup> Ibid.

## 3 The problems to solve

Government has a long-standing and widely accepted role in setting, monitoring, and enforcing standards for food. They do this to ensure that consumers can have a high degree of confidence in the quality and safety of food produced, processed, sold, or exported from Australia or New Zealand. The Act supports these objectives by establishing FSANZ and providing for processes to set and amend food standards, as well as undertake a range of other functions. Using the language of regulation, the Act is designed to:

- Protect the public good by reducing foodborne illness risks
- Stimulate economic opportunities by accounting for some negative externalities and thus indirectly supporting products, which increase consumer surplus
- Address information asymmetries by ensuring that consumers have adequate information and consequently are able to make informed choices which promotes high quality production.

Stakeholders consulted to date have spoken extensively about the value of FSANZ, and its contribution to ensuring food safety as part of its broader role in supporting population health and creating a strong reputation for Australia and New Zealand's food. Successive reviews of different aspects of the system have found that it generally functions well,<sup>17</sup> - though there are opportunities for improvement, particularly in relation to responsiveness, flexibility, and efficacy.

### 3.1 The Terms of Reference have called for a focus on inconsistencies with 'best practice'

The Terms of Reference for the Review called for a focus on areas identified as 'being inconsistent with best practice regulation and standard setting'. Nous considered a number of comparable food regulatory systems, including those in the United States, Canada, and the United Kingdom (a brief summary of these systems is provided at Appendix E). A number of Australian and New Zealand regulatory schemes which have been modernised have also been reviewed and collectively surfaced several common elements of these systems, which have been used to characterise 'best practice'. These elements are detailed below.

#### 3.1.1 Best practice element 1 | The legislative framework underpins efficient and effective regulation

To ensure that their respective food safety systems are efficient and effective, other regulatory schemes have established: clear objectives and appropriate statutory functions; principles-based and risk proportionate statutory processes; and decision-making arrangements and effective legislated governance arrangements.

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<sup>17</sup> For example, a 2005 Review of the Food Regulation Agreement 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 performing reasonably well" and "has to date been reasonably well-functioning and have provided a competitive advantage to Australia's food exports."



## Clear objectives and appropriate statutory functions set a strong direction for the regulatory scheme

While all the international food systems reviewed have positioned food safety as the unequivocal priority of regulation, there is less consistency around how legislation picks up and balances other objectives, such as trade, consumer choice, public health and environmental sustainability. For example, the objectives for the Canadian food act are:

- Improving food safety oversight to better protect consumers
- Strengthening and streamlining legislative authorities
- Enhancing international market opportunities.

Conversely, the general objectives of food regulation in the EU are to:<sup>18</sup>

- Guarantee a high level of protection of human life and health and the protection of consumers' interests. Also guarantee fair practices in food trade, taking into account animal health and welfare, plant health and the environment.
- Ensure free movement of food and feed manufactured and marketed in the Union, in accordance with the General Food Law Regulation.
- Facilitate global trade of safe feed and safe, wholesome food by taking into account international standards and agreements when developing Union legislation, except where this might undermine the high level of consumer protection pursued by the Union.

Regardless of the objectives stated, there is evidence that these international food acts have designed the statutory functions of the standard-setting body and regulators to deliver on these objectives.

## The statutory processes and decision-making arrangements are principles-based and designed to enable risk to drive processes

Modern regulatory schemes employ risk-based decision-making approaches to ensure that rules are proportionate and minimally burdensome for all stakeholders. For example, *the New Zealand Food Act 2014* is explicitly risk-based and categorises food businesses by risk, where higher-risk businesses are subject to more stringent regulatory oversight.

Modern standard setting bodies increasingly do the same. For example, when setting standards relating to the safety of food products Health Canada, the body responsible for setting health and safety standards employs a proactive decision-making framework for identifying, assessing, and managing health risks.<sup>19</sup> Importantly, this risk framework gives consideration to a broad array of potentially affected areas, including environmental risks, socioeconomic risks, industry and government risks, and population health risks. By adopting this broad lens when assessing risk in setting standards, Health Canada not only ensures that standard setting processes are consistent, but also that standards are set with a cognisant understanding of what potential costs and benefits those standards could have to the food sector and beyond.

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<sup>18</sup> Food Law General Principles, European Commission. Available at: [https://ec.europa.eu/food/safety/general\\_food\\_law/principles\\_en](https://ec.europa.eu/food/safety/general_food_law/principles_en)

<sup>19</sup> Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks, August 2000, Health Canada. Available at:

<https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html>

## Legislated governance arrangements support efficient and effective decision-making

The current academic discussion<sup>20</sup> around best practice governance has emphasised a move to smaller, skills-based boards with streamlined nomination processes that better support the organisations objectives and functions.

- **Small boards.** Small boards are valuable not only for minimising governance costs and increasing the efficiency of decision-making, but also for ensuring that all members are active contributors to the board's functions. By reducing their size, modern governance bodies achieve all three benefits – lower governance costs, more efficient decision-making, and more engaged board members.
- **Independent, skills-based boards.** Independent, skills-based boards are best placed to make decisions that support the outcomes pursued by standard setting organisations. Independence, or at least a majority composition of independence, ensures that the board makes decisions in the best interests of the organisation and its objectives, rather than those of partisan groups. In support of this, skills-based boards ensure that they have the capability to effectively deliver their responsibilities. In particular, this means possessing the subject-matter expertise to make decisions in a way that is cognisant of the reality of the organisation.
- **Proactive nomination and appointment processes.** In keeping with best practice, modern governance committees keep a pipeline of potential candidates to fill vacancies as required. By adopting this proactive approach, modern boards reduce decision paralysis brought about by long appointment periods and ensure that the organisation remains effective amidst organisational turnover.

### 3.1.2 Best practice element 2 | Regulatory policy and practice focus on agility and responsiveness

There was a strong emphasis within the reviewed regulatory schemes on building in agility and responsiveness, as discussed below.

#### The legislative frameworks focus on preventing harm

Modern regulatory systems are focused on identifying and mitigating risk rather than responding to it. For example, when the US updated its *Food Safety Modernisation Act* (FSMA), it changed the objective of the regulatory system from responding to public health matters to preventing them. The FSMA also:

- Expanded the FDA's authority to conduct mandatory recalls of contaminated food products
- Enhanced surveillance systems to investigate foodborne illness outbreaks
- Established new preventative controls and food safety plans at some food processing facilities and farms
- Enhanced the FDA's traceability capacity within the nation's food distribution channels
- Increased inspection frequencies of high-risk food facilities (both domestic and foreign facilities)
- Expanded the FDA's authority and oversight capabilities with regard to foreign companies that supply food imports to the US.

From a standard-setting perspective, modern regulatory schemes also place a strong focus on pre-market assessment to ensure quality and safety before products are allowed to enter the market, complemented

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<sup>20</sup> Mangalam, S, Hodges, C & Sharpington, L 2020 'Theory Paper on Contemporary Regulatory Models' prepared by PRISM Institute, Canada for Safe Food Production Queensland. This paper has been developed as part of the jurisdictional consistency project being undertaken as part of the P3 reform program. It was provided to Nous by the Australian Department of Health.

by a strong post-market surveillance role. The balance between the pre/post is also driven by risk, with more low-risk products facing less scrutiny up front. For example, the Australian *Therapeutic Goods Act 1989* requires rigorous consideration of most medicines and therapeutic goods before they are approved for use in Australia, however there are 'lighter touch' pathways available for very low-risk products to be brought to market (such as tongue depressors or band aids) with a stronger post-market compliance monitoring focus.

### **There is an emphasis on partnerships between regulators and regulated entities**

Modern regulatory schemes place an emphasis on detecting and responding to risks and opportunities in order to keep pace with global trends and the broader industry landscape rather than only responding to them. Because of this, they employ partnerships within regulatory schemes with industry and centers of research that are essential for ensuring that policy levers remain consistent across the broader regulatory context. For example, Canada actively partners with businesses to understand the evolving industry landscape and how the regulatory system can best adapt to that context. In particular, Canada employs a series of non-regulatory initiatives, including an integrated risk-management scheme derived from greater use of data, to ensure that both regulators and industry are able to actively pre-empt sources of risk, and work together to resolve them.

### **The Regulatory scheme has in-built systems to actively support innovation**

Many of the regulatory systems revised had features that gave standard-setting bodies and regulators the flexibility to help bring new products to market efficiently and safely. For example, the US introduced a Generally Recognised as Safe (GRAS) pathway to expedite the introduction of very low risk food substances which are analogous to other products already approved and available. In practice this operates as a limited industry self-substantiation scheme.

In the UK and Singapore, very new approaches to regulation are being used in the financial services and therapeutic goods systems, in the form of 'regulatory sandboxes' (see page 95 for detailed examples). These are being used to create bespoke regulatory conditions for products that are ill suited to a static regulatory framework.

## **3.1.3 Best practice element 3 | There is a deliberate effort to harmonise regulation and standards**

There has been a concerted attempt to minimise regulatory burden by minimising duplication or inconsistencies across jurisdictions, as well as greater alignment with international standards.

### **Many modern schemes have replaced jurisdiction-based legislative schemes with unified national schemes**

In recent years, several Australian regulatory schemes have replaced state and territory-based legislation with single national laws and regulators. For example, in Australia the *Marine Domestic Commercial Vessel National Law Act 2012* replaced eight different marine safety regulatory systems with a single regulatory framework for certification, construction, equipment, design, and operation of domestic commercial vessels inside Australia's exclusive economic zone. It also established the Australian Maritime Safety Authority (AMSA) as a single national regulator for domestic commercial vessels. Through this deliberate effort to harmonise regulation, the AMSA is now able to effectively regulate Marine safety without burdening interstate and international traders with a swathe of inconsistent regulation.

Another example of a modern regulatory scheme that replaced jurisdiction based legislative schemes with a unified national scheme is the *Model Work Health and Safety Act 2011 (Cth)*. Written in recognition of the vast disparity in work health and safety protections for workers in different Australian jurisdictions, the

model law was implemented to harmonise protections across Australia. Although the Act needed to be enacted or passed by Parliament in each jurisdiction, most jurisdictions have now developed legislation to give effect to the Model Work Health and Safety Act, including the Commonwealth, with minimal amendment. Although the Act did not reduce worker health and safety to a single national act, it reflects the increasingly recognised need for regulatory unification and harmonisation across all levels of government and effectively created a single set of laws Australia-wide.

### **Modern regulatory schemes support collaboration between countries to apply a common set of standards that support inter-jurisdictional trade**

The European Union, via the European Commission, employs a General Food Law which establishes general principles, requirements, and procedures that underpin decision making in matters of food and feed safety in EU jurisdictions. It covers all stages of food and feed production. Since 2018, this has been supported by the Novel Food Regulation scheme, which acts as the standard setting procedure for food safety in the EU. This procedure establishes a standardised list of approved foods and additives that is applied across participating nations and considers applications from organisations to change those standards in similar way to FSANZ. The system is aided by the European Food Safety Authority which provides scientific advice for the acceptance of applications by industry for the inclusion of certain products.

Further, sophisticated regulators (including both Australian and New Zealand) typically partner with a number of international organisations, such as the International Council of Harmonisation and the Asia-Pacific Economic Cooperation, to promote harmonisation domestically and internationally. These organisations have been important to improve alignment between jurisdictions.

### **3.1.4 The current Australia and New Zealand joint food standards system embodies some – but not all – of these best practice characteristics**

When compared to the elements of best practice identified in section 3.1, several strengths of the Australian-New Zealand joint food standards system become apparent.

#### **The joint food standards system is regarded as a highly effective scheme with a strong emphasis on protecting food safety**

Research and stakeholder views collected to date have indicated that the regulatory requirements set out in the Act have resulted in a very high degree of assurance around the quality and safety of food produced, manufactured or sold in Australia and New Zealand.

FSANZ in its role in administering the Act, plays a vital role in instilling confidence in the quality and safety of the food supply. Stakeholders consulted to date have emphasised FSANZ's independence and technical expertise as highly sophisticated and critical to the success of the scheme. Particularly, by adopting a rigorous approvals process with minimal opportunity for influence from indirect stakeholders, FSANZ ensures that empirical evidence of consumer safety is the deciding factor in the approval of products. In turn their independence means that consumers can have confidence that the process has not been warped by other interests, preserving the credibility of the scheme as a whole.

#### **The Act has a strong preventative focus**

The current FSANZ regulatory scheme employs a rigorous pre-market assessment process characterised by a system of substance inclusion rather than exclusion. FSANZ places an onus on industry to demonstrate that substances are safe before allowing their use in products. Although this creates a much higher burden on industry than other schemes, it is the most effective system of harm prevention.

The Act works in complement to jurisdiction-level food Acts in driving a preventative focus in food safety. For example, in New Zealand food businesses must follow a programme setting out how they will meet their food safety responsibilities and demonstrate to independent verifiers that they are following the plan and meeting the regulatory standards. Where necessary there is enforcement for those that do not comply, for example MPI can direct businesses to recall their product. As an Australian example, in Victoria, food businesses work closely with local council level environmental health officers. Similarly, to New Zealand, these officers adopt a risk-based approach that allows businesses some flexibility to establish their own food safety plan that, whilst relevant to their context, nonetheless upholds a high safety standard.

### **The bi-national nature of the joint food standards system delivers economic and social benefits**

The bi-national nature of the joint food standards system delivers economic and social benefits for both Australia and New Zealand. It 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.

Additionally, the joint food standards system has strengthened ties between Australia and New Zealand as an economic bloc, increasing the incentive for foreign exporters to meet the standards in both countries, and improving the diversity of products available to consumers within each.

### **3.1.5 There are several opportunities to improve the Act to address known tension points and better align it with best practice**

It is important to note that the Act is not fundamentally flawed or ill-equipped to deal with the market failures it is designed to address. Rather, there is evidence that the Act has aged, and the broad policy problems described below reflect an accumulation of small issues where the legislation or FSANZ's operations has not kept pace with changing industry practices and consumer expectations, or modern regulatory thinking.

Three key policy problems have been identified, summarised at Figure 7 and explored in detail below.

Figure 7 | The three broad Policy Problems to solve

Problem number	Policy problem
1	<p><b>In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer</b></p> <ul style="list-style-type: none"> <li>a) The objectives and current functions of FSANZ are not clear</li> <li>b) Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible</li> <li>c) Elements of FSANZ's operations are inefficient</li> </ul>
2	<p><b>Legislation does not enable a strong, resilient and agile food regulatory system</b></p> <ul style="list-style-type: none"> <li>a) Statutory timeframes and resourcing constraints within FSANZ reinforce a piecemeal and reactive regulatory focus</li> <li>b) Food safety and quality no longer guarantee a competitive advantage for Australian and New Zealand food businesses</li> <li>c) There is limited collaboration and integration of effort across the regulatory system</li> </ul>
3	<p><b>Current arrangements undermine the power of a single, joint food system</b></p> <ul style="list-style-type: none"> <li>a) FSANZ is limited in its power to assist in food incidents and food recalls</li> <li>b) Inconsistent interpretation and enforcement of food standards is an enduring issue for the system</li> <li>c) FSANZ has no legislative remit to extend Australia and New Zealand's influence on the international stage</li> </ul>

## 3.2 Policy Problem 1 | In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer

Four sub-issues to Policy Problem 1 are discussed below.

### 3.2.1 The objectives and current functions of FSANZ are not clear

Without concise objectives, the Act is not well positioned to overcome the market failures described in Section 6, including negative externalities and information asymmetries.

#### 'Protecting public health' needs defining

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.

In practice, food regulatory measures established by the Act are already being used to protect both short- and long-term health; in 2013, the Food Ministers' Meeting (then the Forum) issued a ministerial guideline which indicates that *"Public health and safety in relation to food refers to 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 [should] takes into consideration both long-term health impacts and immediate health risks in the development and review of food regulatory measures”.*

The Food Ministers’ Meeting has issued several policy guidelines relating to long-term public health, including those relating to food labelling to support consumers make informed healthy choices; nutrition, health and related claims; fortification of foods with vitamins and minerals; and front of pack labelling, among others.

FSANZ has also finalised a number of amendments to food standards over the years which relate to long-term public health, including the use of additives in highly processed products such as sugar sweetened beverages and appropriate information labelling.

As discussed further below, ministerial policy guidelines are just one of the factors to which FSANZ must have regard when developing food regulatory measures. Clarifying the definition of the term in the primary legislation is an important step to creating the overall strategic direction for the Act and for FSANZ.<sup>21</sup>

### **Facilitation of trade and economic benefits are not explicitly stated goals 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 a domestically or internationally competitive industry. This exclusion of trade in FSANZ’s core objectives does not reflect the importance of a competitive domestic and food export food industry for both Australia and New Zealand.

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. However, this does not provide scope for FSANZ to adequately consider the impact of regulatory measures on industry, particularly small businesses.

### **FSANZ’s objectives do not encompass modern priorities around food sustainability**

FSANZ’s objectives are currently mute on the issues of food sustainability. This leaves FSANZ no levers to consider sustainability issues when developing or reviewing food regulatory measures. Consideration of food sustainability is also critical for the joint Australia-New Zealand food standards system to keep pace with the international market, as trading partners are beginning to expect evidence of food sustainability on exports.

Sustainability in a food regulation context could be limited to environmental impacts of the joint food standards system or could be broadened to encompass food security, health, economic and social impacts. Environmental sustainability contemplates the impact of agricultural practices, food processing, distribution, packaging, and other activities in the food supply chain on climate change, biodiversity, soils and waterways, and ultimately future food security.<sup>22</sup> Examples of environmentally unsustainable practices include high levels of greenhouse gas emissions from livestock, inappropriate aquaculture

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<sup>21</sup> The objectives of the Act should harmonise with the overarching objectives of the food system. Work to develop a vision for the system (and its overarching objectives) is currently underway and changes will be ultimately captured in a revised Food Regulation Agreement.

<sup>22</sup> Food production and the Environment, The University of Melbourne. Available at: <https://fvas.unimelb.edu.au/research/projects/foodprint-melbourne/school-resources/general-resources/food-production-and-the-environment>

practices and excessive plastic packaging. Consumers and other stakeholder groups are increasingly concerned with environmental sustainability of food and are exercising their purchasing power accordingly.

Sustainability is being incorporated into global food discussions, as evidenced by the focus of the United Nations Food Systems Summit 2021,<sup>23</sup> and food regulatory systems are becoming more aware of their critical role in promoting food sustainability. What this role could look like is still being developed.

As a specific example of the role of regulation in food sustainability (but in no way illustrative of the scope of the problem or solution), industry can make unregulated claims regarding the environmental sustainability of a product (e.g., 'dolphin-safe tuna' or 'carbon-neutral beef'). This information asymmetry leads to a 'Market for Lemons' phenomenon, where consumers cannot easily ascertain the veracity of environmental claims, and products with genuinely good environmental attributes cannot establish an appropriate market share. This specific example is less of a concern in New Zealand where the New Zealand Commerce Commission has a clear role in overseeing environmental claims made by industry.<sup>24</sup>

### **FSANZ's objectives do not include a recognition of indigenous culture and food expertise**

Another priority not currently covered by the joint food standards system is the recognition of indigenous culture and food expertise.

In referring to indigenous culture and food expertise in this document the Australian and New Zealand Governments both acknowledge Aboriginal and Torres Strait Islander people of Australia and Māori, tangata whenua of New Zealand.<sup>25</sup> The New Zealand Government has a constitutional requirement to respect its obligations to Māori under the Treaty of Waitangi and to deliver policy in a way that enhances Crown/Māori relations. However, celebrating and fostering Indigenous culture is a live priority for the Australian and state and territory governments as well. Our Governments are joint signatories to the 2020 Indigenous Collaboration Arrangement between Australia and New Zealand.<sup>26</sup>

The current language in the Act is not primed to recognise traditional foods and food production, preservation, and processing techniques. In some instances, such approaches may be dealt with under arrangements for novel (or non-traditional) foods under Standard 1.5.1 of the Food Standards Code. This suggests issues with how the determination of what is 'traditional' under (as defined in 1.1.2 – 8 of the Food Standards Code) is made. A more culturally inclusive framework could better recognise indigenous culture and food expertise and support timely entry to market for indigenous food businesses.

As another example, the current scheme does not adequately support alternative methods of validating the safety of food. While the Act provides for FSANZ to consider contemporary scientific evidence in risk analyses, a framework to consider traditional indigenous knowledge alongside western science will help ensure this type of evidence is appropriately explored. For example, Te Āo Māori's emphasis on respect and reciprocity in relating to the natural world may inform approaches to sourcing and testing evidence.<sup>27</sup> Anecdotally, some Māori agribusinesses may be reluctant to engage in animal testing to assure toxicological safety.

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<sup>23</sup> United Nations Food Systems Summit 2021 – Summit Vision. Accessed on 25/02/2021 from <https://www.un.org/en/food-systems-summit/vision-principles>.

<sup>24</sup> Environmental Claims Guidelines – a guide for traders, (2020). Commerce Commission New Zealand. Accessed via [https://comcom.govt.nz/\\_data/assets/pdf\\_file/0017/220247/Environmental-claims-guidance-July-2020.pdf](https://comcom.govt.nz/_data/assets/pdf_file/0017/220247/Environmental-claims-guidance-July-2020.pdf).

<sup>25</sup> Wording taken from the ANZ Indigenous Collaboration Agreement 2020.

<sup>26</sup> Available at: <https://www.tpk.govt.nz/en/a-matou-mohiotanga/culture/indigenous-collaboration-arrangement>.

<sup>27</sup> Dale, A.R., Perrott, J., Biddle-Walker, T., & Walker, J.K. (2015, April). Tikanga Māori: Animal cadavers used for teaching animal euthanasia. In IIDRC Proceedings Editorial (Ed.), International Indigenous Development Research Conference 2014 (pp.23-30); Maori Party perspective on animal Welfare Amendment Bill, (2020). Pacific Scoop independent news. Accessed via <https://core.ac.uk/download/pdf/70769015.pdf>.

## 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 1).

Table 1 | 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 Food Ministers' Meeting (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.

Upon drafting a regulatory measure, FSANZ refers the matter to the Food Ministers' Meeting for ratification. Some stakeholders have reported that there can then be challenges in progressing an amendment where there may be a political element to the change (for example, stakeholders indicated that anything to do with infant formula often generates debate about the use and promotion of formula as a substitute to human breast milk).

Currently, the Food Ministers' Meeting can reject the draft by 'registering their concerns' (s 86). The Food Ministers' Meeting 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 measure,<sup>28</sup> and this means that the Food Ministers' Meeting 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

<sup>28</sup> The Food Ministers' Meeting 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.

terms of the resourcing required and the cost and delay involved in Food Ministers' Meeting-directed reviews.

### **FSANZ's role could be clarified in certain respects**

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 role in developing and reviewing food regulatory measures, FSANZ 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.

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

While FSANZ's 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 broader role in achieving public health, nutrition, and safety objectives beyond acute food safety issues, such as promoting healthy eating and protecting Australians and New Zealanders from diet-related diseases.<sup>29</sup> 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.

## **3.2.2 Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible**

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 8). 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.

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<sup>29</sup> While public health is recognised as a critical issue for food regulation, the scope of this review as defined in the Terms of Reference is contained to population health protection.

Figure 8 | Process for creating and varying food regulatory measures via applications and proposals

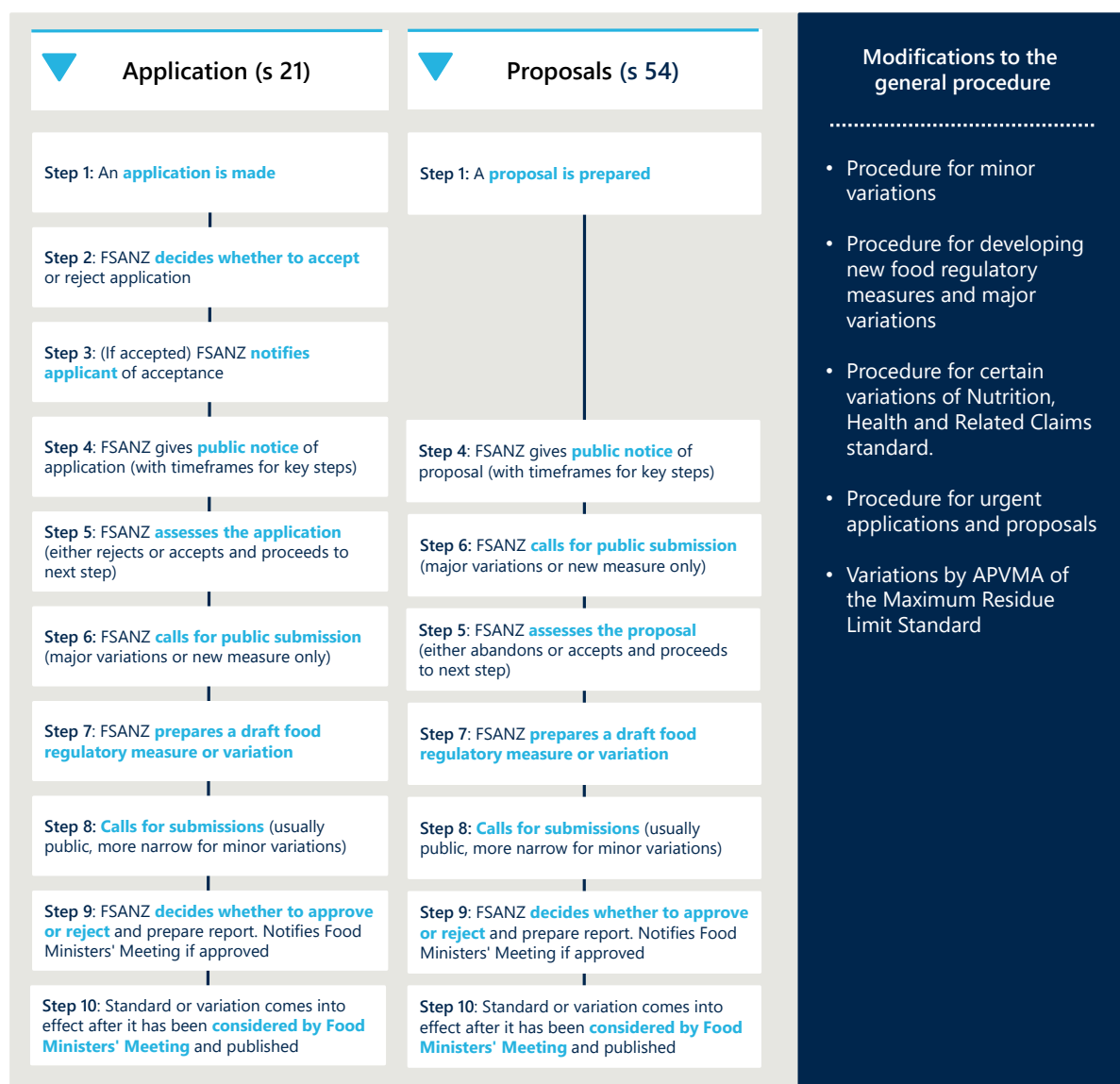


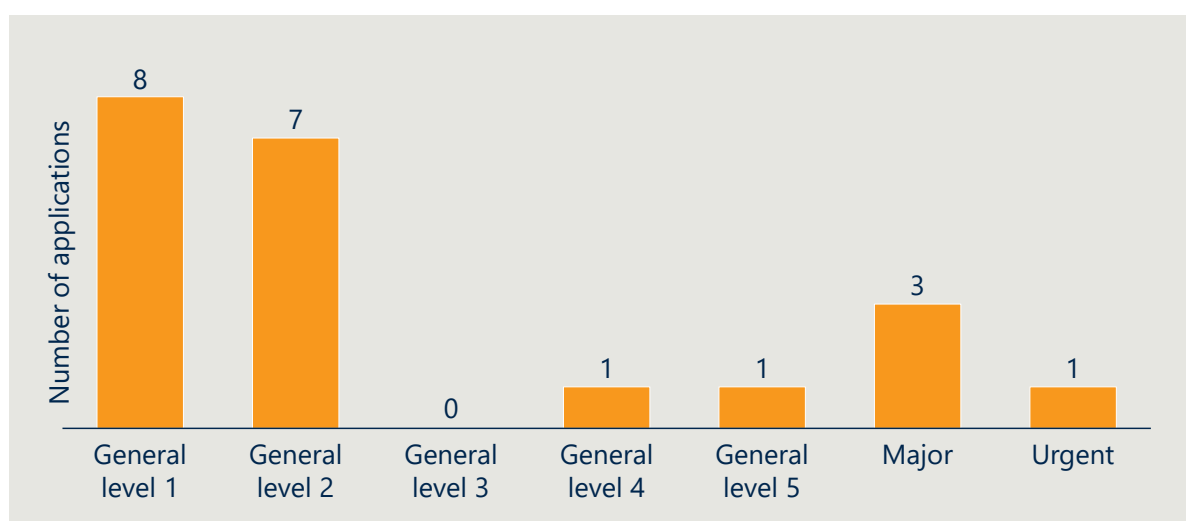
Figure 9 breaks down the number of applications approved by FSANZ in 2019-2020 by level. Applications are categorised by their nature and each level is associated with a maximum expected application administrative time to process:

- General level 1 – up to 240 variable hours. Examples of applications made at this level include those that involve a new source organism for enzymes or a minor change to a labelling requirement.
- General level 2 – up to 380 variable level hours. Examples of applications made at this level include those that involve extending the use of a food or additive or changing the compositional requirement of a food.
- General level 3 – up to 540 variable hours. Examples of applications made at this level include those that involve extending the use of a substance to a specific food or introducing a new microorganism to products.
- General level 4 – up to 680 variable hours. Examples of applications made at this level include those that involve changing the labelling requirement for food or changing a maximum permitted concentration of an environmental contaminant in food.

- General level 5 – more than 680 variable hours. Examples of applications made at this level include those that involve adding a new substance to a limited range of foods or a complex pre-market approval.

Alternatively, applications can be classified as urgent if they require priority assessment, or major if the application involves the development of an entirely new regulatory measure or variation an existing measure that requires substantial technical complexity or a change in scope of the food regulatory measure. Figure 9 demonstrates that the majority of applications received by FSANZ refer to minor changes, which are likely to be fairly low risk. FSANZ's workload is overwhelmed by a high volume of low risk issues which limits its capacity to do higher-impact work.

**Figure 9 | Number of applications received by FSANZ (2019-2020) for each level**



### **Processes to develop, change or review food regulatory measures are inflexible and do not enable a risk-based response for changing food standards**

Current processes for changing or creating food standards present a range of issues. 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 systems.<sup>30</sup>

Currently, FSANZ is required to follow a similarly rigid process for all applications and proposals, regardless of the level of risk involved. For example, FSANZ must go through the same steps to approve low-risk food processing aids as it does to approve more complex changes, such as infant formula formulations.

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. It also represents considerable burden on industry due to the time and costs involved in preparing detailed applications, as well as opportunity costs associated with delays to bring products to market. This burden disincentivises businesses from using the application process, which in turn inhibits innovation and the availability of newer or more cost-effective products to consumers.

<sup>30</sup> FSANZ 2020, *A position paper on FSANZ's resourcing*. Unpublished position paper.



Extensive delays as a result of the FSANZ process are common - for example, application A1155, which concerned the addition of substances to infant formula standards, began review in December 2019, but was only accepted (with amendments) in late November 2020, a year later. This was despite the substances in question having already been fully approved in several comparable foreign jurisdictions.<sup>31</sup>

Under the current legislation, all draft standards or variations must be approved by the FSANZ Board before being ratified by the Food Ministers' Meeting. These arrangements are unique to the joint food standards system; most standard-setting bodies have statutory powers to set and amend standards without ministerial involvement (see examples in Table 2 below). 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 Food Ministers' Meeting.

These arrangements are also not best practice; the National Cabinet Review of COAG Councils and Ministerial Forums in 2020 recommended that, in the interests of reducing bureaucracy and streamlining approaches, ministers' forums and meetings should not have their regulatory and standard-setting roles enshrined in legislation (as a general rule).<sup>32</sup>

**Table 2 | 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 Food Ministers' Meeting 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 (BMF) 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 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.

As a final point regarding cumbersome nature of legislated processes, the pathway for high-level health claims has never been used and is redundant and could be removed to streamline the Act.

<sup>31</sup> While the process to amend the relevant food standards was an inhibitor of timely resolution of this application, it should be noted that Standard 2.9.1 on Infant Formula is politically controversial and some ministers' concerns needed to be explored and reflected in the proposed amendment before it was ratified, contributing to the long timeframes.

<sup>32</sup> The Review of the COAG Councils and Ministerial Forums Report delivered to the Australian National Cabinet in October 2020

## 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. Guidelines are non-binding instruments that provide advice on how industry and other groups can meet obligations created by FSANZ. Codes of practice similarly provide guidance on how to comply with obligations created by FSANZ. Unlike guidance however, in practice, demonstration of compliance with codes of practice can be used as evidence of compliance with obligations arising under jurisdictional legislative schemes that in turn implement standards adopted by FSANZ.

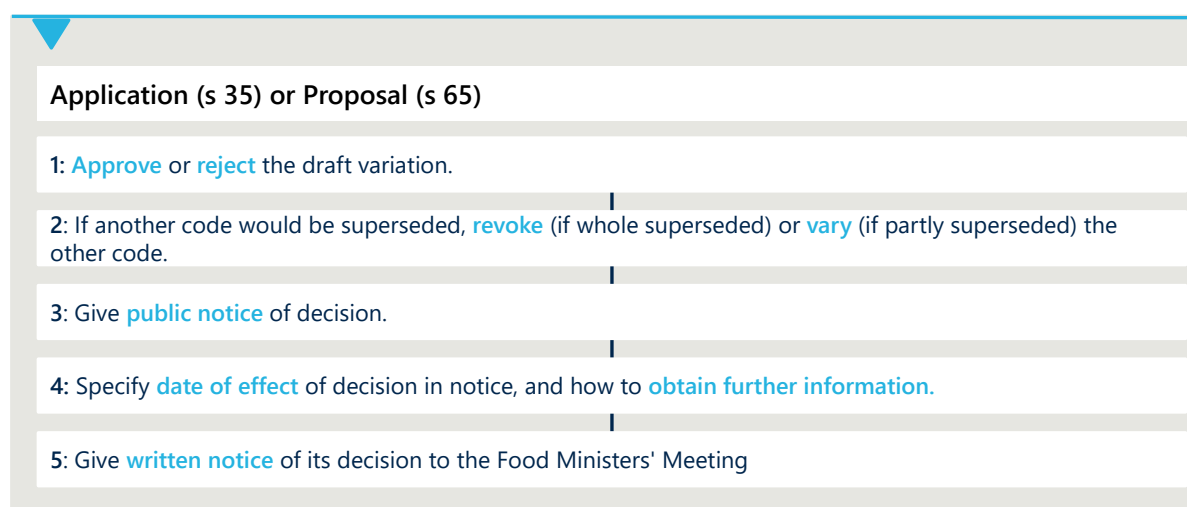
For example, the *Food Act 1984 (Vic)*, which adopts the food standards into law in Victoria, provides a defence of due diligence to industry (s 17E) for demonstrating compliance through codes of practice. Specifically, under this, industry can demonstrate compliance with the standards enforced by the Act in some circumstances if they "complied with a scheme (for example, ... an industry code of practice) that was designed to manage food safety hazards and was based on Australian national or international standards."

Nonetheless, codes of practice are unenforceable, and have little legal effect beyond this limited defence. For them to have practical efficacy, legislative change at a state and territory level would be required to recognise the full suite of regulatory measures employed by FSANZ.

One of the potential barriers to using codes of practice in the past has been that they are translated into law at a jurisdictional level but are not subject to the Food Ministers' Meeting's endorsement, in the way that food standards are. Endorsement by the Food Ministers' Meeting substitutes normal parliamentary debate, which means that using codes of practice could potentially result in legislative changes over which Ministers have had no oversight. This may or may not be appropriate, depending on the level of risk or strategic importance of the matters involved.

The statutory process to develop or vary a code of practice is shown at Figure 10.

Figure 10 | Process for variation to codes of practices from an application or proposal



### 3.2.3 Elements of FSANZ's operations are inefficient

#### FSANZ's legislated governance arrangements prevent it from operating more efficiently

FSANZ's 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 Food Ministers' Meeting. 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 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 joint food standards 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.

Current legislated arrangements for the FSANZ Board raise several issues:

- **Nomination and appointment processes are cumbersome and not in line with best practice.** The legislated requirement<sup>33</sup> to seek input from a large number of prescribed organisations, followed by approval from the Food Ministers' Meeting, 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. For best practice, governance committees should keep a pipeline of potential candidates to fill vacancies as required.<sup>34</sup> Committees should also be majority comprised of independent candidates who can make decisions in the best interest of the organisation and its objectives, rather than on behalf of partisan groups. FSANZ's processes fail to achieve either best practice feature.
- **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 joint food standards system. The Act sets out an extensive list of skills that Board members have to demonstrate expertise "in one or more of". 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. The 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.

#### Technology can be better leveraged to support day-to-day processes

Some stakeholders talked about the obsolescence of some of FSANZ's business processes. This includes a reliance on email and phone calls in the pre-application and application phase, which can lead to inconsistent handling of applications dependent on the case manager assigned, as well as some time

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<sup>33</sup> 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.

<sup>34</sup> Mangalam, S, Hodges, C & Sharpington, L 2020 'Theory Paper on Contemporary Regulatory Models' prepared by PRISM Institute, Canada for Safe Food Production Queensland. This paper has been developed as part of the jurisdictional consistency project being undertaken as part of the P3 reform program. It was provided to Nous by the Australian Department of Health.

inefficiencies expended in the to-and-fro of communications. While raised as an issue (and called out in the Terms of Reference), this was not cited as a priority concern for stakeholders.<sup>35</sup>

### **A sustainable solution to resourcing pressures is required**

Resourcing remains a critical challenge for FSANZ and its ability to deliver on its functions. Currently, only two percent of FSANZ's revenue stream is generated through cost-recovery activities. 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.

A more comprehensive review of FSANZ's substantive funding arrangements is outside the scope of this review but may be picked up as part of the broader work underway in relation to joint food standards system. Further consideration of funding or revenue avenues for FSANZ could have a substantial impact on the effectiveness of the bi-national joint food standards system.

## **3.3 Policy Problem 2 | Legislation does not enable a strong, resilient and agile food regulation system**

While Policy Problem 1 identifies barriers to efficient and effective regulation, Policy Problem 2 relates to challenges to the system being more agile, future-focused and integrated.

These issues are particularly important in the context of thinking about how regulatory burden can be minimised as well as how the Australian-New Zealand food industry can maintain its competitive advantage. This includes thinking about how different agencies can be supported to be more agile, resilient and equipped to make intelligence-led decisions such as to manage risk or promoting population health; build the Australian-New Zealand brand reputation; and strengthen the evidence base around food safety for other reasons.

Three sub-issues have been identified and are explored below.

### **3.3.1 Statutory timeframes and resourcing constraints within FSANZ reinforce a piecemeal and reactive regulatory focus**

Current legislative arrangements reinforce a piecemeal and reactive approach to the creation and variation of food standards.

Under the current arrangements, FSANZ assesses the merits of applications and proposals, each in isolation. This approach makes it difficult to adequately assess the cumulative impacts of food regulation both from economic and health protection perspectives. For example, legislation provides limited mechanisms for:

- Consideration of incremental, accruing impacts on population health (for example, exposure to a multitude of processing aids over time)
- Assessment of the overarching compliance burden and economic impact of food standards over time – especially for small businesses – and how this aligns with the goal of a competitive food industry.

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<sup>35</sup> When considering potential opportunities for better employing the use of technology, some stakeholders talked about the increasing importance of food traceability using hi-tech solutions. This issue could be further explored in the context of the Food Code, and how standards might better recognise the capability of emerging technology.

- This can lead to insufficient consideration of public and population health outcomes and incremental regulatory creep for food businesses.

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.

FSANZ can raise a proposal to undertake a holistic review of a standards, which provides an opportunity to consider the collective impacts of a food standard for different stakeholder groups (and the internal consistency of a standard) or a broader perspective on overall food regulatory system on population health.

However, resourcing constraints facing FSANZ – exacerbated by the statutory timeframes that FSANZ must meet for applications - make it difficult to progress reviews of standards in a timely manner and lead to their effective de-prioritisation in FSANZ's workplan.

FSANZ is primarily funded through an Australian 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. Total FSANZ resourcing has reduced from AUD \$27 million in 2011-2012 to approximately AUD \$20 million in 2019-2020. This is despite Health Portfolio Government Appropriations having almost doubled over the same period – moving from approximately \$1 billion to approximately \$2 billion per annum, and also the fact that the number of projects undertaken annually by FSANZ has increased by approximately 56% over the same period.<sup>36</sup>

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 are not subject to statutory timeframes and therefore are often relatively slow to progress. For example, the current proposal to revise and clarify standards relating to infant formula, P1028, was prepared in 2013 and is still underway.<sup>37</sup>

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.

### **Application trends are changing FSANZ's work and making it more difficult for it to deliver its full range of statutory and non-statutory functions**

The work that FSANZ does is slowly changing. Table 3 demonstrates the number of applications and proposals on FSANZ's workplan over the last three operating years.<sup>38</sup> Key takeaways from this data are:

- **FSANZ is doing similar amounts of work with fewer resources.** Whilst the number of applications accepted and completed by FSANZ is trending up, the number of proposals is commensurately trending down. Nonetheless slimmer budgets, paired with increases in Ministerial reviews and urgent applications (both of which are given priority), have strained FSANZ's capacity for more strategic work. This has particularly affected FSANZ's ability to undertake proposals.

<sup>36</sup> Position paper on FSANZ resourcing, The FSANZ Act Review, FSANZ, 2021.

<sup>37</sup> FSANZ 2017 P1028 Infant formula, available at <https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx>

<sup>38</sup> FSANZ 2020 Food Standard Australia New Zealand Annual Report 2019-20, available at: <https://www.foodstandards.gov.au/publications/Documents/fsanz-annual-report-2019-20-accessible.pdf>

- **FSANZ has been challenged by the increase in paid applications over time.** Because paid applications are prioritised and occupy the same resource base as proposal work, their increase has meant that proposals, which are not paid or prioritised, are inevitably sidelined. This is problematic because proposal work arguably has wider reaching benefit for the broader Australian and New Zealand public.
- **Senior leaders at FSANZ have indicated that they cannot deploy resources most effectively.** When consulted about this data, these leaders expressed that diminishments in budgets and inflexibility in legislation meant that they were unable to address applications as they are submitted, creating delays and slowing outcomes for industry. This had resulted in a steady increase on proposals that were being reviewed in following years, further undermining the efficiency and effectiveness that FSANZ aspires to deliver.

These challenges are partly driven by FSANZ's resourcing constraints - they could be mitigated through additional funding. However, current legislative pathways (in particular, applications and the statutory timeframes attached to them) reinforce a reactive focus that cannot readily be addressed only with additional resources (especially if demand for paid applications continues to increase).

**Table 3 | Applications and proposals on FSANZ's workplan<sup>39</sup>**

Report year	2017-2018	2018-2019	2019-2020
Applications accepted (paid)	17 (10)	13 (9)	17 (16)
Proposals raised	2	3	4
Total applications and proposals accepted and raised	19	16	21
Total proposals still being assessed from a previous year	3	5	7
Applications approved	14	15	15
Proposals approved	2	2	3
<b>Total completed</b>	<b>16</b>	<b>17</b>	<b>18</b>
Urgent	1	0	1
Review	0	0	2

<sup>39</sup> The majority for applications are considered under General Procedure – General Procedure ranges from minimum 240 hours to 1000 hours. All procedures are decided at Admin Assessment – a 15 business daytime period which is used to determine whether a minimum information requirements have been met for FSANZ to consider the application. Occasionally, during assessment, FSANZ may discover a potential allergen, increased dietary exposure limit or toxicological effect, or a consumer issue, which can raise the complexity and amount of time spent on an application. FSANZ may seek more information from an applicant, require more input from areas within FSANZ or external agencies. FSANZ may need to spent time addressing jurisdictional concerns. These matters are not usually picked up until the assessment has commenced, or after consultation.

### 3.3.2 Food safety and quality no longer guarantee a competitive advantage for Australian and New Zealand food businesses

Australian and New Zealand food businesses have historically enjoyed a competitive advantage in regional and global markets given their strong reputation for safe food. This has been supported by the rigorous joint food standards system, in particular pre-market approval assessments undertaken by FSANZ.

However, as other jurisdictions (including middle-income countries with trading relations with Australia and New Zealand) have developed more robust systems to ensure food safety, this has become a less potent means for the Trans-Tasman system to retain its competitive advantage.

Increasingly, competitive advantage of Australia and New Zealand will be linked to how well food supply meets consumers' evolving expectations and needs. Food origin, environmental sustainability and traceability – and the role of food standards in making these transparent – have been cited by stakeholders as examples of areas of current interest to consumers.

### 3.3.3 There is limited collaboration and integration of effort across the regulatory system

#### FSANZ and the Food Ministers' Meeting do not have a shared vision of system priorities

In addition to its role as the decision-maker on all changes to food standards, the Food Ministers' Meeting<sup>40</sup> can request FSANZ to raise proposals or undertake a review of a draft standard or variation. The responsible Minister<sup>41</sup> can also request that FSANZ 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 has reported challenges in taking on an increasing number of Food Ministers' Meeting-directed projects, with little discussion or agreement about items that can come off its workplan.

While the Food Ministers' Meeting and FSANZ have different roles, priorities, accountabilities and operations – which may mean that a shared vision of system priorities is not feasible (or necessarily desirable) – tensions at the interface between policy development and standard-setting (including through requests of reviews) can exacerbate inefficiencies within the system and contribute to significant delays in progressing changes to food standards.

#### There is a lack of intelligence-sharing between stakeholders across the regulatory system

FSANZ currently has extensive professional relationships with agencies involved in food policy, regulation, and research, but has no explicit legislative remit to coordinate or consolidate insights arising from this work. It maintains MOUs with certain bodies and participates in ad-hoc coordination efforts;<sup>42</sup> however, resourcing constraints mean that limited effort is expended in establishing or administering such alliances.

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<sup>40</sup> The Review of the COAG Councils and Ministerial Forums Report delivered to the Australian National Cabinet in October 2020 recommended that the Food Ministers' Meeting is reconfigured and convened in time-limited capacity to progress specific tasks with specified, sun-setting timeframes of no longer than 12 months. The Australian Government has accepted this recommendation. It is assumed that under this arrangement, the Food Ministers' Meeting will continue to meet and progress the policy agenda for the bi-national food system, however its workplan will be more timebound.

<sup>41</sup> Currently the Australian Minister for Health as set out in the Common of Australia Administrative Arrangements Order.

<sup>42</sup> For example, FSANZ is currently working in collaboration with the CSIRO and NZFSSRC to develop a national approach to food safety research in Australia. A concept note published in August 2020 posited the value of a food safety research alliance, in which FSANZ is a key contributor.



As food supply chains and production methods become more complex, more data, information and intelligence could be brought to bear to inform sophisticated regulatory responses and design of regulatory systems. This includes by better understanding consumer preferences and expectations, as well as improving detection and mitigation of risks around food safety (for example, from understanding how non-compliance results in critical incidents; through to monitoring the behaviour of viruses in food).

Increasingly, the joint food standards system lags world leaders in both coordination and application of intelligence relating to food safety and composition. A number of international jurisdictions have mature systems in place to coordinate, consolidate and communicate food safety and food composition data, and deliver value to different stakeholder groups. Examples are shown in Table 4 below.

**Table 4 | Examples of regulatory systems to coordinate food safety data<sup>43</sup>**

#### **New Zealand Food Safety Science and Research Centre (NZFSSRC)**

The NZFSSRC, which was established following New Zealand's Whey Protein Concentrate Inquiry, aims to promote, co-ordinate and deliver food safety science and help ensure New Zealand remains a world leader in food safety. Through a partnership between industry, government, iwi and research organisations, the NZFSSRC delivers high-quality science and research to assure the provision of safe food for domestic consumption and export. It also contributes to ensuring there is a strong science base for food safety decision-making. This is an effective system in New Zealand but does not extend to Australia; improved coordination and resourced collaboration between the two countries could further strengthen the joint food standards system.

#### **Joint Institute for Food Safety and Applied Nutrition (JIFSAN)**

JIFSAN is a collaboration established in 1996 that is jointly administered by the University of Maryland and the US Food and Drug Administration. It aims to provide a multi-disciplinary approach to addressing complex food safety issues by bringing together leaders in industry, government and academia to develop research, education and outreach programs. It is a significant funder of research projects, educator of university students and has trained thousands of food safety professionals from across the globe.

#### **Campden BRI Company**

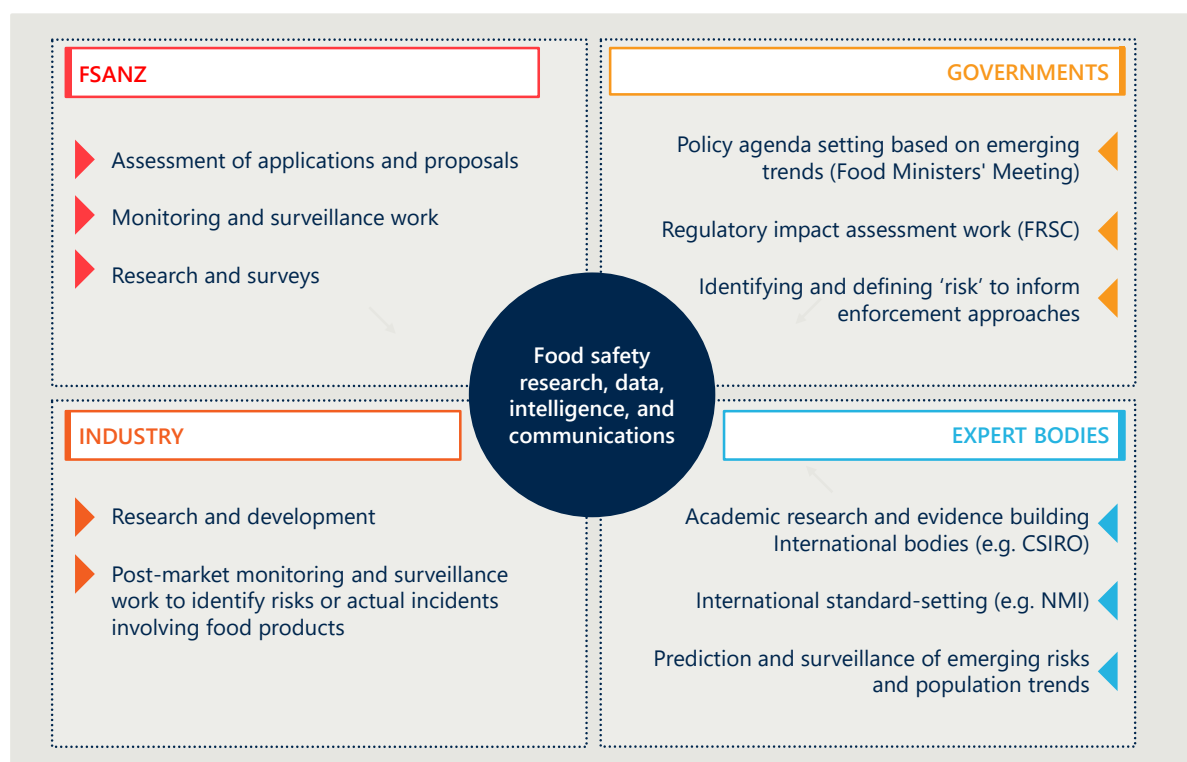
Based in the UK, the Campden BRI company provides food and drink industry with practical scientific, technical and advisory services to promote product safety and quality, process efficiency and product and process innovation. Services include analysis and testing, operational support, research and innovation support, and knowledge management. Projects are funded primarily by industry and, secondarily, through membership fees. All work has a commercial focus and clients include a broad range of food businesses from around the world, across the food supply chain.

Currently, there are a number of highly capable organisations involved in food safety and food composition research across Australia and New Zealand. While recognising the uniqueness of their own operating imperatives - including the need to maintain independence or protect intellectual property – the duplication of effort across the system represents costs that are perhaps unnecessary. There may be economies of scale to better collaboration, combined with more strategic partnerships across the system to facilitate more data-driven, intelligence-led decision making.

An example of the various groups of organisations and the food safety research and data work they might be involved in is shown at Figure 11.

<sup>43</sup> Food Safety Alliance Concept note (prepared by Dr Anne Astin PSM), provided by FSANZ.

**Figure 11 | Entities that generate and make use of food safety research and data**



While this is an issue that could potentially be managed by scaling up resources rather than implementing legislative changes, the lack of relevant statutory functions means that FSANZ may always be challenged to attract adequate resources to orchestrate this work effectively.

In addition, an enhanced legislative remit – for example that provides an explicit function for FSANZ to support greater coordination and integration in relation to food safety and composition research – would provide greater certainty for stakeholders in the system about responsibilities and mandates to drive this work.

### 3.4 Policy Problem 3 | Current arrangements undermine the power of a single, joint food standards system

Policy problem 3 relates to how existing arrangements do not fully capitalise on a single, joint and multi-jurisdictional food standards system.

Australia and New Zealand each have their own unique food policy and regulation systems which are joined through the shared use of food standards.

While it may always be appropriate for Australia and New Zealand to approach elements of food policy and regulation in individual or isolated ways, there are areas related to food standards and the role of FSANZ for which a more unified approach could deliver value for both countries.

Three sub-issues are explored below.

### 3.4.1 FSANZ is limited in its power to assist in food incidents and food recalls

While the Act is geared towards protecting population health and safety by managing negative externalities and information asymmetries, FSANZ currently does not have the statutory functionality to act decisively in an acute situation.

Under the current arrangements, FSANZ can only respond to food incidents and assist with the recall of foods at the requests of States and Territories (s 13(k)). FSANZ cannot instigate a response on its own and it cannot carry out this function on behalf of New Zealand. This means FSANZ must wait for a request from the jurisdictions before taking action. As a result, recalls and other food incident responses are often reactive and inconsistently activated across the system and its jurisdictions. This delayed response can increase risk and confusion for consumers and risks for industry in terms of potential reputation damage.

#### Case study: Lack of central coordination during the strawberry tampering incident in Australia

In September 2018, a food tampering incident occurred involving sewing needles inserted into Australian strawberries. Initially an isolated event in Queensland, the incident escalated to other states and territories involving multiple tampering events in strawberries and other fruit across the country.

The strawberry tampering incident was a national incident, however the responsibility for coordinating the response lay on individual state and territories, with FSANZ's having no clear statutory role to initiate a response.

In the absence of a central agency to coordinate the incident, FSANZ was asked by the Minister for Health shortly after the incident began to investigate the supply chain to understand if the breaches were systemic and to provide urgent and immediate advice to help protect Australians.

FSANZ's report to the Minister for Health on the incident found that, while governments' response to the food incident was timely, lack of a centralised coordination function resulted in inconsistent and incorrect messaging.<sup>44</sup> This caused unnecessary confusion for consumers and significant financial loss for the strawberry industry.<sup>45</sup> The report recommended that, for incidents that occur across Australian jurisdictions, a central agency should be tasked with national coordination including ensuring consistent and quality messaging.

An independent report to FSANZ (not publicly available) on the economic impact of the incident determined the apparent residual impact to be a -8.6% reduction in market value, equivalent to AUD \$24.7 million. The incident also had significant impacts on the season workforce and significant reputation damage to Australian exports as the event was reported internationally.

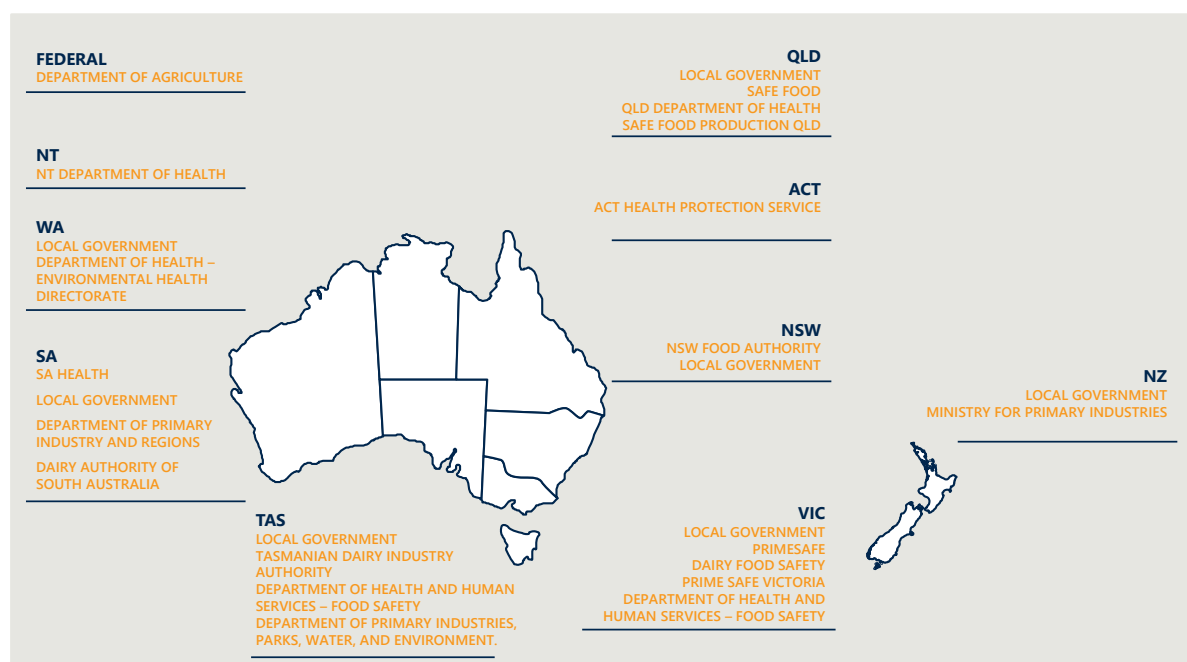
### 3.4.2 Inconsistent interpretation and enforcement of food standards is an enduring issue for the joint food standards system

Enforcement of food standards is performed through diverse institutional arrangements (see Figure 12) that vary across the different jurisdictions. In Australia, these are loosely based on model law provisions set out in the Food Regulation Agreement. Meanwhile in New Zealand, they are in the *Food Act 2014*.

<sup>44</sup> Strawberry Tampering Incident (2018), Food Standards Australia New Zealand. Available at: <https://www.foodstandards.gov.au/publications/Pages/Strawberry-tampering-incident.aspx>

<sup>45</sup> Australian strawberries reputation recovery plan, prepared for the Department of Agriculture and Water Resources (2019), SenateSHJ. Available at <https://www.agriculture.gov.au/sites/default/files/sitecollectiondocuments/ag-food/horticulture/aust-strawberries-reputation-recovery-plan.pdf>.

Figure 12 | Enforcement agencies used in each jurisdiction



The Implementation Subcommittee for Food Regulation (ISFR) which reports through to the Food Regulation Sub-Committee (FRSC) and in turn, the Food Ministers’ Meeting, has an important role to facilitate common approaches to implementing food standards through the development of guidelines. 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 food businesses struggle to understand what they must do to meet their regulatory requirements. This leads to unnecessary burden associated with:

- Discovery costs to understand appropriate interpretation of standards
- Risk averse practices that can limit innovation
- Compliance burdens to adjust practices to ensure compliance with different interpretations of standards.

This is a pronounced issue for Australian food businesses,<sup>46</sup> particularly those that trade across jurisdictional borders. These businesses can face additional costs in adapting their production and distribution chain to meet the most rigorous compliance requirements across the jurisdictions in which they operate. This challenge is demonstrated in the market entry requirements for egg producers.

#### Case studies: inconsistencies across jurisdictions

##### Egg producers

Food Standard 4.2.5 requires all ‘egg producers’ to mark eggs with a unique identifier. However, because market entry requirements are determined at a jurisdictional level, in Queensland and Western Australia, individuals or food businesses with one or more egg producing hens are

<sup>46</sup> This is less of an issue for New Zealand as all food businesses are regulated by a single institution, the Ministry for Primary Industries. Food that is manufactured in New Zealand and meets New Zealand requirements can be legally sold in Australia under the Trans-Tasman Mutual Agreement (and vice versa).

While inconsistency between Australia and New Zealand are not explicitly barriers to economic opportunities, it represents an important fragmentation of the joint food standards system.

'producers' whereas in New South Wales and the Australian Capital Territory a 'producer' has hen(s) that lay 240 or more eggs per week. Victoria and South Australia set the threshold based on a head count of egg producing birds (50) and Tasmania defines a producer as any business or individual that sells eggs to the public or businesses.<sup>47</sup> Meanwhile in New Zealand all packaged eggs must be marked (with some specific exceptions).<sup>48</sup>

These inconsistent market entry requirements have resulted in three core issues:

1. Some food businesses are not required to take steps to manage risks and comply with the food standards despite working with food of the same risk profile (for example, in one jurisdiction, a producer with 49 hens may not have to comply with the Food Standards Code whereas a producer with 50 hens would).
2. In the event of foodborne illness outbreak, there can be traceability issues where food products are not marked or traced. This is a requirement for food businesses that are in scope to comply with the Food Standards Code, but voluntary for those who are not.
3. There can be a competitive disadvantage to food businesses operating in certain jurisdictions, where the cost of regulatory compliance can be higher than other areas. Or conversely, when operating in a jurisdiction with lower cost compliance, there are higher barriers to entry of the other markets.

### **There is variability in regulators' capability and capacity to enforce standards across the system**

A survey completed as part of the recent report into key areas of inconsistency in food regulation found that 74% of stakeholders consulted considered inconsistency in food regulation a 'significant' or 'major' issue for them.<sup>49</sup>

Jurisdictions across Australia and New Zealand are resourced to varying degrees to carry out their monitoring and enforcement activities and this means that the capacity and expertise to regulate effectively is inconsistent across the system.

For example, Australian stakeholders have reported that enforcing compliance with health claims is an area where many agencies have neither the capability nor capacity to pursue.

On the other hand, some regulators have shown real leadership in the food regulation space, having developed highly sophisticated approaches to detecting risk and approaching monitoring and enforcement in a targeted, strategic manner. For example, Dairy Food Safety Victoria has developed 'Dairy RegTech' as a new way for them to monitor food safety compliance with the objective of streamlining the audit processes and reduce administrative paperwork, in addition to closely monitoring food safety. In contrast, other enforcement agencies are using more manual (and potentially less effective) processes.

### **There is some duplication of this work across the system**

All enforcement agencies currently undertake a common set of duties, such as monitoring and enforcing food safety, managing food incidents, creating safe food handling advice and providing education and guidance to industry. This duplication represents an unnecessary burden to government.

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<sup>47</sup> Roberts J & Runge G. (2011) 'Egg Stamping: Benefits, Feasibility and Options For Australian Egg Producers, Australian Egg Corporation Limited. [online] Available at: <<https://www.australianeggs.org.au/dmsdocument/878-egg-stamping-guide-pdf>>

<sup>48</sup> Exceptions include: unpackaged sold eggs, when packaged in the presence of the purchaser, when sold directly at the farm or at a fundraising event.

If all jurisdictions were working to the same regulatory framework and adopted a similar approach to regulatory practice (which retained adequate discretion for regulators to tailor their work for their local contexts and stakeholder groups), duplication of effort could be minimised.

### Regulatory technology that connects jurisdictions into a single, joint food standards system is underutilised

There are barriers to uptake of advances in regulatory technology ('RegTech') across Australia and New Zealand such as the significant establishment costs involved.

The utility of these solutions can also be limited if they are not applied across all jurisdictions. For example, food traceability is critical in food recalls and is also an issue that is of increasing interest to consumers. Currently, the process of tracing products is a largely manual process across Australia and New Zealand. Conversely, the US is investing in a national system of tech-enabled traceability which can characterise the entire supply chain of individual food products within minutes, or even seconds.<sup>50</sup>

### The food-medicine interface is also challenging to navigate

In Australia, products that are consumed orally and make health claims can be classified as either a food or a complementary medicine and are regulated under two separate schemes.

- **Complementary medicines** are defined under the *Therapeutic Goods Act 1989*<sup>51</sup> as: 'a therapeutic good consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and a traditional use'.

'Low risk' complementary medicines must be listed on the Australian Register of Therapeutic Goods (ARTG), while 'high risk' complementary medicines must undergo a safety assessment and be registered on the ARTG.

All complementary medicines are subject to post-market surveillance and must comply with, among other things, advertising roles set out in the Therapeutic Goods Advertising Code<sup>52</sup> which is premised on advertising that promotes the quality use of the product, is socially responsible and does not mislead or deceive the consumer.

- **Food** as defined in the Act as: 'Any substance or thing of a kind used, capable of being used, or represented as being for human consumption'.

As described further in Section 5.3.2, the Food Standards Code enables food businesses to make 'general health claims' taken from a list of more than 200 pre-approved food-relationships in the Standard or self-substantiate a food-health relationship in accordance with certain rules.<sup>53</sup>

'High level health claims' must be based on a food-health relationship pre-approved by FSANZ. There are currently 13 pre-approved food-health relationships for high level health claims listed in the Standard.

The interface between the food and therapeutic goods regulatory systems have proved to be particularly fraught, with evidence that similar products are captured inconsistently within the remit of each scheme, resulting in inconsistent regulation and risk management.

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<sup>50</sup> New Era of Smarter Food Safety – FDA's Blueprint for the Future, 2020

<sup>51</sup> Therapeutic Goods Regulations 1990. (Cwlth).

<sup>52</sup> Therapeutic Goods Administration. (2018) Therapeutic Goods Advertising Code (No. 2).

<sup>53</sup> 'General level health claims' refer to a nutrient or substance in a food, or the food itself, and its effect on health. For example, 'calcium for healthy bones and teeth'. 'High level health claims' refer to a nutrient or substance in a food and its relationship to a serious disease or to a biomarker of a serious disease. For example, 'diets high in calcium may reduce the risk of osteoporosis'.

For example, a 2017 article<sup>54</sup> 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 action.<sup>55</sup>

In Australia, managing the food-medicine interface is largely a regulatory practice issue which requires ongoing collaboration between the TGA and food regulators. Defining 'food' in legislation is not straightforward and any definition is likely to struggle to keep pace with innovation, as consumer expectations of what constitute 'food' is influenced a combination of product composition, packaging and presentation and place of sale, among other factors. There is however a small opportunity that can be explored within the scope of this review, which relates to ensuring that a single role within the health system ultimately has accountability for determining whether a substance is a food or a medicine, and ensuring this arrangement is reflected in both the Act and the Therapeutic Goods Act.

Importantly, this is not an issue where changes to the FSANZ Act can present solutions for both Australia and New Zealand; In New Zealand, Therapeutic Products are regulated under the Medsafe regulatory scheme and *Medicines Act 1981* which have different definitions to Australia's TGA.

### 3.4.3 FSANZ has no legislative remit to extend Australia and New Zealand's influence on the international stage

FSANZ is part of an international network of standard setters and other expert bodies who work collaboratively to share independent, science-based insights about food safety and public health protections. For example, FSANZ leads Australian delegation for some relevant Codex Alimentarius Commission committees, and also co-chairs the APEC Food Safety Cooperation Forum (FSCF).<sup>56</sup> As Co-Chair, FSANZ leads FSCF and the Partnership Training Institute Network, reviews the work and future direction of the Food Ministers' Meeting and reports on work of FSCF to APEC.<sup>57</sup>

This work is instrumental in strengthening the Australian-New Zealand brand, working towards harmonisation of international food standards, and extending Australia and New Zealand's influence over the Asia-Pacific market by creating new economic opportunities for industry.

While FSANZ has a statutory obligation to have regard to harmonisation of food standards, it has no legislative remit to coordinate this broader programme of international relations and contributions.

Importantly, a strong joint food standards system does not mean that Australia and New Zealand would need to coordinate all international activities, but rather in different forums FSANZ could provide more support for one (or both) countries, where appropriate.

#### Discussion questions related to the Policy Problems

<sup>54</sup> The Conversation. (2019). Kids' vitamin gummies: unhealthy, poorly regulated and exploitative. Available at: <https://theconversation.com/kids-vitamin-gummies-unhealthy-poorly-regulated-and-exploitative-76466>

<sup>55</sup> 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/>

<sup>56</sup> Food Standards Australia New Zealand, Codex Alimentarius Commission. Available at: <https://www.foodstandards.gov.au/science/international/codex/pages/default.aspx>

<sup>57</sup> Food Standards Australia New Zealand, Asia Pacific Economic Cooperation. Available at: <https://www.foodstandards.gov.au/science/international/apec>



1. Aside from the three key Policy Problems identified in this RIS, are there other key Policy Problems that should be considered as part of this regulatory impact analysis? If so, what are they and do they manifest differently in Australia and New Zealand?
2. What examples or issues are you aware of in the food regulatory system regarding food sustainability?
3. What examples or issues are you aware of in the food regulatory system regarding recognition of indigenous culture and food expertise?

## 4 Rationale for government action

Australian and New Zealand governments (at all levels) play a vital role in regulating food standards, including by providing a regulatory framework for how foods can enter the Australian and New Zealand markets. These roles are broadly understood and endorsed by all stakeholder groups consulted as part of the Review. Notwithstanding different views about the relative priority of different regulatory objectives, the role for government in ensuring a safe food supply that protects consumers, enables informed decisions and promotes economic opportunities for food businesses is broadly accepted.

Feedback on the earlier scoping paper almost universally acknowledged that:

- There is an **ongoing rationale for regulating food** through an independent standard-setting body
- There is a **need for government action** to modernise the Act to address issues relating to increasing regulatory inefficiency and declining effectiveness of the regulatory framework.

Each of these points is described in turn.

### While markets have changed, there is an ongoing rationale for regulating food through a standard-setting body

By establishing a standard-setting body and processes for creating and changing food standards within a bi-national framework, the Act helps to safeguard the food that Australians and New Zealanders eat. 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 which can be interpreted through a 'market failure' framework:

- 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 **negative externalities**, 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.
- The ability for consumers to make informed decisions about the foods that they eat, including avoiding certain allergens and making healthy eating decisions, is greatly supported by a common framework of standards, especially those related to information and labelling. The bi-national framework for standard setting and development established by the Act thereby helps to address **informational asymmetries** that would likely exist in a private market.
- 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.

### Only government can update the regulatory framework

The FSANZ Act is Commonwealth legislation, which falls within the remit of the Australian Government to reform. Importantly though, in accordance with Article 4(4) of the Treaty, no amendments to the FSANZ Act will be introduced without effective consultation with New Zealand.

Given the ongoing relevance of FSANZ in the system, it falls to government to ensure that the regulatory framework is fit-for-purpose. As described earlier in Section 3, there are several limitations to the Act in its current form which hinder efficient and effective regulation, and government action is now required to effectively respond to there.

## 5 Options to address the Policy Problems

Three reform options have been identified and developed as part of this draft RIS, summarised in the Executive Summary. These represent different degrees of change:

- **Option 1** retains the status quo. It proposes no legislative changes to the Act (or associated changes to FSANZ's operations).
- **Option 2** seeks to modernise the Act to make it agile, resilient and fit-for-purpose. This includes a regulatory framework premised on risk-proportionality and intelligence-led decisions and better integration between system stakeholders. Option 2 protects the health and safety of the Australian and New Zealand populations while minimising regulatory burden on industry.
- **Option 3 builds on Option 2** by enhancing FSANZ's role to reinforce the bi-national nature of the joint food standards system by providing for FSANZ to issue interpretative advice on food standards and take on a range of enforcement activities.

An option to repeal the Act has not been put forward for consideration as part of this draft RIS. In lieu of having Australia and New Zealand specific food standards (and a standard-setting body), the joint food standards system *could* promote food safety outcomes (and public health and safety more broadly) by: routinely and automatically adopting food standards from other jurisdictions (e.g. Codex or other countries); relying on post-hoc penalties and sanctions to deter food businesses from engaging in conduct that compromises the safety of the food supply and/or leveraging other regulatory schemes (such as consumer law) to achieve objectives of food regulation. This would, however, have significant adverse impacts. For example, this would:

- Undermine the ability to tailor food standards and the assessment process to the Australian and New Zealand context, including dietary patterns and industry practices relevant to Trans-Tasman system
- Compromise the competitive advantage currently enjoyed by Australian and New Zealand food businesses given reputation of the Trans-Tasman system in regional and global markets
- Exacerbate system delays and reduce national sovereignty by placing Australia and New Zealand at the whim of developments in Codex standards and/or other jurisdictions (which would make it more difficult to progress important issues for the Trans-Tasman system in a timely manner)
- Rely more heavily on deterrence mechanisms to promote food safety (that is, sanctions of food businesses after non-compliance has occurred) and thereby reduce the ability to prevent food safety harms from occurring in the first instance.

For these reasons, repealing the Act (and FSANZ) is not a tenable reform option. This has been universally acknowledged by stakeholders consulted to-date as part of this review.<sup>58</sup>

Options 2 and 3 presented in this draft RIS present many components that would represent less regulatory intervention and associated regulatory burden, which are in line with the Australian and New Zealand's deregulation agendas. Where specific components have been proposed that involved additional regulation, some discussion has been included about if and how changes might otherwise be achieved without creating additional regulatory burden.

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<sup>58</sup> The scoping paper published as part of this review (from 5 October to 16 November 2020) asked stakeholders whether there was a still a case for regulating food. Responses from 92 submissions universally acknowledged that there was still a relevant case for regulating food.

#### GUIDANCE NOTE:

While this draft RIS presents three broad options for consideration, stakeholders are not being asked to consider the value of each option as an immutable package. Rather, feedback on this draft RIS will inform the combination of components that make up the 'preferred option' when developing the final RIS. For example, to reflect stakeholder feedback, the final RIS might identify Option 3 as the preferred option, where Option 3 encapsulates only two components of reform, rather than the three currently described. Each of those components might look slightly different to how they are presented in this document.

In the interests of exploring the Act as an enabler of the joint food standards system, many ideas in Option 2 and 3 have been expressed as bi-national changes, for example, where FSANZ might take on a function on behalf of both Australia and New Zealand. All of these ideas can be decoupled, that is, they can be reframed as Australia-only or New Zealand-only functions, should this prove more desirable.

Finally, please note that the options presented for consultation are done so without prejudice; they do not represent any form of agreed position from any government in Australia or New Zealand.

## 5.1 Option 1 | Retain the status quo

Option 1 would maintain the Act in its current form, including the objectives, functions, processes for creating and amending food regulatory measures, and the current governance arrangements of FSANZ.

This option would retain the current, and effective, rigorous pre-approval assessment processes for considering any changes to food standards via the existing application and proposal pathways. This option would retain the different procedures for these pathways – *minor, general, major, urgent, and high-level health claims* variations – which despite providing only a limited degree of risk-proportionality have nonetheless managed to largely prevent the market failures that they are designed to address.

The legislative framework may continue to develop over time (for example through incremental changes to the Act and Regulations and policy guidelines), but there would not be more wholesale and substantial change as a result of the Review.

## 5.2 Option 2 | Modernise the Act to make it agile, resilient and fit-for-purpose

Option 2 seeks to Modernise the Act to make it agile, resilient and fit-for-purpose. This includes creating a framework premised on data-driven, intelligence led decision making and better integration between system stakeholders that protects the health and safety of the Australian and New Zealand populations while minimising regulatory burden on industry.

It comprises six key components of change:

- Component 1 | Clarify objectives and functions and reflect these in the Act
- Component 2 | Facilitate risk-based approaches to developing or amending food regulatory measures
- Component 3 | Build in flexibility to create bespoke regulatory sandboxes
- Component 4 | Position FSANZ as the engine of food safety intelligence, equipped to drive forward-looking regulation
- Component 5 | Foster new approaches to working with other agencies, with a focus on intelligence-sharing

- Component 6 | Streamline FSANZ's governance and operations.

Option 2 would involve significant changes to FSANZ's operations, in particular through establishing new processes and procedures for new and refined pathways for changing food standards and enhancing collaborations at interfaces with industry, jurisdictional regulators and policy development stakeholders. It would also involve enhancing FSANZ's intelligence-gathering and coordination functions and establishing processes and procedures to establish and operate the self-certified pathway to bring food products to market.

## 5.2.1 Component 1 | Clarify objectives and functions and reflect these into the Act

Objectives and goals are covered in a number of sections of the Act. The overarching object of the Act and goals for FSANZ are set out in s 3, while s 18 discusses the objectives when developing or varying food regulatory measures (Figure 13).

Figure 13 | Excerpts from the Act

### **S 3 | Object of 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 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.

### **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 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.

### Small changes to the objectives may remove ambiguity and create a clear set of legislated priorities

The following amendments could improve the clarity of the Act:<sup>59</sup>

- Clarifying s 3 of the Act by including 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 objectives could also be amended to reflect their agreed role in relation to public health and safety, as well as in facilitating economic benefits

- **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."
- **Expanding the objectives of FSANZ to recognise trade as a core goal.** Section 3 could be amended to include "an efficient and internationally competitive food industry" and specify that this trade objective is subordinate to public health and safety objectives. In addition, "the regulatory impact on industry, particularly small businesses" should be included as a factor FSANZ must have regard to in s 18(2). These additions will provide a greater impetus for FSANZ to support industry and innovation while not detracting from the overarching goal of promoting public health and safety.
- **Establishing criteria in the Act that the Food Ministers' Meeting must meet to request a review of a draft regulatory measure.** The Act could be amended to legislate criteria that the Food Ministers' Meeting 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 have not been considered in FSANZ's deliberations.<sup>60</sup>
- **Expanding the objectives of FSANZ to address important priorities of food sustainability.** This change would ensure FSANZ can systematically consider food sustainability as a cross cutting issue and ensure that the Act is fit for purpose in the longer term.
- **Expanding the objectives of FSANZ to include recognition of indigenous culture and expertise.** This change would ensure that FSANZ is able to give systematic regard to indigenous culture and food expertise and ensure that the Act is fit for purpose in the longer term.

The addition of these two latter objectives would involve adding to s 18(2) that FSANZ, in developing or reviewing food regulatory measures and variations of food regulatory measures, also has regard to: (f) food sustainability; and (g) recognition of indigenous culture and food expertise. The addition of these two considerations would not change the application of the section; FSANZ would continue to have balanced

<sup>59</sup> Currently the Act, the FRA, and the Treaty use different wording around the objectives of food regulation. Once clarifications are made to the Act, these changes may also be carried through to these other foundational documents.

<sup>60</sup> This alignment could also be achieved by amending the Food Regulation Agreement



regard to the issues outlined in section 18(2). The Act could be amended to ensure that FSANZ has the breadth of statutory functions required to effectively deliver on its objectives.

### **The Act could be amended to ensure that FSANZ has the breadth of statutory functions required to effectively deliver on its objectives**

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 population health objectives. This could provide greater clarity about FSANZ's core reasons for being and transparency about the activities on which FSANZ should be focusing effort.

This improvement 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, such as establishing a statutory function relating to food fraud and food crime.

FSANZ understands food fraud as per the definition in the *Commonwealth Fraud Control Guidelines (2011)*: "dishonestly obtaining a benefit, or causing or loss, by deception or other means."<sup>61</sup> FSANZ's role in relation to food fraud would need to ensure minimal overlap with the role of the Australian Competition and Consumer Commission (ACCC) and other enforcement agencies.

## **5.2.2 Component 2 | Facilitate risk-based approaches to developing or amending food regulatory measures**

Amendments to the legislation could support more efficient and effective processes to develop food regulatory measures. It is important that these amendments do not compromise the overall safety and quality of the Australian-New Zealand food supply nor the economic opportunities for industry.

Component 2 recognises that efficiencies could be gained by reconceptualising the regulatory instruments and statutory processes used to develop or amend food regulatory measures, with risk being the key driver of process. Risk-based approaches mean that high-risk issues necessitate rigorous assessment and oversight, but low-risk issues are allowed less onerous pathways.

Component 2 proposes several ways to achieve this balance, including through:

- Leveraging other regulatory instruments, i.e., guidelines and codes of practice
- Streamlining current pathways to amend food standards, including through expanded use of the process for minor variations, delegation of the FSANZ Board or the Food Ministers' Meeting decision-making and acceptance of risk assessments from overseas jurisdictions
- Creation of new pathways to expediate low-risk amendments including automatic adoption of new standards from select international regulatory systems, minimal check pathways and an industry self-substantiation pathway.

### **Better use of FSANZ's other regulatory instruments could increase the system's agility and responsiveness to change**

The Act provides for 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)).

As discussed previously in section 3, guidelines and codes of practice are ancillary 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, the Act provides for FSANZ to make guidelines

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<sup>61</sup> Fraud Policy Statement and Fraud Control Plan, (2018). FSANZ.

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 does not require ratification from the Food Ministers' Meeting. Increased uptake of these tools (and in a risk-proportionate way) could mean that more information that would otherwise be enshrined in food standards could be developed and varied in a timelier way.

Note however, because codes of practice are not necessarily binding, ancillary legislation within each jurisdiction could be required to give them enforceable effect.

## Implementing a decision-making tool may lead to better uptake of the full suite of 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 and guidelines, which can be created and amended in more agile and responsive ways. This resource could draw on the risk framework outlined in Table 5 in the section below. An example of a low-risk issue that may be better dealt with in codes of practice might relate to sustainable packaging (e.g., encouraging industry to reduce the amount of plastic wrapping). On the other hand, high-risk matters, such as disclosures of allergenic information, would only be appropriate to regulate through food standards.

## Risk could drive processes in relation to applications and proposals

The statutory processes relevant to applications and proposals could be amended to support a level of consultation and assessment commensurate with the risk involved. It could also 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 5. The framework would need to consider the shared risk appetite and preferences of New Zealand and Australian State and Territories.

**Table 5 | Indicative risk framework**

#	Criterion	Key question
1	Alignment with strategic priorities	1. Is the application/proposal a <b>strategic priority</b> (e.g. for innovation, safety, health) as determined by Food Ministers' Meeting?
2	Subject matter / Expertise	2. What <b>expertise</b> is required to make decisions? (e.g. technical scientific capability or broader policy issue)
3	Extent of risk	3. How significant is <b>risk to public health or safety</b> / how <b>complex</b> is the risk assessment?
4	Scope of impact	4. How <b>broad reaching and immediate</b> are social, economic and health <b>impacts</b> ?
5	Existing evidence	5. Is there a strong and relevant <b>evidence-base</b> 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
- The pathway specific to high-level health claims would be abolished
- Provision for urgent amendments could be retained but modified to adopt some of the risk proportionality of a non-urgent amendment.

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.

### **Decision-making arrangements could allow for delegation by the FSANZ Board and Food Ministers' Meeting**

In addition to more flexible, risk-based statutory processes, decision-making arrangements for applications and proposals could be streamlined by removing current barriers to delegation. In particular:

The FSANZ Board's non-delegable duties (set out in s 150) could be removed or revised to enable the FSANZ Board to delegate decision-making responsibilities for draft standards or variations to the CEO. In the interests of transparency, if this change is adopted, internal business processes will need to ensure that the Board retains oversight over emerging risks or trends through appropriate reporting arrangements.

Members of the Food Ministers' Meeting could be given the explicit ability to delegate decision-making to ratify changes to food standards to particular Department officials, thereby preserving each jurisdiction's role in having a 'final say' about new or amended food standards, while recognising that particular Ministers may not feel necessary to have oversight and decision-making authority on all changes to the standards.<sup>62</sup>

Note that for existing application and proposal pathways, this would preserve two-step decision-making arrangements – development and approval of a draft standard or variation by FSANZ before being considered and ratified by the jurisdictions.

### **The Act could provide for FSANZ to accept risk assessments from overseas jurisdictions**

In consultations to date, industry stakeholders spoke about the administrative burden associated compiling the required evidence base to support a comprehensive risk assessment by FSANZ. The burden could be minimised if FSANZ had the statutory ability 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), 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.

This approach could reduce duplication of effort where well-established and evidenced standards or assessments from other countries exists. It could also shorten the time and effort needed for reviews and approvals, currently a major barrier for market entry of new products. This change would bring FSANZ into alignment with provisions in place in other regulatory areas (such as the Therapeutic Goods Administration), which would in turn simplify the regulatory experience for businesses.

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<sup>62</sup> This arrangement could also be achieved by amending the Food Regulation Agreement to include the ability to delegate.

These stakeholders suggested that the change would need to be coupled with relevant information sharing arrangements to ensure the basis for overseas assessments or standards could be properly assessed by FSANZ. They suggested that the scope for considering adoption of standards or risk assessments from overseas jurisdictions should be restricted to specific international bodies (such as Codex). However, they also expressed that there would be value in establishing a process for review of risk assessments and standards in overseas jurisdictions to ensure that those assessments or standards are able to be utilised by FSANZ where appropriate. This would expedite changes to standards and considerably reduce resource requirements for FSANZ.

Overall, while this change 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 made, especially where there are divergences in scientific opinions.

### **The creation of new pathways could expedite low-risk amendments to food standards**

Currently regulatory measures can be developed or varied subsequent to an application or a proposal only. This approach is insensitive to the relatively minimal risk posed by substances that have been approved by comparable international regulators. Relying on applications or proposals to be raised and assessed with the same degree of rigour to more high-risk amendments creates administrative burden for both industry and FSANZ that may be unnecessary.

Two new pathways could be introduced to leverage the international evidence base:

- **Automatic adoption of new standards from select international regulatory systems.** FSANZ could undertake an annual harmonisation process, when deemed appropriate, to adopt new standards into the Food Standard Code. For example, this could result in automatic adoption of new standards created for the Codex Alimentarius.
- **Minimal check pathway.** This option would provide FSANZ a pathway to expedite consideration of standards that have been approved by a comparable overseas regulator (for example, the Food and Drugs Authority in the United States, Food Standards Agency in the United Kingdom, Health Canada or the European Commission).<sup>63</sup> FSANZ may undertake minimal assessments of the suitability of the standards within the Australian-New Zealand context of dietary and consumption trends and/or to consider different outcomes of assessments from such regulators.

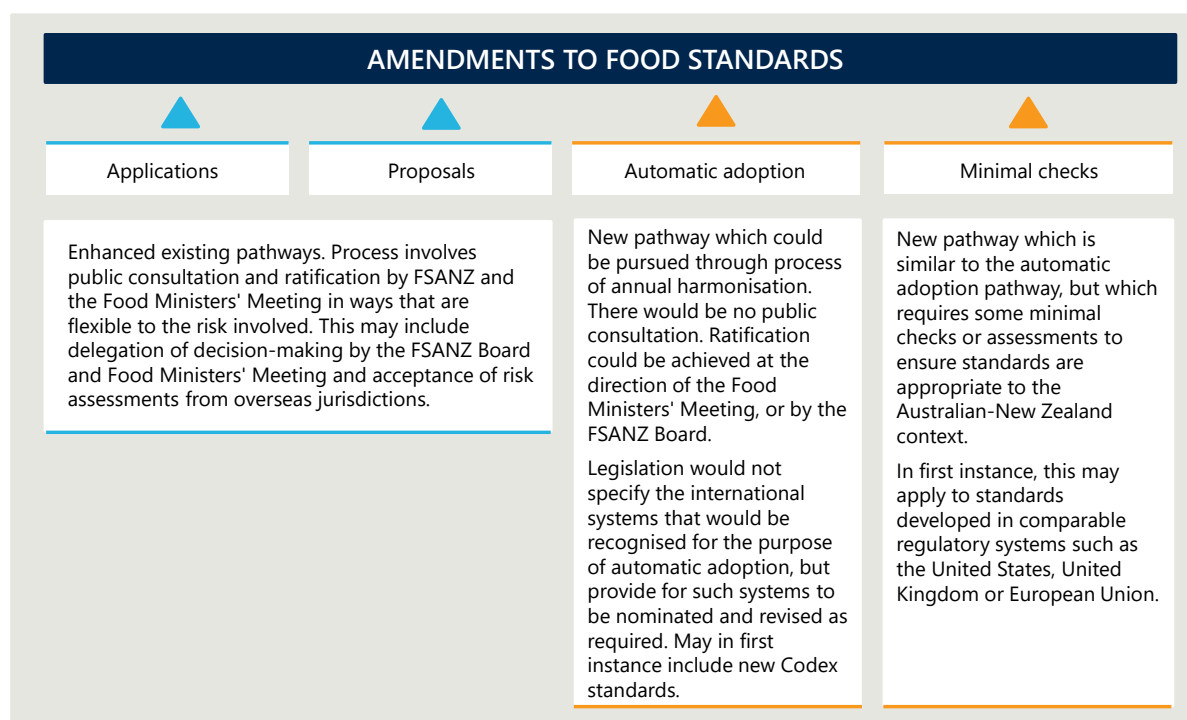
These pathways could be subject to different decision-making arrangements than applications and proposals; for example, not requiring the Food Ministers' Meeting's ratification of these changes (and instead providing for FSANZ to be the final decision maker). Alternatively, the Food Ministers' Meeting could undertake periodic, annual ratification of all changes made through these pathways.

The four pathways to amend food regulatory measures are shown visually at Figure 14.

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<sup>63</sup> Note that GRAS Affirmations and GRAS Notifications do not constitute approval by the USFDA

Figure 14 | Proposed pathways to amend food regulatory measures



### An additional pathway to bring very low risk products to market could support greater economic opportunities for food businesses

Currently, FSANZ's regulatory attention is focused on pre-market approval (through considering applications and proposals to change standards). The proposed automatic adoption and minimal check pathways also adopt a pre-market assessment focus. On the other hand, an additional pathway could take a post-market focus for foods that present very low risk to consumers.

There is a growing trend internationally for modern regulatory systems to take a partnership approach with industry to establish shared goals for the system, recognising that industry has a vested interest (by way of reputation, profits/sales and growth) to ensure risks are well managed.<sup>64</sup> Appropriately leveraging this interest can lead to stronger working relationships between regulators and industry and minimise duplication of risk management efforts.

In addition to the automatic adoption and minimal checks pathway, an industry self-substantiation pathway could be introduced. Introducing an industry self-substantiation pathway to bring products to market may further support FSANZ's transition to risk-based and efficient regulation. This may be specific to very low-risk products, such as food additives that are very similar to other products that are already covered by food standards.

Of note, this pathway would not result in changes to food standards, but rather exempt products from being required to be listed in food standards if they are 'generally recognised as safe' by qualified experts.<sup>65</sup>

<sup>64</sup> Canadian Food Inspection Agency 2019, *Targeted Regulatory Review: Agri-food and Aquaculture Roadmap* available at: <<https://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/forward-regulatory-plan/agri-food-and-aquaculture-roadmap/eng/1558026225581/1558026225797>>

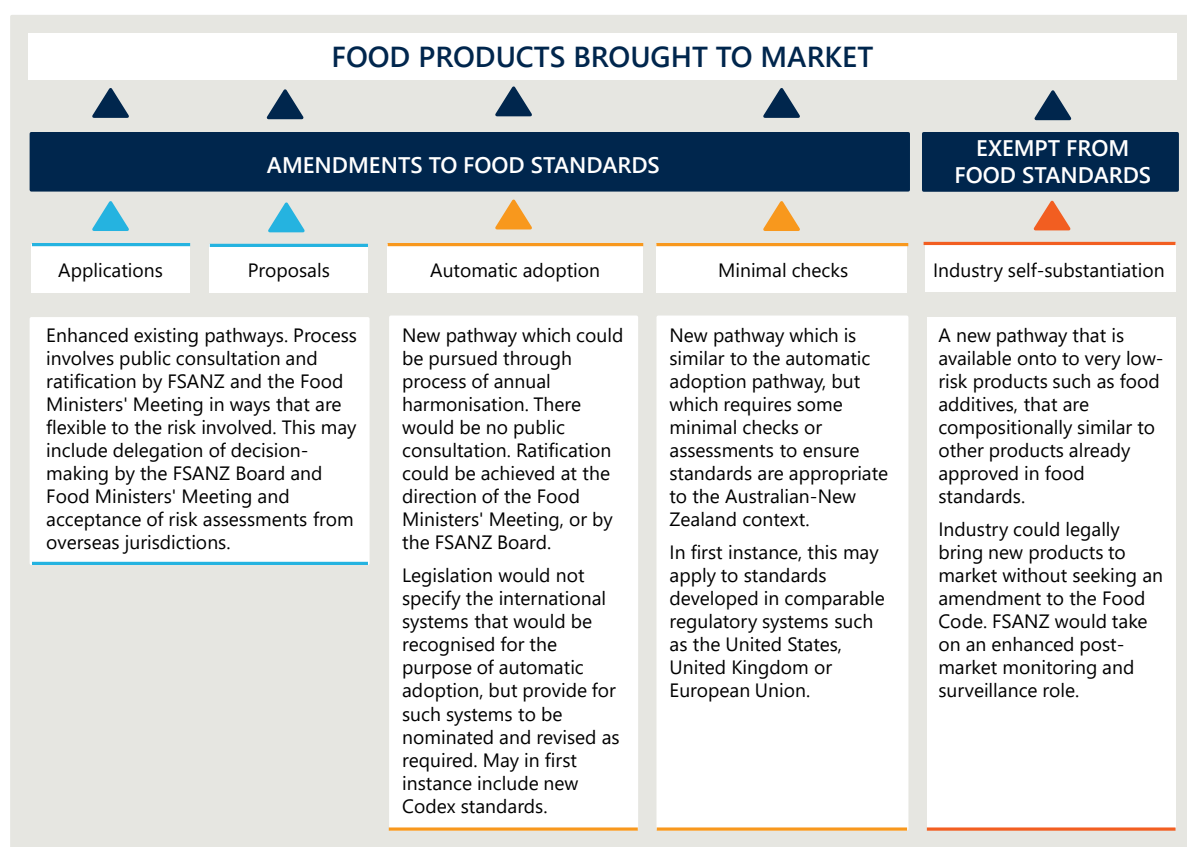
<sup>65</sup> A 'Generally Recognized as Safe (GRAS)' provision is available to businesses in the United States under the Federal Food, Drug and Cosmetic Act. A food substance may be GRAS either through scientific procedures (e.g. application of generally available and accepted scientific data, information, or methods, which ordinarily are published), where the quantity and quality of scientific evidence provided is equivalent to that normally required to achieve approval of a substance as a food additive. Utilisation of GRAS pathways does not

In addition to the legislative changes required to give effect to such a change, there would be operational shifts required, where:

- FSANZ could assist industry to understand the industry self-substantiation pathway and the evidentiary threshold requirements in the pre-market phase
- Post-market monitoring and surveillance work could be enhanced, to ensure ongoing compliance or address identified safety risks
- Should there be instances of non-compliance, FSANZ would first work with industry in an educational capacity to support remedial action
- If further interventions are required, FSANZ would advise jurisdictional enforcement agencies, you could use the suite of enforcement tools afforded to them under their own legislation.

The five possible ways to bring products to market proposed in Component 2 are shown in Figure 15 below.

**Figure 15 | The five potential pathways to bring a product to market**



### 5.2.3 Component 3 | Build in flexibility to create bespoke regulatory sandboxes

Under the current legislation, there are limited arrangements to support industry to innovate with products that do not fit neatly within the existing, static regulatory framework. Giving FSANZ the ability to

result in FDA approval. Notably, there has been significant criticism of GRAS pathway in the US context where it has been misused. Should this reform idea be implemented in the Australian New Zealand context in the form of industry self-substantiation pathways, careful implementation planning would be required to ensure that food businesses were supported to understand eligibility criteria for this pathway.

implement more flexible regulatory arrangements on a case-by-case basis to test new ideas could support innovation and improve market outcomes.

While there are distinct arrangements for regulation of novel (or non-traditional) foods (under Standard 1.5.1 of the Food Standards Code), these require food businesses to make an application to FSANZ. Novel food cannot be sold as a food or food ingredient unless listed in the Standard, which require pre-market assessment by FSANZ to establish their safety.

Greater flexibility could be introduced in the Act to enable FSANZ to create temporary exemptions to food regulations, on a case-by-case basis, to enable a food business (or businesses) to pilot new ideas. This could pertain, for example, to the introduction of new food products or ingredients to markets or the use of new technologies in the production and testing of food products. This could provide a mechanism to test new ideas outside of the constraints of the joint food standards system, understand how well it works and provide basis for generation of evidence prior to changes being made to food standards.

Exemptions could be granted in a range of forms – for example restricted authorisations, temporary allowances or exceptions, waivers or modifications to rules. This could be undertaken where there is a particularly compelling public health, social or economic rationale for granting exceptions to existing food regulations.

FSANZ would need to develop an overarching framework to ensure fair and proportionate setting of exemption terms and conditions and the duties of exempt businesses (e.g. reporting). The requirements could be adjusted over time as new information on the product, ingredient or technology is received.<sup>66</sup>

This idea is informed by 'regulatory sandboxes' – a recent development in regulatory models that support businesses to test innovative ideas. It was piloted in financial regulation and has since been expanded to other regulatory contexts. For example, Health Canada currently a regulatory sandbox pathway for Advanced Therapeutic Products (which existing regulations are not well equipped to handle).<sup>67</sup> A definition of this concept is provided in the callout box below.

A **regulatory sandbox** generally refers to a regulatory "safe space" that creates an environment for businesses to test products with less risk of being "punished" by the regulator for non-compliance. In return, regulators require applicants to incorporate appropriate safeguards to insulate the market from risks of their innovative business. It typically involves a framework set up by a regulator to allow pilot testing of innovations by private firms in a controlled environment (e.g., exemptions, allowances, time-bound exceptions etc.) overseen by regulators.<sup>68</sup>

Creation of time-bound regulatory sandboxes could occur in advance of broader updates to standards, and indeed may provide the evidence-base (and sense of urgency for) updating particular standards. They may be especially useful in relation to standards that have been identified as burdensome for industry and/or anachronistic in light of evolving industry practices. For example, industry stakeholders have cited *Standard 1.5.2 Food derived from gene technology* and *Standard 1.2.7 Nutrition, health and related claims* as examples that have particular adverse impacts on innovation due to widespread difference in interpretation between jurisdictions.

In these ways, a regulatory sandbox approach could provide greater confidence for food businesses and reduce current disincentives to research and development into innovative food products and production and processing systems and techniques. This increased innovation could have a significant impact on driving growth in the food manufacturing sector. Swinburne University estimates that innovation within the food manufacturing sector is responsible for approximately AUD \$350 million in annual exports, AUD

<sup>66</sup> Mangalam, S, Hodges, C & Sharpington, L 2020 'Theory Paper on Contemporary Regulatory Models' prepared by PRISM Institute, Canada for Safe Food Production Queensland. This paper has been developed as part of the jurisdictional consistency project being undertaken as part of the P3 reform program. It was provided to Nous by the Australian Department of Health.

<sup>67</sup> Ibid.

<sup>68</sup> Ibid, p. 33.



\$1.88 billion in annual business turnover, and 4,572 additional jobs created per annum. Simplistically, even a 1% growth in innovation from approaches such as regulatory sandboxes equates to AUD \$3.5 million in exports.

#### 5.2.4 Component 4 | Position FSANZ as the engine of food safety intelligence, equipped to drive forward-looking regulation

Stakeholders have reflected on the need for the system to be more proactive and forward thinking to better detect and manage risks, as well as consider the regulatory burden faced by industry more holistically. There is some interest in understanding how data might be more effectively harnessed from across the system for the benefit of various stakeholder groups.

While there are many highly capable entities that generate food safety research and data, there is duplication of effort across the system and missed opportunity to harness the benefits from economies of scale. To this effect, FSANZ could be positioned to be the engine room of this system, with a clear legislative remit and appropriate resourcing to drive the collection, consolidation and communication of food safety or food composition data to facilitate intelligence-led<sup>69</sup> decision making. This would leverage FSANZ's technical expertise and scientific capabilities (including data collection and analysis) to deliver more value to the joint food standards system whilst bringing it in line with other regulatory leaders.

FSANZ could consolidate an expansive repository of food safety or food composition information through several key activities. These activities would have the effect of creating a 'virtuous cycle' of intelligence gathering and application:

- **Resourcing FSANZ to undertake more timely, holistic, and regular reviews of food standards.** FSANZ could implement a more strategic approach to the review of standards, based on an ongoing quality oversight and monitoring role that 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 would draw on FSANZ's existing technical and scientific expertise as well as its coordination and monitoring roles. This proposal would require no change to legislation as the function is already provided in the FSANZ Act.

This reform idea could help to ensure ongoing relevance of standards, including considering the cumulative impact on health, safety, and regulatory burdens, and provide for a more systematic and strategic approach to reviewing them. This idea would leverage FSANZ's existing coordination roles and expertise.

- **Equipping FSANZ to coordinate food safety research across Australia and develop strategic relationships with New Zealand food safety research entities.** 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. 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 does not, however, resolve larger research coordination issues in the bi-national context.

Given FSANZ's scientific and technical expertise and extensive domestic and global networks, it could have a function to coordinate food safety research across Australia and develop strategic relationships with New Zealand food safety research entities. This would require a coordinated approach to prioritising research issues and bringing together relevant parties, and could include managing relationships with New Zealand food safety expert bodies, and potentially with other comparable international regulators involved in food safety assessments.

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<sup>69</sup> 'Intelligence' in this context refers to insights from food safety and food composition data.

- **Positioning FSANZ as the guardian of key food safety databases.** FSANZ could assume a role as the custodian of a composition / nutrition / food safety data base that is used for analysis of trends / emerging issues. This could build in first instance on the information already held by FSANZ in relation to the Australia Total Diet Survey, branded food composition and modelling work for the Health Star Rating calculator.
- **Providing for FSANZ to collate and create consumer-facing food safety education materials.** 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 and as not been extended to New Zealand which has separate arrangements for food education. This could be broadened to enable FSANZ to undertake this work on its own initiative.

These actions could potentially create a powerful bank of intelligence that could support FSANZ to be more future-focused and responsive in its efforts to:

- Prioritise reviews of standards where there is evidence of emerging risk
- Take a more informed position when assessing applications and proposals
- Progress FSANZ's reputation and credibility on the world stage
- Inform how regulation might best continually adapt to meet consumer expectations and protect and enhance Australia and New Zealand's competitive advantage in regional and global food markets.

Component 5 below sets out how this information could be used strategically by other organisations across the joint food standards system.

### 5.2.5 Component 5 | Foster new approaches to working with other agencies, with a focus on intelligence-sharing

FSANZ's credibility and status as a trusted entity derives in part from its independence, however it works within a broader regulatory ecosystem. Currently FSANZ works with other agencies at key interfaces in fairly discrete ways, however there may be opportunities to foster more collaborative partnerships that make optimal use of FSANZ's expertise and reduce fragmentation across the system.

FSANZ's collaboration with other agencies should focus on the sharing of food safety intelligence (Component 4 | Position FSANZ as the engine of food safety intelligence, equipped to drive forward-looking regulation). This sharing will support stakeholders and the collective food regulation system make shared, intelligence-led policy, research, and enforcement decisions. This enhanced collaboration and sharing across the system does not impact FSANZ's independence when making decisions regarding the development or amendment of food regulatory measures.

#### **FSANZ and the Food Ministers' Meeting could undertake periodic joint agenda-setting to agree on the proposals on which to focus**

FSANZ and the Food Ministers' Meeting 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 Food Ministers' Meeting come together to agree on 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.

This would align with the October 2020 Review of COAG Councils and Ministerial Forums which has recommended that the Food Ministers' Meeting (then the Forum) maintains a workplan of actions that sunset after 12 months. Note that this was an Australian only review, excluding New Zealand. Collaborative agenda setting might be an important mechanism for the Food Ministers' Meeting to curate its workplan moving forward.

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.

During these joint priority setting events, FSANZ could share intelligence about emerging food safety and population health risks to inform the Food Ministers' Meeting's policy agenda.

### **FSANZ could partner with government to make intelligence-led decisions and reduce duplication of efforts**

FSANZ could work alongside government stakeholders and provide its expertise at strategic points of time. This collaboration could support intelligence-led decisions in relation to policy agenda setting for the joint food standards system and supporting the joint food standards system to be more responsive and forward looking. This could include:

- **Earlier involvement with the FRSC to understand the potential food safety and regulatory impact of changes to food standards.** FSANZ could be engaged early by FRSC to establish a shared understanding of the safety and regulatory impact measures that will feed into an assessment of a proposal, drawing on FSANZ's technical and scientific expertise. This engagement may emphasise work that will be undertaken by each party at different stages of the process and identify opportunities to minimise duplication.
- **Collaborating with jurisdictional enforcement agencies to identify emerging risks and activate the appropriate regulatory response.** Currently, jurisdictions undertake significant work to hone a risk-based approach to regulation, based on their own perceptions of where the most pressing risks lie. FSANZ could use its intelligence base to highlight emerging risks and position enforcement agencies to stand up a proactive response and manage issues before they arise.

FSANZ currently has the statutory remit to coordinate food recalls in Australia, but only at the request of States and Territories. Stronger collaborations between FSANZ and the jurisdictions (including New Zealand) will facilitate more timely identification of risks and enable swift responses to better protect the public and minimise reputational damage to industry.

- **Enhanced collaboration based around information sharing could also extend to international partnerships with overseas jurisdictions (including standard-setting bodies and other regulators).** This could leverage FSANZ's existing work, relationships and presence in regional and global forums. There is some precedent for this; since 2013, FSANZ and Health Canada have been working together on the safety of genetically modified foods under a formal agreement to facilitate sharing of safety assessments of food derived from genetically modified organisms. This helps to reduce duplication and share scientific expertise between the jurisdictions. Additional formal partnerships could be established to support greater sharing of information (including risk assessments) which could enhance use of the *automatic adoption* and *minimal checks* pathways that are included in Component 2 of Option 2. Option 3 Component 4 further builds on this international role of FSANZ.

## FSANZ's databank could be available to drive high-quality research and policy work both across and outside government.

FSANZ could make available its data hold to other stakeholders for various purposes. This could include:

- **Informing project work carried out by FSANZ at the request of the jurisdictions.** This could be similar to, or build on, work already completed such 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.
- **Providing data or data-linkage services to the general public,** which may include universities, expert food safety bodies, or industry. Of note, the Act also readily provides for FSANZ to make available its knowledge, expertise, equipment, facilities and intellectual property on a commercial basis (s 13(o)). This means that such services could potentially be offered through fee-for-service arrangements, which in turn might generate a new revenue stream for FSANZ.

Operationally, obtaining and maintaining data would involve building on FSANZ's infrastructure already in place to better link with other data sources in the system and then scale the insights.

## 5.2.6 Component 6 | Streamline FSANZ's governance and operations

The changes outlined in previous components of Option 2 | Modernise the Act to make it agile, resilient and fit-for-purpose may have the effect of releasing latent capacity in FSANZ. Additional changes could also be made to facilitate more efficient administration of the organisation.

### Legislation could support more efficient and effective governance

FSANZ's board arrangements could be more strengthened by:

- **Creating a smaller, more explicitly skills-based Board.** 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. Consideration could be given to appropriate Australia and New Zealand-specific contextual knowledge, and the Chairperson and/or CEO could have a formal input or decision-making role. (issues.)
- **The Board could be consolidated to eight people,** including a Chairperson and seven members. 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 could be particularly sensible if The Board is granted powers to delegate decision-making duties to the CEO (as discussed in Section 5.2.2)
- **Streamlining nomination and appointment processes for board members.** 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 Food Ministers' Meeting's role in signing off on all Board appointments. This option would seek to improve the quality of the FSANZ board through more efficient during the appointment of board members.<sup>70</sup>

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<sup>70</sup> Note that changes to the legislated composition and nomination process of the board would also need to be reflected in the Food Regulation Agreement and the Food Treaty between Australia and New Zealand.

- **Moving to a virtual by default board meeting model.** Easily implemented, this change would bring two benefits. Firstly, it would substantially reduce the costs of facilitating the governance of FSANZ. Secondly, it would enable more flexible and responsive governance, currently impeded by the barrier of needing to organise face-to-face meetings internationally.

### **Investment into business solutions could help staff work more efficiently**

Investing in an online portal might facilitate a move away from ad hoc email and phone-based communication, reducing administrative burden and time costs for industry and FSANZ involved in a back and forth communication. The business portal could include automatic widgets to help the user to navigate to pre-existing support materials.

While outside the scope of the Review, there may also be an opportunity for FSANZ to consider the broader uses of technology when stipulating labelling requirements in food standards. For example, the increased uptake of QR codes as well as the internet more broadly means that some information that has traditionally been presented on a physical label may be presented on another medium (such as a website), while still being accessible at the moment such information is required.

### **New cost-recovery mechanisms for industry-initiated work have not been proposed as part of this review**

Funding arrangements are largely agreed outside of the Act and are therefore out of scope for this review. Cost recovery mechanisms on the other hand are captured within the Act and have been called out in the ToR for the review.

Consultations and research to date explored the option of expanding the provisions for cost-recovery within the Act to include industry-initiated work for which FSANZ is currently not remunerated. This might include a broader list of applications (i.e. beyond just applications that would confer an exclusive capturable commercial benefit) and for other services such as pre-application assistance and advice.

Consultations and research conducted to date indicate that these changes could bring additional compliance burden, particularly for small businesses, without significantly improving FSANZ's revenue streams. Testing this assumption and the potential for greater cost recovery is the subject of a specific discussion question for this review.

A separate, targeted review on funding arrangements may be warranted to include overall contributions made by government's and the potential for states and territories to directly contribute to project-specific funding.

## **5.3 Option 3 | Build on FSANZ's role to reinforce the bi-national nature of the joint food standards system**

Option 3 seeks to change the Act to give FSANZ broader statutory functions aimed at reinforcing the bi-national nature of the joint food standards system. It builds on Option 2, and incorporates all of the components set out in Option 2, as well as four additional components of change:

1. Provide for FSANZ to coordinate food incident responses, on its own initiative
2. Provide for FSANZ to give greater guidance on food standards
3. Position FSANZ to take on an enforcement role
4. Clarify legislation so FSANZ can extend Australia and New Zealand's influence on the international stage.

Option 3 would involve an expansion in FSANZ's operations, in particular through a greater role in relation to enforcement guidance and/or activities.

### 5.3.1 Component 1 | Provide for FSANZ to coordinate food incident and food recall responses, on its own initiative

While FSANZ has a collaborative relationship with jurisdictions and a strong track record of effective partnerships in times of emergency, under current legislation, FSANZ can only coordinate food incidents and food recalls at the request of Australian states and territories (Section 13(1k)), and under state and territory laws. FSANZ does not carry out this function on behalf of New Zealand.

As a consequence of Option 2 | Component 4, FSANZ will have even more data and intelligence at hand about emerging risks and actual events across Australian, New Zealand and internationally. This means that FSANZ may have relevant information ahead of jurisdictions about where a food recall or incident response is required.

FSANZ statutory functions could be amended to provide for FSANZ, 'in consultation with the States and Territories, or on its own initiative to coordinate action to respond to food incidents and food recalls'. This function could also be extended to New Zealand.<sup>71</sup>

### 5.3.2 Component 2 | Provide for FSANZ to give greater guidance on food standards

#### FSANZ could reduce interpretive uncertainty through the provision of greater guidance on food standards

Under this component, FSANZ would have the remit and resources to provide comprehensive guidance about food standards. 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.

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.

- **Resourcing FSANZ to assist Australian businesses to prepare an evidence dossier to substantiate general health claims.** Australian stakeholders have reported frustration with inconsistent monitoring and enforcement self-substantiated general health claims. This has been less of an issue for New Zealand, where MPI already works closely with industry in the pre-market phase. FSANZ could

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<sup>71</sup>New Zealand exercises separate functions in respect to food recall and food incident responses under New Zealand legislation (the Food Act 2004 and the Animal Products Act 1999), in coordination with Australia when required.

replicate the work MPI does to assist Australian businesses to understand and prepare to meet the required evidentiary thresholds, so that more organisations are compliant with regulations, which in turn might reduce the stress placed on States and Territories to carry out post-market enforcement. This could be a cost-recovered activity.

The Act and the *Therapeutic Goods Act* are both currently administered by the Australian Minister for Health. There is an opportunity as part of this review of the Act to develop greater clarity by giving the Minister responsibility and powers under both Acts to determine if a product is a food or a medicine.

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

- **Providing for a 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*.
- **Providing for a 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."

### 5.3.3 Component 3 | Position FSANZ to take on an enforcement role

FSANZ could take on an enforcement role to address known pain points in the system and encourage greater uptake of best practice in regulator behaviours. An enforcement role could be extended to New Zealand by negotiation under the Food Treaty.

This idea can be explored at two levels: FSANZ taking on limited enforcement activities contained for example, to enforcement of food labels and novel foods; or FSANZ taking on a much broader remit to become a single, bi-national regulator.

#### Option 1 | FSANZ could take on limited enforcement activities

The legislation could be amended to provide FSANZ with an enforcement function specific to select food standards. In first instance, this could include standards that have been reported to be challenging to enforce at a jurisdictional level due to capability or capacity issue, such as food labels (including health claims) and novel foods.

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

While this change provides the primary advantage of dealing with some of the known stress points in the food regulatory enforcement system, it might also create opportunities for FSANZ to demonstrate how insights generated through its work on intelligence gathering (explored in Option 2, Component 4) can directly inform an enforcement approach. By communicating these insights through existing governance channels such as the ISFR, there may be an opportunity to support a capability uplift across the system to apply more intelligence-led enforcement approaches.

#### Option 2 | FSANZ becomes the single, bi-national regulator

As previously noted, all ideas are presented here as having bi-national effect, but these can be decoupled i.e. to position FSANZ as an Australia-only or New Zealand-only national regulator.



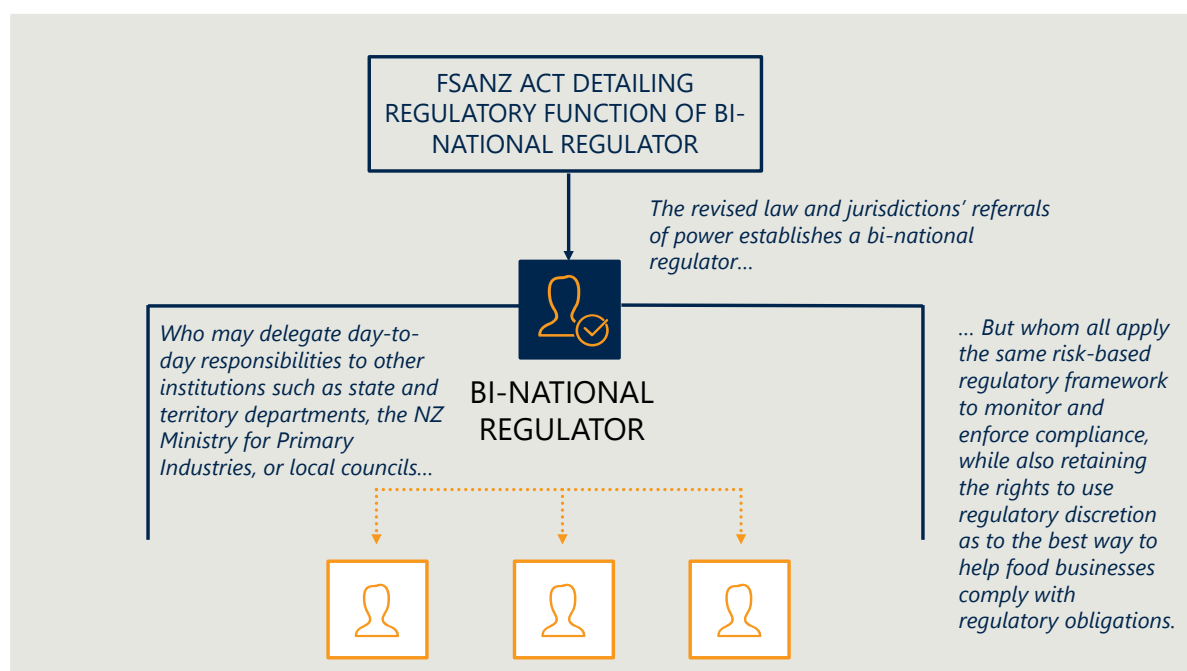
FSANZ could have a fully-encompassing enforcement role that includes responsibility for overseeing all food standards. This would mean it would have statutory functions relating to coordinating the enforcement of food standards (and have the relevant legislative powers to do so), however, the institutional arrangements utilised to deliver on this function could be more complex.

As the regulator, FSANZ could have responsibility for setting the regulatory framework, for example, by:

- Developing and applying a framework to assess certain businesses or activities' risk profile
- Developing training programs for enforcement officers
- Interfacing with other regulators on matters that may impact multiple regulatory schemes
- Investing in technology that is compatible across all jurisdictions
- Establishing appropriate governance to ensure that matters are managed at the most appropriate level with regards to complexity.

However, as shown in Figure 16 below, FSANZ may outsource day-to-day regulatory responsibilities to other institutions, i.e., existing jurisdictional regulatory bodies.

**Figure 16 | A single law, single regulator model can utilise different institutional arrangements but operate under a single regulatory framework**



Implementing such a model would mean that:

- The current enforcement workforce from jurisdictional departments or ministries of health and agriculture, local councils and independent regulators could carry out regulatory functions on a day-to-day basis (which would not displace the existing workforce) but could escalate to FSANZ for issues or matters where technical expertise would be an advantage for resolution.
- All jurisdictional agencies would operate under the same practice framework and would access and apply the same interpretation of food standards. This would reduce the duplication of effort for each agency to develop their own resources.
- Local enforcement bodies would retain the ability to exercise discretion in how to enforce compliance (but operate against a consistent legislative framework), which will continue to support a more tailored approach to regulating in areas of varying sizes, industry maturity and locally available resources.



There would also be potential for FSANZ to recognise other enforcement bodies, such as private auditors, for example those used by major food business as part of their internal quality assurance processes. Where such arrangements are in place, food businesses may be subject to fewer or less intensive inspection regimes by government.

There is strong precedent for a national Australian regulator replacing state and territory-based arrangements in Australia. An example for Marine safety is shown overleaf.

#### **CASE STUDY: Australian Maritime Safety Authority**

Marine safety regulation underwent significant reform with the introduction of the *Marine Safety Domestic Commercial Vessel National Law Act 2012*. The intergovernmental agreement signed by all jurisdictions provides that the Australian Government applies the Commonwealth law to the extent of their constitutional reach, and each jurisdiction will apply the model law to any 'gap' in this reach.

The Act established the Australian Maritime Safety Authority (AMSA) as a single national regulator for domestic commercial vessels, however, regulatory functions are delegated to states and territories to manage on a day-to-day basis.

State-based legislation specifies particular standards that must be met within the jurisdiction. The National Standard for Commercial Vessels is being introduced progressively to all jurisdictions.

To the authors' knowledge, there is no precedent of a single bi-national regulator overseeing regulatory affairs in Australia and New Zealand, and no direct equivalent is in the international regulatory schemes researched.

### **5.3.4 Component 4 | Clarify legislation so FSANZ can extend Australia and New Zealand's influence on the international stage**

FSANZ is part of an international network of standard setters and other expert bodies who work collaboratively to share independent, science-based insights about food safety and public health protections. This includes leading Australian input into relevant Codex Alimentarius Commission committees and co-chairing the APEC Food Safety Cooperation Forum.

While FSANZ has the statutory obligation to have regard to harmonisation of food standards, it does not have the legislative remit to coordinate this broader programme of international relations and contributions. This means its influence is limited.

This component seeks to build better strategic relationships with comparable international regulators to either share assessments or standards or make these together for mutual benefit as part of the harmonisation process. Ultimately greater harmonisation with international standards will create new or strengthened trade channels which will benefit Australia and New Zealand businesses.

Component 4 entails minor changes to the legislation to clarify this objective of extending Australian and New Zealand influence as a key obligation of FSANZ.

## 6 Impacts of reform options

Reform options can be assessed against three core criteria

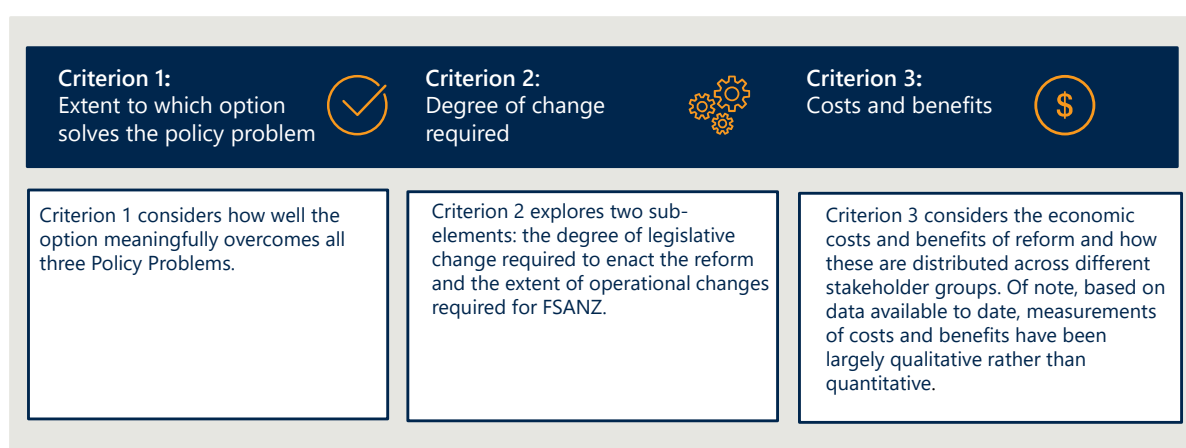
### GUIDANCE NOTE

The preferred option for reforming the FSANZ Act will ultimately be identified in the final RIS, based on an assessment of each option against three evaluation criteria. Specifically, the final RIS will conclude the overall net benefit of each option, and how key costs and benefits are distributed across key stakeholder groups.

This draft RIS *commences* this analysis and summarises the available research, data and consultation outputs. It does not attempt to calculate a net benefit for each option, or to describe in absolute terms how the costs and benefits are distributed across stakeholder groups. This information will be developed with regards to feedback received on this draft RIS.

The three criteria are detailed in Figure 17.

Figure 17 | Overview of the evaluation criteria<sup>72</sup>



### 6.1 Impacts of Option 1 | Retain the status quo

#### 6.1.1 Extent to which Option 1 solves the Policy Problems




##### Option 1 does not meaningfully address the Policy Problems identified

The Act is not fundamentally flawed or ill-equipped to deal with the market failures it is designed to address. Nonetheless, Option 1 **would not meaningfully address the Policy Problems** summarised in Figure 18. In particular:

<sup>72</sup> **Criterion 1 | Extent to which the option solves the policy problem**, considers how well the option meaningfully overcomes all three Policy Problems. By tying this to the Policy Problems, Criterion 1 includes an exploration of how well the option supports efficient and risk-proportionate regulation; whether it improves or detracts from Trans-Tasman consistency; how it changes the relationships between the different players in the food regulatory ecosystem; and whether it is likely to facilitate trade while protecting health and safety; among other matters.

- **The Act would remain inefficient to administer** with little ability to tailor regulatory oversight and processes to the level of risk. Cumbersome processes can stifle innovation and limit consumer choice of food products by imposing significant 'barriers to entry' to the Australian and New Zealand markets.
- The Act, in its current form, **does not optimally support a strong, resilient and agile regulatory system** that leverages the technical, scientific expertise and capabilities of FSANZ to deliver value to the regulatory system, through a more intelligence-led and less fragmented system.
- The current arrangements would continue to undermine the **power of a single, joint food standards system**. Known tensions and inconsistencies in the enforcement of the standards would not be addressed and uptake of best regulator practice will continue to vary across system jurisdictions.

Figure 18 | Impact of Option 1 on Policy Problems

Option meaningfully addresses policy issues	Policy problem
	<p><b>In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer</b></p> <ul style="list-style-type: none"> <li>a) The objectives and current functions of FSANZ are not clear</li> <li>b) Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible</li> <li>c) Elements of FSANZ's operations are inefficient</li> </ul>
	<p><b>Legislation does not enable a strong, resilient and agile food regulatory system</b></p> <ul style="list-style-type: none"> <li>a) Statutory timeframes and resourcing constraints within FSANZ reinforce a piecemeal and reactive regulatory focus</li> <li>b) Food safety and quality no longer guarantee a competitive advantage for Australian and New Zealand food businesses</li> <li>c) There is limited collaboration and integration of effort across the regulatory system</li> </ul>
	<p><b>Current arrangements undermine the power of a single, joint food system</b></p> <ul style="list-style-type: none"> <li>a) FSANZ is limited in its power to assist in food incidents and food recalls</li> <li>b) Inconsistent interpretation and enforcement of food standards is an enduring issue for the system</li> <li>c) FSANZ has no legislative remit to extend Australia and New Zealand's influence on the international stage</li> </ul>

## 6.1.2 Degree of change required

### As no changes are proposed, no change is required

Option 1 proposes continuing the status quo regulatory system. This means that stakeholders would continue to operate under the current scheme, and while no change is required, government, FSANZ, industry and other stakeholder must continue to exert effort to meet their regulatory obligations, including complying with food standards (industry) and administering the scheme (FSANZ and government stakeholders). Choosing the status quo is not choosing an option without costs. Under it, FSANZ will continue to face an ever more burdensome workload with more constrained resources and limited tools to rectify the long-term challenges they face.

### Insights into what stakeholders have reported so far...

Stakeholders have reported that Option 1 represents a missed opportunity to ensure that the Act is appropriately future-focused and flexible to respond to evolving government priorities, consumer preferences and industry practices, and to support the Food Ministers' Meeting 's third system priority for 2017-2021: *to maintain a strong, robust and agile food regulatory system*.

Many government, industry, consumer, and FSANZ stakeholders observe that this carries significant opportunity cost and that this option would represent a missed opportunity to ensure that the Act remains fit-for-purpose and is adequately future-focused. Stakeholders have been anxious for this review and have participated passionately in consultation activities.

## 6.1.3 Costs and benefits

### There are costs and benefits associated with the current legislative framework

Different stakeholders experience distinct costs and benefits under FSANZ's status quo food safety standards scheme (see Table 8). The most notable burden is that the status quo regulatory scheme imposes a substantial cost on industry (see Table 6), applications to change standards are costly and take a long time (in many cases up to a year). Conservative initial estimates posit a regulatory burden of approximately AUD \$1 million (NZD \$1.07 million) per year.

Importantly, this cost is currently borne by a small number of stakeholders (for example, only 21 applications and proposals were accepted in 2019-2020). Stakeholders have reported that the costs associated with the application process is a real barrier to many small and medium businesses seeking variations to food standards - this is particularly problematic, as the burden associated with complying with food standards (which is out of scope for this Review) is significant and shared across food businesses of all sizes.

Beyond the costs of preparing an application, delay costs can be substantial for industry. For example, one business reported lost revenue of AUD \$130,000 (NZD \$139,100) for every month their application took to be approved (in addition to the USD \$40 million that had already been spent on research and development). This particular application took 11 months to finalise - based on the average number of applications FSANZ receives each year (and assuming for the point of illustration that each application is similarly delayed and incur a similar delay cost), the current legislative framework represents up to AUD \$21.5 million (NZD \$23.0 million) per year in opportunity costs alone.

The uncertainty of this system, informed by limited recognition of foreign approval processes, has stifled innovation, making it difficult for new products to enter the Australian and New Zealand markets. This undermines consumer outcomes and reduces the ability for Australian and New Zealand industry to be competitive as exporters of new products.

**Table 6 | Estimated regulatory burden (administrative costs) on industry of status quo**

Reform element	Annual regulatory burden	10-year regulatory burden
Option 1   Status quo (AUD)	AUD \$1.077	AUD \$10.770
Option 1   Status quo (NZD)	NZD \$1.152	NZD \$11.524

These problems are themselves a symptom of a further burden – namely that FSANZ itself is increasingly overwhelmed with the administration of the current regulatory system. Presently, administration of procedures under the status quo are expected to cost approximately AUD \$5.4 million (NZD \$5.8 million)

over the next ten years (see Table 7). Without further resourcing or a change to FSANZ's functions, this burden is likely to only grow.

**Table 7 | Cost for the administration of procedures under the status quo<sup>73</sup>**

Reform element	Total cost over 10 years (level 1 and 2 procedures) (AUD)	Total cost over 10 years (level 1 and 2 procedures) (NZD)	Total hours
Option 1   Status Quo - Varying or developing food standards	AUD \$5,388,000	NZD \$5,765,160	73,760 hrs

Despite the cost of administering the scheme under the status quo, it yields substantial benefits. With its strong emphasis on prevention, the scheme has been highly effective at ensuring the safety and health of Australian and New Zealander consumers. That safety has had an indirect benefit for industry – the strong reputation for reliable and high-quality products in the Australia – New Zealand market has provided industry with a highly marketable reputation, improving their ability to export profitably.

**Table 8 | Costs and benefits of Option 1 (status quo)**

Stakeholder	Costs or Benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>Substantial administrative costs imposed by time consuming and costly processes to make applications to change food standards (including significant evidentiary requirements for straightforward applications). One stakeholder estimated that an average application cost AUD \$150,000 (NZD \$160,500) to develop. With FSANZ currently receiving approximately 20 applications per year, this represents AUD \$3 million (NZD \$3.21 million) in total costs annually if this reflected all stakeholders, or AUD \$30 million (NZD \$32.1 million) over ten years.</li> <li>Delay costs or foregone economic opportunities as a result of: <ul style="list-style-type: none"> <li>Delays in bringing products to market, due to inefficient processing of applications and proposals. (One industry stakeholder faced opportunity costs amounting to AUD \$130,000 (NZD \$139,100) per month for an application that took 11 months to be approved. Extrapolating this data (see page 104) leads to up to AUD \$21.5 million (NZD \$23.0 million) per year in opportunity costs alone.)</li> <li>Deterrent effect for prospective applicants due to time and cost of making an application (<i>barriers to innovation</i>)</li> <li>Limited harmonisation with international and overseas standards (for exporting businesses).</li> </ul> </li> <li>Substantial compliance burden associated with (a) interpretive uncertainty around food standards and (b) inconsistent interpretation across jurisdictions.</li> </ul>

<sup>73</sup> Different procedures for assessing changes to food regulatory measures are legislatively enshrined. The hours involved in assessing different procedures are included in FSANZ's 'Application Guidelines' (a legislative instrument in accordance with s 23(1) of the Act. The Handbook available at: <https://www.foodstandards.gov.au/code/changes/Documents/FSANZ%20Application%20Handbook%201%20July%202019.pdf?csf=1&e=z0iKEe>

Stakeholder	Costs or Benefits	Description of costs or benefits
Industry	Benefits	<ul style="list-style-type: none"> <li>Current assessment processes are well understood and legislated requirements for consultation on changes to food standards are supported.</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Costs	<ul style="list-style-type: none"> <li>Moderate administrative costs associated with monitoring and enforcing food standards in presence of interpretive uncertainty. This is beyond the costs incurred by jurisdictional governments to monitor and enforce compliance with food standards, which is a cost associated with jurisdiction-level food acts.</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Benefits	<ul style="list-style-type: none"> <li>The status quo has delivered good public health and trade outcomes over many years and the joint food standards system has a strong track record and international reputation. It has effectively prevented the market failures that it was designed to address.</li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>Small effect on consumer choice through limitation in range of food products available (due to deterrent effect, delays in processing applications).</li> </ul>
Consumers	Benefits	<ul style="list-style-type: none"> <li>Sustained assurance around the quality and safety of the Australian – New Zealand food supply which will support confident investment into food and food businesses.</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>Substantial operational costs associated with administering an outdated and inflexible Act (e.g. time involved in assessing applications and proposals through broadly one-size-fits-all approach with limited ability to draw on international evidence-base). The total funding for FSANZ between 2017 and 2020 was approximately AUD \$60 million (NZD \$64.2 million), AUD \$20 million per annum (NZD \$21.4 million) following a decrease of almost a third since 2011. Assuming that FSANZ's total funding remains stable, total funding over the next ten years is estimated to be AUD \$200 million (NZD \$214 million).</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>N/A</li> </ul>

#### Discussion question related to the assessment of Option 1

- Would the impact of pursuing Option 1 represent a positive, negative or neutral outcome for your sector?
- What are the key risks borne by different stakeholder groups for this option? What is the likelihood of these risks, and what would be the magnitude of consequence if they occur?
- Do you have any data on hand that will help to quantify the cost of delays when bringing products to market through the current process? If so, please provide these data.
- Are there other costs and benefits (qualitative or quantitative) that should be considered as part of this impact analysis? If so, who would bear these costs and benefits?
- Are you aware of any data that may assist in quantifying the magnitude of these costs and benefits? If so, please provide these data.
- What risks are borne by your sector as a whole and by different stakeholders under Option 1 (i.e. retain the status quo)?




10. (For jurisdictional regulators) What resources (FTE) do you dedicate to monitoring and enforcement of food standards? What are the costs associated with these arrangements?

## 6.2 Impacts of Option 2 | Modernise the Act to make it agile, resilient and fit-for-purpose

### 6.2.1 Extent to which Option 2 solves the policy problems

As summarised in Figure 19, Option 2 would result in a modern, fit-for-purpose regulatory framework. It would address Policy Problem 1 and 2 to deliver a more agile, resilient and fit-for-purpose regulatory framework but would not substantially overcome current impediments to strengthening the bi-national nature of the joint food standards system.

Figure 19 | Impact of Option 2 on Policy Problems




Option meaningfully addresses policy issues	Policy problem
	<p><b>In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer</b></p> <ul style="list-style-type: none"> <li>a) The objectives and current functions of FSANZ are not clear</li> <li>b) Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible</li> <li>c) Elements of FSANZ's operations are inefficient</li> </ul>
	<p><b>Legislation does not enable a strong, resilient and agile food regulatory system</b></p> <ul style="list-style-type: none"> <li>a) Statutory timeframes and resourcing constraints within FSANZ reinforce a piecemeal and reactive regulatory focus</li> <li>b) Food safety and quality no longer guarantee a competitive advantage for Australian and New Zealand food businesses</li> <li>c) There is limited collaboration and integration of effort across the regulatory system</li> </ul>
	<p><b>Current arrangements undermine the power of a single, joint food system</b></p> <ul style="list-style-type: none"> <li>a) FSANZ is limited in its power to assist in food incidents and food recalls</li> <li>b) Inconsistent interpretation and enforcement of food standards is an enduring issue for the system</li> <li>c) FSANZ has no legislative remit to extend Australia and New Zealand's influence on the international stage</li> </ul>

An overview of how Option 2 addresses Policy Problems 1 and 2 is shown at Figure 20.

Figure 20 | Impact of Option 2 on Policy Problem 1 and 2

FROM...	TO...
<b>POLICY PROBLEM 1</b>	
In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer	The Act is fit for purpose and underpins efficient and effective regulation
The objectives and current functions of FSANZ are not clear	Objectives and functions are clarified, including a clear authorising environment for FSANZ to lead key functions related to public health and safety
Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible	Processes and decision-making arrangements to amend food standards are reconceived to support more flexible and risk-proportionate approaches
Elements of FSANZ's operations are inefficient	FSANZ's operations are streamlined through changes to FSANZ's legislated governance and investments in business solutions
<b>POLICY PROBLEM 2</b>	
Legislation does not enable a strong, resilient and agile food regulatory system	The Act supports an agile, resilient and collaborative food regulatory system
Statutory timeframes and resourcing constraints within FSANZ reinforce a piecemeal and reactive regulatory focus	FSANZ is positioned as the engine of food safety intelligence, enabled to drive forward-looking regulation
Food safety and quality no longer guarantee a competitive advantage for Australian and New Zealand food businesses	FSANZ successfully keeps pace with changing consumer expectations and can better leverage food regulatory measures to reflect these
There is limited collaboration and integration of effort across the regulatory system	FSANZ collaborates with Food Ministers' Meeting, governments and others to drive intelligence-led decisions and quality research and policy work

### Component 1 (legislative changes to clarify the objectives and functions of FSANZ) would create a clear direction for the future

Option 2 Component 1	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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Clarifying the objectives and functions of FSANZ in the Act would support a clear, common understanding across the joint food standards system of the strategic direction and functions of FSANZ. These amendments would ensure alignment with the current work FSANZ undertakes and provide guidance on which activities FSANZ should be focusing on. Amendments to the Act also represent an opportunity to harmonise the objectives and functions of FSANZ with the vision for the joint food standards system, which is currently being developed through a separate piece of work. Expanding the objectives to explicitly reference trade as a core objective of FSANZ (although subordinate to public health objectives) would better reflect the importance of a competitive domestic and export food industry for both Australia and New Zealand.






Expanding the objectives of the Act would give clear responsibility for FSANZ to promote food sustainability, an increasingly important issue for governments, consumers, and international trade partners. This would enable FSANZ to assess risks in the joint food standards system more broadly, taking account of a range of interconnected factors and bring benefits for diet-related health and safety, economic prosperity and environmental sustainability. This would also mean fewer occasions where food sustainability issues ‘fall through the cracks’ between regulatory systems, each with no clear remit to deal with these issues. For example (but in no way illustrative of the scope of the problem or solution), regulation of sustainability claims by food products (e.g. ‘dolphin-safe tuna’ or ‘carbon neutral beef’) would reward food businesses that are accurately marketing products to consumers and allowing consumers to make more informed choices.

Expanding the objectives of the Act will also enable FSANZ to implement regulatory measures that appropriately recognise indigenous culture and food expertise.

The inclusion of additional considerations to which FSANZ must have regard to s 18 (i.e. regulatory impact on business, food sustainability and indigenous culture and expertise) may have the effect of creating additional tensions, and potentially delays in decision-making, when factors are in conflict.

Additionally, adding further dimensions to the Act or FSANZ’s objectives will in fact increase the level of regulation at play. the Food Ministers’ Meeting could request FSANZ to consider some of these additional factors, for example, by making relevant ministerial guidelines. However, this is unlikely to result in the same systemic consideration of regulatory burden placed on small businesses, sustainability issues or indigenous culture and expertise as would be afforded by these additions to legislation.

## Component 2 (less prescriptive processes for changing food standards) is instrumental in modernising the Act




Option 2 Component 2	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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Option 2 would reduce the regulatory burden on food businesses, particularly small businesses, when seeking to bring food products to market and make changes to food standards. The new streamlined processes outlined in Component 2 will give FSANZ and the Food Ministers’ Meeting the flexibility to target resources and effort according to risk and refocus their time on high-risk products and important strategic priorities.

This approach will maintain the necessary regulatory oversight while providing greater agility and efficiency, resulting in timelier outcomes for stakeholders. Less burdensome processes will help incentivise businesses to use the application process and reduce opportunity costs associated with delays in bringing products to market.




An industry self-substantiation pathway for very low-risk products (e.g. certain food additives) would enable businesses to bring products to market without making an application to change food standards (or waiting for FSANZ to adopt relevant international standards). This would provide specific benefits for smaller food businesses that are less likely to be able to afford to apply for changes to food standards (even through streamlined pathways and more risk-proportionate processes).

## Component 3 (flexibility to create new regulatory sandboxes) would support industry innovation

Option 2 Component 3	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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The creation of regulatory sandboxes would foster innovation and reduce regulatory impost to industry. Regulatory sandboxes involve providing FSANZ with an enhanced ability to expand and tailor the regulatory framework in an agile way, on a case-by-case basis. This reform could, for example, provide greater ability for food businesses to (a) undertake research & development on innovative products or (b) provide different avenues for market access that cannot readily be accommodated into existing requirements under food standards. This could support a more open and active dialogue between FSANZ and industry, changing the nature of the relationship between the regulatory system and business (noting FSANZ is not the regulator per se).

## Component 4 (positioning FSANZ as an engine of data and intelligence) would provide the foundations for intelligence-led decisions

Option 2 Component 4	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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### Proposed changes would create a rich data repository that could be curated and mined by FSANZ for key insights

Component 4 proposes building on FSANZ's role to support collection and analysis of data, such as related to dietary patterns, trends in food safety, international developments, and practical application and implications of food standards for Australian and New Zealand population. This has the potential to overcome the silos currently in place around the collection, collation and application of food data for example through:

- Supporting more intelligence-led decision-making by government in relation to food policy development and monitoring and enforcement
- Enhancing competitive advantage currently enjoyed by Australian and New Zealand food businesses in regional and global markets
- Ensuring standards remain fit-for-purpose and future-focused, including addressing inconsistencies that arise within and between standards, to reduce regulatory burden for industry and support protection of public health and safety
- Supporting effective prioritisation of reviews of standards where there is evidence of emerging risks
- Providing the basis for consumer-facing food safety education materials that could increase consumer awareness about food safety issues, with a focus on consolidating information into a single repository.

Creating a new statutory role for FSANZ incurs additional regulation. While FSANZ could take on this function without a legislative remit, this function could need to be clearly captured and appropriately remunerated in any funding agreement with the Australian and New Zealand Governments.




### Regular, holistic reviews of standards would support reduced compliance burden for industry and provide the basis for consistent, fit-for-purpose standards

Component 4 also involves resourcing FSANZ to undertake regular, holistic reviews of standards. This would benefit industry by providing an improved mechanism for:

- Identifying and addressing inconsistencies between food standards that impose regulatory burden or increase 'interpretive uncertainty' around food standards
- Ensuring that standards remain fit-for-purpose over time given changes in industry and regulatory practice (e.g., due to technological progress and international and domestic trends in food production and retailing) as well as changing consumer preferences and expectations. This could help to safeguard and enhance the competitive advantage enjoyed by Australian and New Zealand food businesses given the strong reputation of the Trans-Tasman system in regional and global markets.
- Providing overarching consideration of trade, competition and marketing impacts and compliance burden implications for food standards as-a-whole. This is in contrast to the current piecemeal consideration, including opportunities for greater international harmonisation. This would help to mitigate risks of regulatory creep and the cumulative burden for industry as a result of incremental changes to food standards and piecemeal consideration of their impacts.

Holistic reviews would also be an important opportunity to reflect contemporary research around population health risks, and to consider how regulatory tools might be appropriately used to mitigate obesity and food-related chronic disease.

### Component 5 (fostering approaches to working with other agencies) would reduce duplication and enhance the collective impact of actors across the system

Option 2 Component 5	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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Component 5 retains FSANZ's independence while leveraging opportunities to improve the way FSANZ works in relation to the broader regulatory ecosystem. Component 5 addresses the issue of limited collaboration and integration of effort across the regulatory system.

### Greater coordination at standard-setting/policy development interface would improve system alignment and confidence in the regulatory system

Establishing a mechanism for regular joint-agenda setting between FSANZ and the Food Ministers' Meeting to regularly agree system goals and priority changes to food standards – in particular, proposals to prioritise in any given year – could help to improve progression of FSANZ's workplan and support more strategic resource allocation. This would also provide opportunity to recognise or align FSANZ's efforts with broader governmental objectives to promote efficiencies across the joint food standards system. Agreeing items that would be de-prioritised or removed from the workplan could also promote broader confidence in the ability for the regulatory system (and FSANZ in particular) to progress issues in a timely and transparent manner. These benefits would likely outweigh any additional, marginal costs associated with establishing and operating a mechanism or forum for joint agenda setting; however, it is critical that this does not compromise FSANZ's independence or ability to exercise its executive oversight functions effectively – both are vital strengths of the existing regulatory system.




### Component 5 would reduce duplication and enhance collective impact by fostering more strategic end-to-end partnerships between FSANZ and other stakeholders

Enhanced partnerships across the joint food standards system (both within and beyond the Trans-Tasman system) could deliver greater value to the joint food standards system and reduce costs that relate to duplication and administration for example through:

- Reducing duplication in the system including the administrative burden borne by different agencies to undertake siloed research and data collection

- Increasing FSANZ's capacity to increase efficiencies and/or take on more strategic work via a potential new revenue stream from selling data or data-linkage services
- Reducing duplication in time and effort borne by FRSC in pre-proposal regulatory assessment work where this could be supported by FSANZ
- Creating long-term efficiencies through enhanced sharing of information (including risk assessments) with overseas jurisdictions.

## Component 6 (streamline FSANZ governance and operations) would achieve moderate efficiency gains and enable effective strategic oversight

Option 2 Component 6	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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### Changes to Board composition and appointment processes would improve the breadth of Board expertise

Changes to nomination and appointment processes and composition of the FSANZ Board could help to improve the breadth of Board expertise (with flow-on benefits for oversight and statutory decision-making). This would be achieved in two ways:

- Improved ability to ensure appropriate breadth of skills across FSANZ Board (including ability to strategically fill capability gaps)
- Enhanced pool of potential candidates for Board positions (through removing requirement that members *must* be nominated by prescribed organisations).

Reducing the Board to a more manageable size and streamlining appointment processes will also help improve Board efficiency and free up resources for delivering on core objectives.

### Investment into business solutions would improve FSANZ's day-to-day efficiency

Investing in an online portal might facilitate a move away from ad hoc email and phone-based communication, reducing administrative burden and time costs for industry and FSANZ involved in a back-and-forth communication.

## 6.2.2 Degree of change required

### Option 2 would require a moderate degree of change




Implementation of Option 2 will require moderate change. Significant legislative amendments would be required to give effect to FSANZ's clarified objectives and functions, and new and streamlined pathways for changes to food standards. There would be moderate operational changes required for FSANZ, industry and jurisdictions to adopt new processes for amending food standards and operationalise the framework for regulatory sandboxes, and significant operational changes for FSANZ to stand up the intelligence-gathering and coordination function.

#### Insights into what stakeholders have reported so far...

Many stakeholders have been supportive of the proposed changes, particularly those that reduce regulatory burden and support innovation. However, other stakeholders have indicated their concern that the broader public health agenda has been sidelined, and that there is an overemphasis on progressing industry interests at the expense of a rigorous system that prioritises safety over profit.

Some stakeholders have also raised concerns regarding the expanded role for industry self-certification via an industry self-substantiation pathway (including increased risk of adverse health outcomes) and the risk to FSANZ's independence from greater industry and government collaboration.

## Moderate change would be required to implement Component 1 (legislative changes to clarify the objectives and functions of FSANZ)

Option 2 Component 1	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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### Moderate legislative amendments would be required to give effect to these changes

Amendments would be required to sections of the Act related to FSANZ's objectives (e.g. s 3 and s 18) and functions (e.g. s 13). These amendments may include clarifying existing wording or adding additional objectives or functions. New provisions may also be required to ensure that FSANZ has the statutory powers required to deliver on these objectives and functions. These new provisions may relate to FSANZ taking on a more formalised role to advise on food fraud and food crime.

It is important that the revised objectives and functions in the Act are harmonised with the Food Regulation Agreement and the Australia-New Zealand Joint Food Treaty. This harmonisation will ensure all regulatory vehicles are aligned to a coherent, system-wide strategic direction.

### Proposed amendments to the objectives and functions mainly formalise work that FSANZ already undertakes

The changes suggested in Component 1 mainly seek to better align the Act with the actual work that FSANZ already undertakes. This means that the proposed amendments would have limited impact on FSANZ's operations. FSANZ already undertakes a role in relation to food fraud and food crime. There may be some capability uplift required to support FSANZ's new objective of considering food sustainability and recognition of indigenous culture and food expertise when developing or varying food standards.

#### Insights into what stakeholders have reported so far...

Stakeholders have spoken at length about the importance of how the objectives are framed and what this means for the broader system. While unanimous in their support for 'the protection of public health and safety' as being the paramount objective of the Act and overarching goal for FSANZ, stakeholders reported diverse views on the interpretation and relative importance of wording in s 18. For example:




- **Australian government stakeholders** have spoken of the importance of the joint food standards system as an instrument to the broader food policy agenda, and the need for jurisdictions' views and priorities to figure prominently in how regulatory measures were shaped. That said, an issue that has been identified is that FSANZ and the Food Ministers' Meeting work to slightly different rules in their roles in developing and ratifying food standards.
- **New Zealand Government stakeholders** have spoken about the importance of aligning the Act with the objectives of the Food Treaty. In particular, they have emphasised the need to empower the joint nature of the system and promote its trade focus. New Zealand stakeholders have expressed support for the FSANZ Act to better reflect Indigenous cultural tradition and the intent of the Te Tiriti o Waitangi (The Treaty of Waitangi).
- **Industry stakeholders** have stressed the importance of a strong and competitive food industry – premised on rigorous food safety standards – in which innovation was fostered, and Australian

and New Zealand food businesses can genuinely compete for market share on an international stage. Industry stakeholders have consistently supported the inclusion of trade as an objective in the Act and did not view this inclusion as jeopardising the objective of protecting population health, recognising this drives demand for products.

- **Consumer advocates** have extolled the importance of informed choice and the importance of regulation to mitigate information asymmetries between businesses and consumers. Some stakeholders also cited the opportunity for the regulatory framework to more systematically consider the environment impact and sustainability of food, and issues around food security and wastage.
- **Public health stakeholders** have encouraged a much broader interpretation of population health which positioned the Act to use regulatory measures to promote a healthy food supply. This includes controls to minimise consumption of unhealthy foods which can lead to food-related chronic disease as well as fortify more food products with vitamins and minerals where this may lead to population-level benefits.

While public health is recognised as a critical issue for food regulation, the scope of this review (as set out in the Terms of Reference) is contained to 'population health protection'. The Food Ministers' Meeting is currently directing work as part of their 2017-2021 Food Regulation System priorities to consider how public health objectives to reduce chronic disease related to overweight and obesity can be achieved.

## Significant change would be required to implement Component 2 (streamlined processes for changing food standards)

Option 2 Component 2	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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### Significant legislative changes are required streamline changes to food standards

Giving effect to Component 2 would require a significant rewrite of Part 3 of the Act (as well as other related sections) to give effect to the proposed changes.

'Risk' would need to be a flexible concept, with a clear framework agreed and enshrined in the appropriate regulatory instrument, but this could (and should) be updated periodically to reflect changes in industry practices, consumer expectations and political appetites for oversight.

There would also be flow on effects on implementing Component 2 to the Food Regulation Agreement and Food Treaty, particularly to reflect new arrangements around decision-making.

### There would be work for FSANZ, industry, and jurisdictions to adopt new processes

There would be considerable work for FSANZ to operationalise legislative changes required for Component 2. This would involve establishing and operating new processes and procedures for new and refined pathways to develop and amend food standards.

A strong regulatory strategy would also be required to ensure that stakeholders across the system were clear on their new roles and responsibilities and could take charge to implement their own relevant operational policies and procedures. FSANZ may need to recalibrate its relationship with industry to provide additional support and foster a greater partnership-approach to compliance, while carefully maintaining its independence.

State, territory and New Zealand governments would also need to confer with their ministers to explore their own preferences with regards to risk ensuring that jurisdictions retained an appropriate level of oversight over food standards, without impeding the agility of the reformed regulatory approach.

#### **Insights into what stakeholders have reported so far...**

##### **Stakeholders have supported more risk-proportionate processes, provided the standards of safety and quality are not compromised**

Stakeholders have provided broad support for amending legislation to support more efficient and effective processes to develop food regulatory measures – provided they do not compromise the overall safety and quality of the Australian-New Zealand food supply.

Industry stakeholders consulted to date are generally very supportive of streamlined processes and decision-making arrangements, noting that this would reduce regulatory burden in terms of:

- overall length of time of the application process (from administrative assessment to approval)
- quantum of tasks required to compile and submit applications.

Industry stakeholders have been supportive of the effect these changes would have on timeliness in bringing products to market. Feedback gained to date indicates a particular interest in exploring ways to better leverage the international evidence base to inform safety assessments of products and work towards timelier harmonisation with international standards.

There has been some concern from jurisdictional stakeholders regarding the use of codes of practice and how these might come into effect in states, territories and New Zealand without jurisdictions being involved in ratifying their contents. In their current form these codes of practice may not be binding. Because jurisdictions are not obligated to formally recognise codes of practice, for this option to take effect it would require follow on legislation at the jurisdictional level to recognise the full suite of regulatory measures developed by FSANZ.

##### **Enhanced role for industry self-certification is a significant concern for some stakeholders**

Some stakeholders have observed that rigorous pre-approval of products before entering the Australian and New Zealand markets is a core strength of the existing system that should not be compromised.

To this effect, many stakeholders consulted to date have expressed concerns around a move to co-regulation, such as an expanded role for industry self-certification via an industry self-substantiation pathway. Specific concerns highlighted include the potential conflict between the objectives of protecting public health and safety and food businesses' own commercial imperatives. Industry stakeholders have expressed concerns that any increased risks to consumer health will have impacts on consumer confidence and reputation of the joint food standards system, which is respected for its high standard of quality and safety.

Stakeholders have cited the general-level health claims experience in Australia as evidence of poor industry conduct (absent pre-approval checks) and the need for regulatory safeguards to mitigate these. Stakeholders have also highlighted the difficulties (time, cost and coordination) in removing self-substantiated general-level health claims that do not meet requirements and cite similar examples in other contexts (such as removing self-listed medicines from the Australian Register of Therapeutic Goods).

Some stakeholders have expressed significant reservations that enhanced capacity for self-regulation by industry would also have deleterious impacts for the joint food standards system, given perceptions that this would support industry interests rather than those of the community. If implemented, careful consideration would need to be given to ensure that it was applied narrowly and that structures were established that ensured FSANZ retained sufficient oversight of new products in

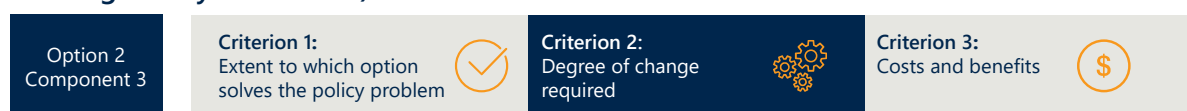


the market. In addition, FSANZ would need to ensure that it retains clear transparency for how things will be assessed in order to protect consumer and industry confidence.

Stakeholders have also observed risks that enhancing role for industry self-substantiation – such as through a ‘Generally recognised as safe’ list of ingredients – could lead to ‘scope creep’ over time; even if such a list were restricted to very low-risk and safe products initially, this could be expanded over time outside of the initial intent. The opposite is also true – stakeholders expressed that in many cases the narrow scope of industry self-substantiation processes meant that they only had a very small impact on food regulatory efficiency as a whole. If a similar system was implemented by FSANZ, there would need to be a clear framework in place that defined the criteria of ‘very low-risk foods’ in adequate detail to mitigate against unintended scope creep over time. This framework would need to be carefully considered to ensure it also remains broad enough to be useful for industry.

If Option 2 were the preferred option, these risks and stakeholder concerns would need to be actively managed during implementation.

### Moderate change would be required to implement Component 3 (flexibility to create new regulatory sandboxes)



### Minor changes to the Act would empower FSANZ to set regulatory sandboxes

Giving effect to Component 3 requires adding provisions to enable FSANZ to create temporary exemptions to food regulations on a case-by-case basis. This exemption could be granted in a range of forms – for example restricted authorisations, temporary allowances or exceptions, waivers, or modifications to rules. Similar to the power to exempt ‘Advanced Therapeutic Products’ in Canada’s Food and Drugs Act, the Act would need to define the type of products, ingredients or technologies for which the regulatory sandbox pathway is available. For example, this could be for items that are so novel and complex that the current regulations are not equipped to handle them, and that provide a compelling public health, social or economic rationale for granting the exemption.

The introduction of regulatory sandboxes would require FSANZ to implement regulatory arrangements (including associated terms and conditions) on a tailored, case-by-case basis. This will require significant effort to set up and operationalise the regulatory framework, engage with industry to agree on the terms and conditions on a case-by-case basis, and build capability to adjust the requirements over time.

FSANZ would also need to provide educational support to both industry and jurisdictions to support uptake and enforcement of the approach. The use of regulatory sandboxes also could free FSANZ from ineffective regulatory instruments for specific products and allow them to use their resources more efficiently.

While regulatory sandboxes are gaining momentum in other regulatory systems, there is no precedent in the food space. This limits the ability for FSANZ to adopt or learn from existing arrangements, instead requiring FSANZ to become a world leader in this space.

#### Insights into what stakeholders have reported so far...

##### Stakeholders have indicated support for initiatives that enable innovation

Industry stakeholders have indicated support for initiatives that foster the introduction of new innovative food products to markets and innovative approaches to food production and processes. Industry stakeholders have indicated that the requirements for developing standards in relation to novel foods can be a deterrent. In particular, *Standard 1.5.2 Food derived from gene technology* and

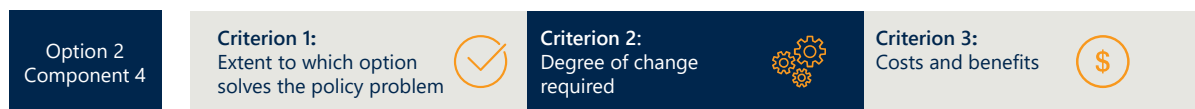


*Standard 1.2.7 Nutrition, health and related claims* have been cited as examples that have particular adverse impacts on innovation.

Exactly how regulatory sandboxes could work in the food standards context has been a point of live discussion, and further feedback on this matter is specifically requested as part of this draft RIS.

Stakeholders have also indicated that enabling more flexible regulatory environments for specific products and businesses creates a risk of undue regulatory capture, if FSANZ is perceived to be subject to influence of specific food businesses seeking to create favourable regulatory circumstances to conduct research and business. Appropriate safeguards would need to be in place to reduce the risk of regulatory capture including clear and transparent frameworks or eligibility criteria to develop regulatory sandboxes, with appropriate, publicly available reporting on how these are used.

## Moderate change would be required to implement Component 4 (position FSANZ as an engine of data and intelligence)



### Legislative changes would not be strictly necessary to create this new role for FSANZ

FSANZ could take carriage of work to collect, consolidate and communicate food safety data with other stakeholders without a legislative backing. For example, memorandums of understanding could be effective in establishing relevant relationships with parties in the regulatory ecosystem, and the substantive funding arrangement for FSANZ between the Australian and New Zealand Government could explicitly capture and provide for this work.

However, this non-regulatory approach may create complexities around the right (or the appropriateness) for FSANZ to share, or potentially sell data related products and services. A relevant statutory function set out in s 13 may therefore go some way to minimise ambiguity.

### Significant operational changes would be required to stand up the function

Component 4 would require significant changes to FSANZ's operations to improve their intelligence-gathering and coordination functions. FSANZ has significant existing technical and scientific expertise as well as coordination and monitoring capability to build on. Additional capability and capacity would be required to be able to:

- Consider the cumulative impact of health, safety, and regulatory burdens during holistic reviews
- Collect, maintain, and analyse large, diverse databases
- Identify and communicate insights that are relevant to different stakeholders.

FSANZ has existing infrastructure including data platforms in place to build on. There would be effort required to establish linkages with other data sources and then scale the impact of the data however these costs are not yet possible to estimate. Adjustments to governance arrangements would also be required to mitigate against any possible conflicts of interest arising from FSANZ's role in coordinating food safety research.

There are also challenges in establishing funding arrangements for 'one-to-many' activities like intelligence gathering. Current cost recovery mechanisms are designed for reactive regulation (e.g. fees for processing an application) where there is a nexus between the applicant paying for the regulatory service received. Current Australian Government cost recovery guidelines do not support cost recovery for

intelligence and surveillance activities.<sup>74</sup> FSANZ would instead need to seek funding through a levy or appropriations.




#### Insights into what stakeholders have reported so far...

**Stakeholders have recognised FSANZ's expertise in food safety data and intelligence, but did not necessarily feel it was the natural choice to lead the sector moving forward**

While consideration of FSANZ's functions should ultimately be resource agnostic, concerns about constrained resources have dominated stakeholder feedback on this topic. Government stakeholders expressed concerns that broadening FSANZ's activities may detract attention and resourcing away from FSANZ's core responsibilities. Anecdotally, some noted that other research organisations, such as universities, consumer groups or crown owned research institutes (in New Zealand), were better placed for gathering this food safety data.

Industry stakeholders felt that there was substantial opportunity for FSANZ to expand on the effectiveness of its current operation, a goal which is inconsistent with expanding its role in food safety data and intelligence. They felt that this could be achieved through a dedicated FSANZ internal unit which, if adequately resourced, could deliver holistic reviews of standards to ensure their ongoing relevance and appropriateness.

### **Significant change would be required to implement Component 5 (fostering approaches to working with other agencies)**

Option 2 Component 5	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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### **Legislative changes are not required to support better collaboration across the system**

No legislative changes are required to give effect to Component 5, including to set up a commercial arm for data fee-for-services. However, Component 5 requires Component 4 to be in place, i.e., the positioning of FSANZ as the engine of food safety intelligence, which requires some legislative changes.

### **FSANZ is highly capable to work with other stakeholders across the joint food standards system**

Minimal changes would be required to strengthen and expand the remit of FSANZ's existing relationships with industry, jurisdictional regulators and policy development stakeholders at key interfaces. FSANZ has a strong relationship with the Food Ministers' Meeting and FRSC and, with stakeholder buy-in, could readily establish the joint agenda setting sessions and earlier involvement engagements. It is likely that FSANZ would need more capacity to effectively engage with each jurisdictional enforcement agency to identify emerging risks and activate appropriate regulatory response.

### **The establishment of a commercial arm will require significant operational changes**

Significant operational changes would be required to set up a commercial arm of FSANZ that provides data or data-linkage services to the general public for a fee. This would include set-up effort to determine the pricing structure, service-level agreement, operating model and governance arrangements with FSANZ.

Some stakeholders have expressed unease with the potential for FSANZ to benefit commercially (with no compensation returned) from data shared by other entities across the joint food standards system in the

<sup>74</sup> Australian Government Cost Recovery Guidelines (RMG 304), Department of Finance, 2020. Available at: <https://www.finance.gov.au/publications/resource-management-guides/australian-government-cost-recovery-guidelines-rmg-304>




spirit of collaboration. Stakeholders' good faith with FSANZ may be jeopardised if FSANZ proceeds with fee-for-service arrangements.

### **Protecting FSANZ's independence and apolitical nature is vital and a key implementation risk for stakeholders**

Many stakeholders consulted have noted that FSANZ's independence as a scientific-based standard-setting body is a key strength of current arrangements – not just for FSANZ but for the joint food standards system as a whole – and that this underpins confidence and trust in the system. Stakeholders have expressed concerns that role expansions (including more collaboration with policy development entities, jurisdictional regulators and industry) could compromise FSANZ's independence (perceived or actual) which could adversely affect allocation of effort (to serve specific stakeholder interests) or decision-making. If Option 2 were the preferred option, implementation and communication would need to carefully manage stakeholder concerns about FSANZ's independence.

In relation to joint agenda setting with FSANZ, agreeing items that would be de-prioritised or removed from the workplan could also promote broader confidence in the ability for the regulatory system (and FSANZ in particular) to progress issues in a timely manner. Stakeholders consulted to-date have observed a lack of transparency around when – or if – items will be progressed (noting that some proposals have been on the workplan for more than a decade).

### **Limited change would be required to implement Component 6 (streamline FSANZ governance and operations)**

Option 2 Component 6	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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### **Minor changes to legislation would be required to support more efficient governance arrangements**

Minor changes would be required to Part 4 Division 1 of the Act to streamlining FSANZ's governance and options. These changes include a simplified board constitution provision that gives effect to a smaller, more skills-based Board and changes to the nomination and appointment process.

Greater investment into business solutions would not require any legislative changes.

### **There would be some, limited effort required to update logistical elements of Board nominations and appointments**

FSANZ would need to make some changes to Board policies and processes to align with the updated nomination and appointment process. This would require some up-front effort but once established could reduce workload for the Minister, the Food Ministers' Meeting and FSANZ.

Investment in a new online portal would likely be led by an external organisation however FSANZ would be required to provide input into the development and then implement new processes for online communication.

Training in virtual engagement methods may be required to ensure virtual board meeting models are effective.

#### **Insights into what stakeholders have reported so far...**

**Many stakeholders have expressed significant concerns around changes to FSANZ's governance, especially the size of the board**

Component 6 proposes to adopt more streamlined nomination and appointment processes (including by removing requirement for nominations to be sought from organisations prescribed in the Regulations) and to reduce the size of the Board by one-third. This would support a more skills-based Board that aligns with contemporary best practice approaches to regulatory governance.

Several stakeholders consulted to-date have expressed reluctance about changing the governance arrangements, noting in particular the:

- breadth of expertise required (given the multi-disciplinary and multi-faceted nature of food regulation)
- need to ensure both Australia's and New Zealand's interests are appropriately reflected in the Board's strategic decision-making
- could reduce (or distort) representation of interests of specific stakeholder groups.

Public health and consumer stakeholders voiced concern about these important perspectives being diluted, and cited challenges in bringing their expertise and viewpoints to FSANZ through other mechanisms, for example, by instigating an application to vary a food standard to achieve better public health or consumer outcomes.

Streamlining governance arrangements (especially through a smaller Board) would need to involve careful communication and consideration to address these stakeholder concerns.

### 6.2.3 Costs and benefits




#### **Option 2 will bring substantial initial and ongoing costs but will bring significant benefits to all system stakeholders**

There are substantial costs and benefits associated with this Option.

- For industry, this option will present some initial and ongoing compliance and substantive costs associated with transitioning to new arrangements. However, benefits include an AUD \$4.190 million (NZD \$4.483 million) reduction in the regulatory burden over 10-years (Component 2), improved competitive advance from more credible claims about sustainability, higher profits and improved consumer surplus. Reduced barriers to engaging in the process to vary food standards may also increase the number of applications to vary food standards lodged by small businesses.
- For governments, there would be adjustment costs, compliance and enforcement costs associated with regulatory sandboxes, resourcing and establishment costs to set up new processes (e.g., Component 6). Conversely, the benefits would include improved system alignment, greater efficiency and timeliness on progress related to Ministers' strategic priorities and more effective regulation.
- For Consumers, costs include potential increased confusion (related to Component 1), potential increased risk of adverse health outcomes from a risk-based regulatory approach. Identified benefits include increased confidence in sustainability and safety of food, enhanced choice, improved access to information.
- For FSANZ, this option would present some one-off establishment costs to set up new processes and arrangements and ongoing operational costs associated with these new arrangements. There would also be a reduction in administrative costs of AUD \$1.2 million (NZD \$1.28 million) over 10 years from the establishment of a smaller board (Component 6).

Benefits for FSANZ would be significant. There would be improved role clarity, operational agility and flexibility and improved efficiency through new pathways to change food standards delivering additional capacity savings of 24,000 hours (AUD \$1.755 million or NZD \$1.876 million) over 10-years.

## There is a clear net benefit associated with Component 1 (legislative changes to clarify the objectives and functions of FSANZ)

Option 2 Component 1	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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### Legislative changes would achieve significant benefits for all stakeholders, but may have some minor administrative costs

The proposed legislative changes to the objectives and functions would have no cost for stakeholders (other than the exception noted below) and would deliver significant benefit to all stakeholders by providing greater clarity on FSANZ's objectives and functions and consistency across the joint food standards system.

The possible exception is costs involved in expanding the objectives to include food sustainability, which may have additional administrative cost for industry to evidence sustainability claims and one-off and ongoing costs for FSANZ to set up the processes and policies required to consider sustainability issues.

The promotion of food sustainability will increase the reputation of the joint food standards system, as trading partners are beginning to expect evidence of food sustainability on exports. Regulating food sustainability will also bring businesses who make genuine sustainability claims the benefit of an appropriate market share. This will occur due to increased consumer confidence in the veracity of sustainability claims (addressing the 'Market for Lemons' dilemma described on page 26).

Expanding the Act's objectives would also support greater recognition of indigenous culture and food expertise and facilitate entry of indigenous foods to the broader market, thereby protecting traditional culture and food expertise and creating new economic opportunities for indigenous entrepreneurs, particularly in regional Australia and New Zealand.<sup>75</sup>

### Economic costs and benefits for different stakeholder groups have been identified

Table 9 shows the costs and benefits for Component 1 by stakeholder group.

**Table 9 | Costs and benefits of Component 1, Option 2 (clarify objectives and functions and reflect these into the Act)**

Stakeholders	Costs or benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>Additional administrative costs to demonstrate the food sustainability as part of applications to amend food standards. For example, a manufacturer would need to commission an independent certifier to sign off that a product's carbon emissions were indeed offset.</li> <li>Administrative costs for indigenous businesses engaging with the joint food standards system and bringing traditional foods to market (based on the assumption that previously deterred from making application as not fit-for-purpose)</li> </ul>

<sup>75</sup> There is potentially another issue regarding how any wealth generated through the commercialisation of traditional goods is returned in part to indigenous communities. While an important matter, this issue was considered to fall outside the objectives of the Act.

Stakeholders	Costs or benefits	Description of costs or benefits
Industry	Benefits	<ul style="list-style-type: none"> <li>• Recognition of trade as an objective within the Act will provide a stronger basis for domestic standards to align more closely with international standards (such as Codex), allowing industry to access export markets more easily</li> <li>• Fewer delays in finalising amendments to food standards (and associated opportunity costs) due to FSANZ and the Food Ministers' Meeting working to a common set of criteria about the factors that should influence the design of food standards, and permissible claims</li> <li>• Improved reputation of the joint food standards system from international trade partners from greater focus on food sustainability</li> <li>• Improved competitive advantage for Australian and New Zealand food businesses from more credible claims about food sustainability and the reduced impact of food on the environment; high-quality producers will be able to be rewarded for making better quality products (e.g. better environmental attributes). Market share of low-quality producers will decrease.</li> <li>• Higher profits for businesses (producer surplus)</li> <li>• For indigenous businesses, engagement with regulatory system pathways that are respectful of indigenous world views</li> <li>• Economic opportunities for indigenous businesses from bringing traditional foods to the broader market, including indigenous businesses in regional Australia and New Zealand</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Costs	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Benefits	<ul style="list-style-type: none"> <li>• Improved system alignment (between FSANZ and the Food Ministers' Meeting) for consistent requirements around requests for reviews</li> <li>• Better alignment of the objectives of the Act with that of a modern food system, with clear linkages to the Food Regulation Agreement and Food Treaty</li> <li>• Better sustainability outcomes that are aligned with broader policy objectives</li> <li>• Appropriate recognition of indigenous culture and food expertise</li> <li>• Better alignment (through inclusion of trade as an objective) of the FSANZ Act with whole of government policies to increase the value of Australia's agricultural industry to AUD \$100 billion by 2030<sup>76</sup></li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>• Risks of a large number of new product claims about sustainability attributes, leading to confusion and increased search cost</li> </ul>




<sup>76</sup> Delivering Ag2030 (2020), Australian Department of Agriculture Water and the Environment. Available at: <https://www.agriculture.gov.au/sites/default/files/documents/delivering-ag2030.pdf>.

Stakeholders	Costs or benefits	Description of costs or benefits
Consumers	Benefits	<ul style="list-style-type: none"> <li>Increased consumer confidence that the joint food standards system appropriately reflects current societal expectations, such as consideration of food sustainability</li> <li>Appropriate recognition of indigenous culture and food expertise</li> <li>Consumers are able to make better-informed decisions and thus chose to purchase products that are better aligned with their preferences, resulting in higher consumer surplus</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>One-off establishment costs to set up processes and policies to consider sustainability issues when developing and reviewing food regulatory measures</li> <li>One off establishment costs to set up processes and policies to consider indigenous culture and food expertise when developing and reviewing food regulatory measures</li> <li>Ongoing operational costs associated with delivering with their broader range of statutory functions</li> <li>Ongoing operational costs arising from more complex decision-making due to additional factors that FSANZ must have regard to under s 18</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>Improved role clarity for FSANZ and reduced ambiguity around focus of FSANZ's work</li> <li>Authority to promote food sustainability</li> <li>Authority to recognise indigenous culture and food expertise</li> </ul>

#### Discussion questions related to the assessment of Option 2, Component 1

- Would the impact of pursuing Option 2, Component 1 represent a positive, negative or neutral outcome for your sector?
- If FSANZ's objectives were broadened to include sustainability, how should sustainability be defined? For example, do you support a limited definition of sustainability (i.e. environmental impacts) or a broad definition of sustainability (i.e. environmental, health, economic and social impacts)
- What economic opportunities might arise for Australian and New Zealand industry from a greater focus on sustainability?
- How can FSANZ's activities better recognise indigenous culture and food expertise? Is this the right framing? What differences between the Australian context and the New Zealand context are important to consider? What changes are required to the FSANZ Act to enable this?
- What economic opportunities might arise for indigenous businesses from bringing traditional goods to the broader market?

#### Component 2 (streamlined approaches to food standards) presents significant costs and benefits

Option 2 Component 2	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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## Risk-based approaches to changing food standards would support innovation and reduce regulatory burden for industry

Option 2 would reduce regulatory burden on industry through more risk-proportionate and streamlined processes for making changes to food standards. The benefits of Component 2 include:

- Reduced administrative and compliance costs for industry applicants through (a) reduction in number of tasks required to compile and submit applications, particularly in relation to evidentiary requirements and (b) reduction in time required to prepare, submit and respond to questions about applications
- Improved access to regulatory system for stakeholders that are currently unable to (and deterred from) seeking applications due to cost and time
- Improved economic opportunities (reduced delay costs) associated with faster assessment processes, increased engagement with regulatory system and higher profits (producer surplus)
- Improved certainty about regulatory obligations (and ability to seek clarity on priority issues) through use of codes of practice and industry guidelines.

Estimated change in regulatory burden for industry as a result of streamlining processes and decision-making arrangements (including introduction of an industry self-substantiation pathway) are shown in Table 10. This estimates that there would be an average annual reduction in regulatory burden (through reduced administrative costs for businesses) of AUD \$419,000 (NZD \$448,000), or a 10-year reduction of AUD \$4.190 million (NZD \$4.483 million). These figures take into account the moderate substantive compliance cost associated with transitioning to the new processes and increase in post-approval administration costs from the industry self-substantiation pathway (for example, in providing information on request to FSANZ). Detailed assumptions underpinning this estimate are at Appendix D.

**Table 10 | Estimated change in regulatory burden (administrative costs) on businesses from changes to processes and decision-making arrangements in Option 2**

Reform element	Regulatory burden Annual (AUD)	Regulatory burden 10-year period (AUD)	Regulatory burden Annual (NZD)	Regulatory burden 10-year period (NZD)
Option 1   Status quo	AUD \$1.077m	AUD \$10.770m	NZD \$1.152m	NZD \$11.524m
Option 2   Modernise the Act	AUD \$0.633m	AUD \$6.330m	NZD \$0.677m	NZD \$6.773m
<b>Change in regulatory burden</b>	<b>AUD \$0.419m</b>	<b>AUD \$4.190m</b>	<b>NZD \$0.448m</b>	<b>NZD \$4.483m</b>

The streamlined processes and decision-making arrangement would also bring substantial economic benefits associated with bringing products to market faster and increased producer surplus. This in turn would encourage greater innovation and additional economic benefit.

This would likely have flow-on benefits for consumers in terms of enhanced consumer choice of food products leading to increased consumer surplus (as greater use of the international evidence base and streamlined processes would support more rapid access to market and reducing 'deterrent effect' by promoting greater engagement with regulatory framework).

It is noted that the specific proposal for the introduction of an industry self-substantiation has the potential of increasing the risk of food-borne illness or adverse health outcomes for the community if an unsafe food was able to enter the market. This could lead to impacts on consumer confidence and perception of the Australian and New Zealand food industry.



### Case study: Implications of streamlined approaches to food standards on industry

In 2020, an application was made to FSANZ by an industry stakeholder that involved an estimated research and development investment of USD \$40 million. Advice from the stakeholder indicates that every month of delay in approving the application, created costs of approximately AUD \$130,000 (NZD \$139,100) for the company. Under the current system, the assessment of an application such as this takes approximately 11 months before approval is granted (if at all). With the proposed Component 2 reforms, the existing process could be shortened by at least 50%, and in some cases, to as little as 4 – 6 weeks. For the application of this particular stakeholder this would have represented at least AUD \$715,000 (NZD \$765,050) saved from the implementation of Component 2 from reduced application delays (assuming that their application would fit into one of the low-risk pathways that result in shorter timeframes). Other industry stakeholders would similarly benefit from streamlined approaches.

For illustration, if all 15 of the general Level 1 and 2 applications that were submitted to FSANZ in 2019-2020 attracted similar delay costs to this case study, the avoided delayed costs associated with using one of the low-risk pathways for all applications would be AUD \$10.725 million (NZD \$11.475 million).

Further, this is in addition to the cost of making the application itself, estimated by stakeholders to be approximately AUD \$60,000 (NZD \$64,200) for a simple application, AUD \$240,000 (NZD \$256,800) for a moderate application, and AUD \$900,000 (NZD \$963,000) for a complex application.

### More flexible processes and decision-making arrangements would support significant operational savings for FSANZ

Component 2 of Option 2 would support more efficient processes for FSANZ by creating new pathways to change food standards and enabling more flexible processes for existing pathways.

By introducing new pathways that enable FSANZ to adopt standards from other jurisdictions (international or national) – either through automatic adoption or minimal assessment – significant organisational capacity could be freed up in the medium- and long-term that would enable FSANZ to focus on higher priority and impact work. There would be considerable efficiencies where routine adoption or minimal assessments do not require sign-off of the Food Ministers' Meeting.

By enabling more flexible and less-prescriptive processes for existing pathways (applications and proposals), FSANZ would be able to tailor its approach to the level of risk and allocate resources in a more efficient manner, in particular reducing the time and effort spent on low-risk applications. Enabling the FSANZ Board and Ministers to delegate decision-making would also save time and administrative costs associated with current one-size-fits-all decision-making arrangements.

The legislation currently provides for applications to be processed through a general, minor or major pathway, and FSANZ has written guidance it uses that estimates the number of hours required to process these. Currently, the 'minor' pathway is scarcely used, however an equivalent procedure could be adopted for 'low-risk' applications. Based on the assumption that 50% of applications currently considered by FSANZ are low risk (mostly processing aids), this could result in significant time and cost savings.<sup>77</sup>

Table 11 below provides a rough indication of capacity that could be freed up at FSANZ by undertaking more risk-based procedures.

Based on maximum hours per procedure, each application that would be subject to the 'low risk' procedure would save approximately 187 hours of FSANZ's time per application (amounting to AUD \$13,660 (NZD \$14,616) per application). Based on projected demand associated with applications over the next 10 years this would amount to approximately AUD \$175,000 (NZD \$187,250) in savings per annum.

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<sup>77</sup> Information provided by FSANZ .

Assuming stable growth in applications over a 10-year period, FSANZ can expect that this will amount to over 24,000 hours of assessment time saved and operational savings to FSANZ of over AUD \$1.755 million (NZD \$1.875 million) over the next 10 years.

Additional capacity could help to mitigate the substantial resourcing challenges that FSANZ currently faces and support more timely assessment and resolution of proposals, particularly those with significant social, economic and health benefits. This would help to build confidence (and reduce frustrations expressed by many stakeholders) in the timeliness of the regulatory system. Importantly, this does not infer that fewer resources are required.

**Table 11 | Indicative capacity created through risk-proportionate pathways (for Level 1 and Level 2 general procedures)<sup>78</sup>**

Option	Change (assumption)	Total over 10 years (\$ AUD)	Total over 10 years (\$ NZD)	Total over 10 years (hours)
Option 1   Status Quo	No change	AUD \$5,388,000	NZD \$5,765,000	73,760
Option 2   Modernise the Act	Enhanced use of more flexible approach for low-risk changes (akin to current minor procedure) for 50% of general procedures <sup>79</sup>	AUD \$3,633,000	NZD \$3,887,000	49,730
<b>Difference</b>		<b>AUD \$1,755,000</b>	<b>NZD \$1,878,000</b>	<b>24,030</b>

**There would be substantive set up costs (for FSANZ and jurisdiction regulators) but this would improve operating efficiency over the medium- to long-term**

Establishing new pathways to expedite adoption of overseas standards (either international Codex standards or national standards from overseas jurisdictions) – as well as enhancing ability to draw on risk assessments from international evidence-base – would impose substantive short-term costs for FSANZ in developing new processes, policies and procedures to set up these pathways. This would, however, save time, cost and effort in the medium- to long-term by providing substantially streamlined pathways (via automatic adoption and minimal assessment) that are less resource intensive to administer and process. This would likely reduce the number of applications to change food standards, as many applications to amend the Code (such as enzyme processing aid applications) are often already approved in other countries.<sup>80</sup> This would also enable proposals to move much faster through assessment processes than they do currently by freeing up organisational capacity.<sup>81</sup> There would be some ongoing costs to operationalise the industry self-substantiation pathway including post-market monitoring and surveillance work.

Industry self-substantiation pathways shift the risk oversight from pre-market assessment to post-market surveillance. This has the potential of increasing the risk of food-borne illness or adverse health outcomes

<sup>78</sup> Different procedures for assessing changes to food regulatory measures are legislatively enshrined. The hours involved in assessing different procedures are included in FSANZ's 'Application Guidelines (a legislative instrument in accordance with s 23(1) of the Act. The Handbook available at:

<<https://www.foodstandards.gov.au/code/changes/Documents/FSANZ%20Application%20Handbook%201%20July%202019.pdf?csf=1&e=z0iKEe>>

<sup>79</sup> Assumption underpinning this calculation is that 50% of general procedure applications could be re-allocated to a streamlined approach (using minor procedure as a reference point, which has a maximum of 100 hours). This includes level 1 general procedure (maximum of 240 hours) and level 2 general procedure (maximum of 380 hours).

<sup>80</sup> Data from FSANZ (Background Brief) submitted as part of this Review.

<sup>81</sup> Input from FSANZ Executive (interviewed as part of Review).

for the community if an unsafe food was able to enter the market. This could lead to impacts on consumer confidence and perception of the Australian and New Zealand food industry. This risk could be mitigated by only allowing industry self-substantiation pathways for low-risk products, such as food additives that are very similar to other products that are already covered by food standards.

This reform also presents a potential risk to consumers associated with post market surveillance rather than pre-market assessment. Under a pre-market assessment scheme, the risk of consumer harm is very low – products are excluded from the standards until they are rigorously assessed as safe, and only then are consumers exposed to them. Under a post-market surveillance scheme consumer will be exposed to products in some circumstances without this assessment, making exposure to unsafe products more likely. Indeed, under a post-market surveillance scheme it is possible that the first-time safety problems are identified after they have caused harm to consumers. Although the risk is much lower than an unregulated system, post-market surveillance poses a greater risk to consumers than pre-market assessment.

### Economic costs and benefits for different stakeholder groups have been identified

Table 12 shows the costs and benefits for Component 2 by stakeholder group.

**Table 12 | Costs and benefits of Component 2, Option 2**




Stakeholder	Costs or benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>Moderate substantive compliance costs associated with transitioning to new processes and requirements for applications to change food standards and industry self-substantiation pathways (including training costs and organisational changes)</li> <li>Offset by reduced administrative and substantive compliance costs for industry to make applications to vary food standards due to (a) less onerous requirements in generating risk assessments and other evidence and (b) associated faster processing times</li> </ul>
Industry	Benefits	<ul style="list-style-type: none"> <li>Improved access to making applications to vary food standards for stakeholders that are currently unable to (and deterred from) seeking applications due to cost and time</li> <li>Improved economic opportunities (reduced delay costs) associated with faster assessment processes and alternative pathways, higher profits (producer surplus) for businesses</li> <li>Greater access to authoritative advice on regulatory obligations, including through tailored and industry-specific advice in guidelines and codes of practice</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Costs	<ul style="list-style-type: none"> <li>Adjustment costs for jurisdictional regulators to monitor and enforce food regulation including industry self-substantiation pathways, with enhanced use of additional legislative instruments</li> <li>Offset by reduction in Food Ministers' Meeting administrative costs due to responsibility to ratify lower- risk or lower-priority amendments being delegated to other appropriate decision-makers within jurisdictions</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Benefits	<ul style="list-style-type: none"> <li>Improved use of the Food Ministers' Meeting's expertise for high-priority issues</li> <li>Greater efficiency and timeliness around the progress of proposals on issues of strategic priority to Ministers, due to released capacity at FSANZ</li> </ul>

Stakeholder	Costs or benefits	Description of costs or benefits
Consumers	Costs	<ul style="list-style-type: none"> <li>More risk-proportionate processes could increase the risk of food-borne illness or adverse health outcomes for community. While managing risk of foodborne illness is critical, it is important to note that most consumers do not have expectations that any food will be entirely risk free, evidenced by the fact that many consumers choose to eat foods that are well known to be higher-risk, such as sushi or rare steak.</li> </ul>
Consumers	Benefits	<ul style="list-style-type: none"> <li>Enhanced consumer choice of food products (Assumption that greater reliance on international assessments, streamlined processes and alternative pathways support enhanced innovation in food production and quicker access to market) leading to increased consumer surplus</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>One-off establishment costs to establish processes, policies and procedures for developing or varying food standards</li> <li>Substantive operational costs associated with operationalising each other the pathways to amend food standards, including a greater operational presence around post-market surveillance and monitoring</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>Improved operational efficiency in processing applications and proposals (and improved allocation of resources) through application of risk-based pathways</li> <li>Improved operational efficiency and greater capacity for high priority matters, through using streamlined pathway for low-risk issues</li> </ul>

### Discussion questions related to the assessment of Option 2, Component 2

16. Would the impact of pursuing Option 2, Component 3 represent a positive, negative or neutral outcome for your sector?
17. Do you think this Component should also include the ability for the Food Ministers' Meeting to delegate to the FSANZ Board for decision-making? If so, for what decisions should this delegation include?
18. What types of issues do you think can be appropriately dealt with in codes of practices or guidelines?
19. Can you provide data to quantify the administrative burden on industry associated with compiling the required evidence base to support a comprehensive risk assessment by FSANZ?
20. Are you aware of any data to demonstrate the potential savings for industry if FSANZ had the statutory ability to recognise and adopt international risk assessments?

### The economic value of implementing Component 3 (flexibility to create new regulatory sandboxes) is somewhat uncertain

Option 2 Component 3	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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### The literature is illustrative of the potential benefits of regulatory sandboxes, but the extent of these benefits is difficult to measure

The success of a sandbox is dependent on its' parameters and the effectiveness of the innovations that arise from the sandbox. As there is limited precedent for regulatory sandboxes in other food regulatory

systems, the possible uptake and subsequent innovation is difficult to measure. There are two empirical examples of implemented regulatory sandboxes:

- **The United Kingdom** – In 2016 the UK launched a regulatory sandbox scheme for the financial services in a bid to increase innovation in the sector. Despite measurement difficulty there is good preliminary evidence to suggest that the scheme was effective. In a paper published in 2017, the UK's financial conduct authority stated that 75-77% of firms accepted into the scheme had successfully completed testing of new innovations, and that 90% of those had continued to develop wider markets following testing. Specifically, testing in the regulatory sandbox had helped firms raise much needed finances, and "allowed the regulator to work with innovators to build appropriate consumer protection safeguards for the new products and services."<sup>82</sup>
- **Singapore** – Following the UK's example, in 2016 the Monetary Authority of Singapore (MAS) published the Fintech Regulatory Sandbox Guidelines, which state that "the MAS will provide support to increase efficiency, manage risks better, create new opportunities and improve people's lives."<sup>83</sup> As with the UK, the scheme was open to businesses in the financial sector, although unlike the UK, only six firms were approved for the scheme. Despite this small sample size (CF: UK's 87 sandboxes awarded), preliminary findings have been promising; all firms awarded preliminary approval under the sandbox scheme were eventually granted full approval.

These examples illustrate the potential for regulatory sandboxes to create producer surplus opportunities in the food industry. Simplistically, even a 1% growth in innovation in Australia from approaches such as regulatory sandboxes equates to AUD \$3.5 million (NZD \$3.745 million) in exports, as per research from Swinburne University introduced in section 5.2.3.<sup>84</sup>

Regulatory sandboxes are potentially less accessible for small and medium enterprises who may not have the resourcing and expertise needed to access this approach compared to larger organisations. It is important that the process of engagement with industry on terms and conditions of regulatory sandboxes recognises resource limitations of small and medium-sized enterprises and is accessible to businesses of different sizes.

### **Economic costs and benefits for different stakeholder groups have been identified**

Table 13 shows the costs and benefits for Component 1 by stakeholder group.

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<sup>82</sup> Chen C., Regulatory Sandboxes in the UK and Singapore: A Preliminary Survey (2019), European Economics: Microeconomics & Industrial Organization eJournal. DOI:10.2139/ssrn.3448901

<sup>83</sup> Monetary Authority of Singapore, Fintech Regulatory Sandbox Guidelines (2016)  
<<http://www.mas.gov.sg/~media/Smart%20Financial%20Centre/Sandbox/FinTech%20Regulatory%20Sandbox%20Guidelines%2019Feb2018.pdf>>. ('Singapore Fintech Guidelines')

<sup>84</sup> Swinburne University estimates that innovation within the food manufacturing sector in Australia is responsible for approximately AUD \$350 million in annual exports, AUD \$1.88 billion in annual business turnover, and 4,572 additional jobs created per annum. Note this report is not publicly available.

**Table 13 | Costs and benefits of Component 3, Option 2 (build in flexibility to create bespoke regulatory sandboxes)**

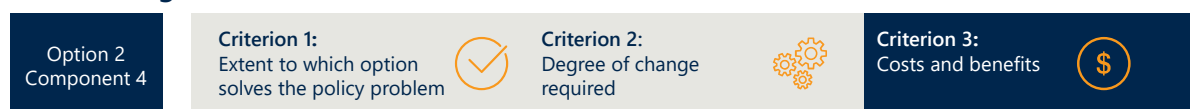
Stakeholder	Costs or Benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>Initial substantive compliance costs associated with transitioning to new processes for 'Regulatory Sandbox' (including training costs and organisational changes) (that are potentially prohibitive for small and medium enterprises to access regulatory sandboxes)</li> <li>Ongoing administrative costs required to demonstrate compliance with regulatory requirements for regulatory sandboxes (i.e. holding and submitting information in response to requests from FSANZ)</li> </ul>
Industry	Benefits	<ul style="list-style-type: none"> <li>Improved access to regulatory system by stakeholders that are currently unable to (and deterred from) accessing because products are not readily accommodated into existing requirements under food standards</li> <li>Improved economic opportunities (reduced delay costs) associated with faster speed-to-market and reduced compliance burden, including enhanced opportunities for innovation. (A growth in innovation of 1% from approaches such as regulatory sandboxes equates to AUD \$3.5 million (NZD \$3.745 million) in exports, as per research from Swinburne University<sup>85</sup>).</li> <li>Better support from regulators in ensuring regulatory compliance in bringing products to market</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Costs	<ul style="list-style-type: none"> <li>Potentially significant compliance costs (set up and ongoing) associated with building the capacity and capability to enforce compliance with regulatory sandboxes</li> <li>Increase in enforcement costs associated with businesses and activities that have temporary exemptions through Regulatory Sandbox</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Benefits	<ul style="list-style-type: none"> <li>Improved economic opportunities arising from a more competitive joint food standards system</li> <li>More effective regulation of food products that don't fit well within the traditional, static regulatory framework</li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>Greater risk of adverse outcomes for consumers (e.g. short- and long-term health) where ingredients, products etc., are not subject to rigorous pre-market approval</li> </ul>
Consumers	Benefits	<ul style="list-style-type: none"> <li>Enhanced consumer choice of food products (through faster speed-to-market and enhanced innovation in food production)</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>One-off establishment costs and ongoing operational costs to administer Regulatory Sandbox approach</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>Improved operational agility and flexibility through additional pathways</li> </ul>

<sup>85</sup> Swinburne University estimates that innovation within the food manufacturing sector in Australia is responsible for approximately AUD \$350 million in annual exports, AUD \$1.88 billion in annual business turnover, and 4,572 additional jobs created per annum. Note this report is not publicly available.

### Discussion questions related to the assessment of Option 2, Component 3

21. Would the impact of pursuing Option 2, Component 3 represent a positive, negative or neutral outcome for your sector?
22. What are examples of novel food products and ingredients and new technologies used in the production and testing of food products that could be appropriately and safely introduced using regulatory sandboxes?

### Implementing Component 4 (position FSANZ as an engine of data and intelligence) could be high-reward



### Some new resources and investments would be required by government

Investing in Component 4 would require some establishment and operational costs from Australian and New Zealand governments to fund FSANZ to undertake a broader role. In particular, some investment would be required to:

- Undertake holistic, regular reviews of standards (recognising that this may have similar resourcing implications as a major proposal. This would require one-off establishment costs to set up the new policies, processes and procedures and ongoing operational costs to undertake the reviews.
- Improve FSANZ's intelligence-gathering roles, including data collection, analysis and custodianship and post-market surveillance (though these roles would build from existing functions that FSANZ undertakes). This would require one-off establishment costs and ongoing costs of establishing databases, including tech platforms and appropriate security measures, as well as additional personnel to keep this data up to date, monitor changes, and communicate emerging trends.

While many of these roles are expected to yield efficiencies over the long-term (as noted below) these would represent some up-front (and, in some cases, ongoing) investment. There are also additional challenges that arise with cost recovery models for intelligence activities due to their 'one-to-many' service. This would require funding through a levy or appropriations.

### Economic costs and benefits for different stakeholder groups have been identified

Table 14 shows the costs and benefits for Component 4 by stakeholder group.

**Table 14 | Costs and benefits of Component 4, Option 2 (position FSANZ as engine of food safety intelligence, equipped to drive forward-looking regulation)**

Stakeholder	Costs or Benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>• Time and resources required to provide input to, and be consulted on, changes to food standards as part of regular, holistic reviews</li> <li>• Periodic costs to change practices (e.g., food composition, labelling) based on outcomes of reviews of standards</li> <li>• Cost associated with establishing memorandums of understanding to share data with FSANZ</li> </ul>






Stakeholder	Costs or Benefits	Description of costs or benefits
Industry	Benefits	<ul style="list-style-type: none"> <li>Improved mechanism for (a) identifying and addressing inconsistencies between food standards that impose regulatory burden on industry, and (b) ensuring that standards remain fit-for-purpose over time given changes in industry practice (e.g. due to technological progress)</li> <li>Improved mechanism for providing overarching consideration of compliance burden for food regulatory measures, as opposed to current piecemeal, including opportunities for greater international harmonisation</li> <li>Potential for improved access to databases (including food composition) that will support regulatory compliance efforts and support innovation</li> <li>Enhanced access to food safety experts, knowledge and capability through greater collaboration (improving competitive advantage and decisions)</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Costs	<ul style="list-style-type: none"> <li>Time and resources required to provide input to, and be consulted on, changes to food standards as part of regular, holistic reviews</li> <li>Resources required to fund FSANZ to deliver against new remit</li> <li>Challenges in cost recovery of regulatory services. Fees can be charged where industry directly receives a service (one-to-one relationship between FSANZ providing an approval or assessment to an individual business). Surveillance and intelligence are a one-to-many service (FSANZ provides a service that many businesses benefit from), so harder to cost recover through fee-for-service arrangements. Needs to be funded through a levy or appropriations.</li> <li>Risk of overzealous regulation, by allowing FSANZ to “go looking for problems to fix”</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Benefits	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>Risk of nanny-state overzealous regulation reducing individual freedoms and choice</li> <li>Cost associated with establishing memorandums of understanding between consumer groups and FSANZ regarding the sharing of data</li> </ul>
Consumers	Benefits	<ul style="list-style-type: none"> <li>Greater consideration of health effects of standards (short- and long-term) for consumers could improve public health outcomes and provide mechanism to address substantial costs of chronic health conditions driven by dietary patterns</li> <li>Improved ability for consumer and public health bodies to provide input to FSANZ’s workplan to support improved health outcomes for consumers</li> <li>Improved access to food safety information (in a consolidated source) could support more informed consumers and reduce search costs (related to fragmented information across multiple sources)</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>One-off establishment costs to set up policies, processes and procedures for undertaking holistic reviews (assuming done outside proposal pathway)</li> <li>Ongoing operational costs to undertake holistic reviews of standards</li> </ul>

Stakeholder	Costs or Benefits	Description of costs or benefits
		<ul style="list-style-type: none"> <li>One-off establishment costs and ongoing costs of coordinating food research, including managing strategic relationships with agencies across Australia, New Zealand and internationally</li> <li>One-off establishment costs and ongoing costs of any updates to base infrastructure (including tech platforms and appropriate security measures) linking to other data sources and obtaining and maintaining high quality data. This includes additional personnel to keep this data up to date, monitor changes, and communicate emerging trends</li> <li>Potential operational costs from scope creep (i.e. FSANZ is asked to, or on their own initiative, extend intelligence-gathering activities from food safety to other health matters)</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>Improved intelligence through review process to monitor the efficacy of food standards to deliver greater value for the joint food standards system</li> <li>Enhanced credibility, reputation and competitive edge for FSANZ on regional and global stages as a world leader in food safety</li> </ul>

#### Discussion questions related to the assessment of Option 2, Component 4

23. Would the impact of pursuing Option 2, Component 4 represent a positive, negative or neutral outcome for your sector?
24. Should a function for FSANZ's to collect, consolidate and communicate food safety data be legislated?

### Component 5 (improving interfaces across the system) could represent strong benefits but a real risk of compromising FSANZ's independence

Option 2 Component 5	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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### There are benefits from working more efficiently across the system, but potentially at a cost to FSANZ's trusted position and reputation

Improving collaboration and integration of effort across the regulatory system would bring benefits to multiple stakeholders. These benefits include reduced costs that relate to duplication across the system and reduced compliance burden associated with a more intelligence-led regulatory approach. Industry, researchers and governments will obtain better access to food data to support innovation and decision-making. Enhanced collaboration and intelligence-led decisions also have the potential for improving consumer confidence in the quality of the joint food standards system.

However, with greater collaboration with industry and government bodies, there is a potential for FSANZ's independence to be compromised and for FSANZ to become susceptible to undue regulatory capture. This impacts FSANZ's ability to meet its stated objectives and could result in decreased public trust in FSANZ and the joint food standards system more broadly.

Component 5 would require some ongoing costs from FSANZ to undertake ongoing partnerships services and additional set up costs (e.g. establishing organisational arrangements and service pricing structure), if FSANZ were to proceed with offering data or data-linkage services through fee-for-service arrangements. However, the arrangement would be such as to ensure these costs were covered once the service is up and running.

## Economic costs and benefits for different stakeholder groups have been identified

Table 15 shows the costs and benefits for Component 5 by stakeholder group.

**Table 15 | Costs and benefits of Component 5, Option 2 (foster new approaches to working with other agencies, with a focus on intelligence-sharing)**

Stakeholder	Costs or benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Industry	Benefits	<ul style="list-style-type: none"> <li>Reduced compliance burden associated with a more intelligence-led and risk-based regulatory approach from jurisdictions (enabled by partnerships)</li> <li>Better access to food data (potentially on a fee-for-service basis) could stimulate innovation and reduce costs of industry-initiated data generation</li> </ul>
Governments (Australia and New Zealand)	Costs	<ul style="list-style-type: none"> <li>Adjustment costs (set and ongoing) in participating in partnerships with FSANZ and other stakeholders (e.g. sharing information)</li> <li>Reduced duplication and associated costs involved in regulatory impact assessment work currently undertaken by both FSANZ and FRSC</li> </ul>
Governments (Australia and New Zealand)	Benefits	<ul style="list-style-type: none"> <li>Opportunity to access more timely and predictive information about risks, population health trends associated with food consumption and consumer expectations to inform their priorities and other policy work</li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Consumers	Benefits	<ul style="list-style-type: none"> <li>Improved access to high quality data supporting more effective and efficient research (with flow on benefits for consumers)</li> <li>Potential for improved confidence in safety, security and sustainability of food supply, and integrity of food production and processing systems (enabled by enhanced collaboration)</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>Ongoing operating costs to provide partnership services to different stakeholder groups</li> <li>Costs associated with establishing commercial arm of organisation and determining service pricing structure</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>Reduced duplication with government agencies and other stakeholders</li> <li>Potential for improved working relationships with stakeholders, with flow on reputational benefits</li> </ul>

### Discussion questions related to the assessment of Option 2, Component 5

25. Would the impact of pursuing Option 2, Component 5 represent a positive, negative or neutral outcome for your sector?
26. Would stakeholders (including universities, expert food safety bodies or industry) be willing to pay for data or data-linkages services from FSANZ?

## Component 6 (streamlining FSANZ's governance and operations) will bring efficiency gains

Option 2  
Component 6

Criterion 1:  
Extent to which option  
solves the policy problem



Criterion 2:  
Degree of change  
required



Criterion 3:  
Costs and benefits



### A smaller, more streamlined Board will bring efficiencies but potentially weaken representation

There will be some one-off establishment costs to set up the explicitly skill-based nomination and appointment processes, however, there would be significant efficiency benefits in the medium to long term.

These efficiency gains would come from modest cost-reductions from administering a smaller (8-person) Board. Annual administrative costs related to Board meetings would reduce by approximately AUD \$37,000 (NZD \$40,000)<sup>86</sup> and salary costs would reduce by AUD \$170,000 (NZD \$182,000) each year.<sup>87</sup> Over a 10-year period, these savings would amount to almost AUD \$2.1 million (NZD \$2.25 million).

Nonetheless, some stakeholders expressed concern that a more streamlined board would undermine adequate representation. This was particularly the case for New Zealand stakeholders, who suggested that a smaller board would adversely affect its ability to address New Zealand specific challenges.

### Economic costs and benefits for different stakeholder groups have been identified

Table 16 shows the costs and benefits for Component 6 by stakeholder group.

**Table 16 | Costs and benefits of Component 6, Option 2 (streamline FSANZ's governance and operations)**

Stakeholder	Costs or benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>Potentially reduced influence over FSANZ's board decisions due to fewer members with an explicit industry focus</li> </ul>
Industry	Benefits	<ul style="list-style-type: none"> <li>More streamlined and efficient communication through use of business portal</li> <li>Improved economic opportunities attributable to more rapid decision-making around applications and proposals</li> </ul>
Governments (Australia and New Zealand)	Costs	<ul style="list-style-type: none"> <li>One-off establishment costs to set up explicitly skill-based nomination and appointment processes</li> <li>Potentially reduced influence of New Zealand's priorities on Board decisions, if careful consideration is not made to ensure fewer New Zealander members are appointed as a result of the streamlining</li> </ul>
Governments (Australia and New Zealand)	Benefits	<ul style="list-style-type: none"> <li>More efficient nomination and appointment processes for Board members and associated reduction in administrative costs (for Department of Health)</li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>N/A</li> </ul>

<sup>86</sup> Data provided by FSANZ in a submission to this Review.

<sup>87</sup> Data on Board member remuneration available in FSANZ Annual Reports. Estimates also provided by FSANZ in a submission to this Review.

Stakeholder	Costs or benefits	Description of costs or benefits
Consumers	Benefits	<ul style="list-style-type: none"> <li>Potentially greater representation of consumer through board members appointed based on skill</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>One-off costs to set up skills-based appointment and nomination processes</li> <li>Reduced administration costs (AUD \$37,000 or NZD \$40,000 annually) and salary costs (AUD \$170,000 or NZD \$182,000 annually) from administering a smaller (8-person) Board (AUD \$2.1 million or NZD \$2.25 million total over 10-year period)</li> <li>Reduced cost by moving from a face-to-face to a virtual board meeting model (AUD \$25,000 to AUD \$35,000 (NZD \$26,750 to NZD \$37,500) per meeting, AUD \$100,000- AUD \$120,000 (NZD \$107,000 – NZD \$128,400) per year, and AUD \$1 million – AUD \$1.2 million (NZD \$1.07m – NZD \$1.28m) per 10-year period)</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>Improved ability to ensure appropriate breadth of skills across FSANZ Board (including ability to strategically fill capability gaps) and implications for Board's decision-making</li> <li>Enhanced pool of potential candidates for Board positions (through removing requirement that members <i>must</i> be nominated by prescribed organisations)</li> <li>Improved operational efficiency from administering a smaller Board</li> <li>More streamlined and efficient communication with industry through use of business portal</li> </ul>

#### Discussion questions related to the assessment of Option 2, Component 6

27. Would the impact of pursuing Option 2, Component 6 represent a positive, negative, or neutral outcome for your sector?

#### Discussion questions related to the assessment of Option 2

28. What are the key risks borne by different stakeholder groups for this option? What is the likelihood of these risks, and what would be the magnitude of consequence if they occur?

29. Are there other costs and benefits (qualitative or quantitative) that should be measured in relation to Option 2? If so, who would bear these costs and benefits?

30. Are you aware of any data that may assist in quantifying the magnitude of these costs and benefits? If so, please provide these data.

31. Should the Act provide for more of its work with industry to be offset through cost recovery mechanisms? For example, should FSANZ seek to broaden the types of applications for which it charges fees; should the provision of interpretative advice attract fees; or are there other activities for which FSANZ should cost recover?

32. What would be the impact on industry (especially small to medium businesses) or consumers of FSANZ cost-recovering for a broader range of activities?

33. How often do you currently engage with the food regulation system through making applications to change food standards?
34. What are the most significant barriers that you or your organisation faces when trying to engage with the food regulation system?
35. Would you be more likely to engage with the food regulation system through the new pathways proposed in this regulatory impact statement? If so, which pathways would you be most likely to use and why?




## 6.3 Impacts of Option 3 | Build on FSANZ's role to reinforce the bi-national nature of the joint food standards system

### 6.3.1 Extent to which Option 3 solves the policy problems

#### Option 3 could potentially solve all three Policy Problems

As summarised in Figure 21, Option 3 (which incorporates all components of Option 2) could solve all identified policy problems.

Figure 21 | Impact of Option 3 on Policy Problems

Option meaningfully addresses policy issues	Policy problem
	<p><b>In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer</b></p> <ol style="list-style-type: none"> <li>a) The objectives and current functions of FSANZ are not clear</li> <li>b) Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible</li> <li>c) Elements of FSANZ's operations are inefficient</li> </ol>
	<p><b>Legislation does not enable a strong, resilient and agile food regulatory system</b></p> <ol style="list-style-type: none"> <li>a) Statutory timeframes and resourcing constraints within FSANZ reinforce a piecemeal and reactive regulatory focus</li> <li>b) Food safety and quality no longer guarantee a competitive advantage for Australian and New Zealand food businesses</li> <li>c) There is limited collaboration and integration of effort across the regulatory system</li> </ol>
	<p><b>Current arrangements undermine the power of a single, joint food system</b></p> <ol style="list-style-type: none"> <li>a) FSANZ is limited in its power to assist in food incidents and food recalls</li> <li>b) Inconsistent interpretation and enforcement of food standards is an enduring issue for the system</li> <li>c) FSANZ has no legislative remit to extend Australia and New Zealand's influence on the international stage</li> </ol>

In addition to addressing Options 1 and 2 through the same mechanisms set out in section 6.1.1, this option would help address the third policy problem, by promoting a more unified joint food standards system. This deliver significant value to Australia and New Zealand's food industry. It would:

- Reinforce the single food market, for which the joint scheme was intended to support

- Minimise the burden faced for industry and other stakeholders from different monitoring and enforcement standards
- Uplift capability across all institution to adopt cutting-edge regulatory technologies and practices, thus minimising the financial impost of administering regulation
- Make best use of the available expertise and capacity across the system, which ensures that regulatory matters are dealt with by the most appropriate body in a timely and efficient manner.




Figure 22 outlines how Option 3 would modernise FSANZ to address all three policy problems.



Figure 22 | Impact of Option 3 on Policy Problem 1, 2 and 3

FROM...	➤	TO...
<b>POLICY PROBLEM 1</b>		
In its current form, the Act does not support efficient and effective regulation, and is burdensome to administer	➤	The Act is fit for purpose and underpins efficient and effective regulation
The objectives and current functions of FSANZ are not clear	➤	Objectives and functions are clarified, including a clear authorising environment for FSANZ to lead key functions related to public health and safety
Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible	➤	Processes and decision-making arrangements to amend food standards are reconceived to support more flexible and risk-proportionate approaches
Elements of FSANZ's operations are inefficient	➤	FSANZ's operations are streamlined through changes to FSANZ's legislated governance and investments in business solutions
<b>POLICY PROBLEM 2</b>		
Legislation does not enable a strong, resilient and agile food regulatory system	➤	The Act supports an agile, resilient and collaborative food regulatory system
Statutory timeframes and resourcing constraints within FSANZ reinforce a piecemeal and reactive regulatory focus	➤	FSANZ is positioned as an engine of food safety intelligence, positioned to drive forward-looking regulation
Food safety and quality no longer guarantee a competitive advantage for Australian and New Zealand food businesses	➤	FSANZ successfully keeps pace with changing consumer expectations and can better leverage food regulatory measures to reflect these
There is limited collaboration and integration of effort across the regulatory system	➤	FSANZ collaborates with Food Ministers' Meeting, governments and others to drive intelligence-led decisions and quality research and policy work
<b>POLICY PROBLEM 3</b>		
Current arrangements undermine the power of a single, joint food system	➤	Arrangements reinforce the bi-national nature of the food system
FSANZ is limited in its power to assist in food incidents and food recalls	➤	FSANZ has the statutory power it needs to respond in an efficient and timely way to food incidents and food recalls
Inconsistent interpretation and enforcement of food standards is an enduring issue for the system	➤	FSANZ provides greater guidance on food standards to reduce confusion for businesses and promote consistent, best practice enforcement
FSANZ has no legislative remit to extend Australia and New Zealand's influence on the international stage	➤	FSANZ can full extend Australia and New Zealand's influence over food standard setting and support greater international trade opportunities

## Component 1 (provide for FSANZ to instigate food incident and food recall responses) would address the current limitation in FSANZ's ability to respond




Option 3 Component 1	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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### Providing for FSANZ to instigate food incidents and food recalls would build further agility into the regulatory scheme

Implementing this component would directly address the issue of FSANZ having limited power to assist in critical incidents.

FSANZ already works closely with states and territories to coordinate food recalls. A change in statutory functions does not represent a significant shift in FSANZ's current activities, but rather formalises their role and provides in the statutory remit the ability to initiate the function in a timely and responsive way, while continuing to work closely with jurisdictions. This could avoid problems arising from a lack of central coordination body, as was encountered during the strawberry tampering incident (described on section 3.4.1).

## Component 2 (provide for FSANZ to give greater guidance on food standards) partially solves the issue of jurisdictional inconsistencies

Option 3 Component 2	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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### Increased guidance would provide greater certainty for industry, jurisdictional regulators and other stakeholders and promote a more consistent approach

Component 2 involves introducing new regulation; however it is by design aimed at reducing regulatory burden associated with ambiguity inherent to the current system. That is, different interpretations among jurisdictions leads to inconsistencies in enforcement among regulators. By providing additional mechanisms for interpretive advice – through non-binding industry guidelines and the power to provide binding rulings that would be applied by the regulators – Option 3 would help to reduce interpretive uncertainty and improve consistency.

Increased interpretive guidance would particularly benefit smaller food businesses, including sole-traders, who reportedly can find it difficult to understand their regulatory requirements, and do not tend to have ready access to independent legal advice or support to assist in understanding how to comply with food standards. Meanwhile a more consistent enforcement approach across jurisdictions will aid medium and larger businesses operating across jurisdictional boundaries.

While this component of Option 3 does address many of the issues in Problem 3, it alone does not fully reinforce the bi-national nature of the joint food standards system. Jurisdictions would still regulate their own industries and have the ability to adopt different approaches to enforcement if they deemed necessary.

## Component 3 (positioning FSANZ to take on an enforcement role) could uplift regulator capability across the joint food standards system

Option 3 Component 3	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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There are two levels to Component 3: a limited enforcement role for FSANZ; or a full bi-national regulator role. Both these levels address Policy Problem 3 to a different degree. This is detailed below.

### **Positioning FSANZ to take on a limited enforcement role would overcome known tensions in the system and provide a model for good regulatory practice**

Component 3 does not represent an overall increase in regulation, but rather reconfigures how regulation and the associated regulatory burden is distributed across different legislative frameworks. It would enable FSANZ to effectively address many of the known tensions in the system. For example, a limited enforcement role would:

- Leverage FSANZ's existing expertise in areas like labels and novel foods to manage enforcement in this space and model good regulatory practice in its jurisdictions
- Give FSANZ remit to invest in new technologies relevant to labels or novel foods in a way that delivers value for all jurisdictions
- Give FSANZ very practical experience in enforcement. This would influence how it approaches data analysis and risk identification, leveraging the intelligence it generates from Option 2. FSANZ could then take key lessons learnt to the ISFR and use this governance system as a mechanism to raise regulator capability and improve consistency across the system.
- Improve the current frictions at the food-medicine interface, at least in Australia. Currently, a significant proportion of the issues around whether a product is a food or medicine relate back to how it is labelled and presented. This change would mean the policy and enforcement responsibilities of both food and medicine would be contained with the Australian Department of Health (albeit, in different divisions) and as a result, internal Department-wide governance channels could be leveraged to facilitate timely resolution of any issues.




This component would address many of the aspects of Policy Problem 2.

### **A single, bi-national regulator for the joint standards system would enhance the single, bi-national joint food standards system**

FSANZ would significantly address Policy Problem 2. It would achieve this by:

- Delivering a more consistent interpretation of standards and enforcement across states and territories and New Zealand, which would ultimately reduce the regulatory burden
- Enacting and modelling best regulatory practice and delivering a more consistent experience for stakeholders across jurisdictions
- Respond with more agility and effectiveness to sectoral change. This promotes economies of scale for investments in new systems or approaches too, such as in regulatory technology. There is however also a risk that a single, bi-national regulator is too large to effectively regulate and therefore leads to a more inefficient system.

### **Component 4 (Clarify legislation so FSANZ can effectively meet its objective of harmonisation of food standards in an international context) would give FSANZ the necessary legislative remit**

Option 3 Component 4	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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FSANZ performs important work internationally to harmonise food standards and extend Australia and New Zealand's influence in the Asia-Pacific market. This work helps create new economic opportunities for

Australia and New Zealand's food industry. Currently, however, FSANZ does not have the legislative remit to coordinate this work effectively.

Component 4 would address the problem by providing FSANZ with the statutory authority to coordinate the programme of international relations and contributions it undertake as a standard setting body, and where necessary secure adequate funding to progress its work.

### 6.3.2 Degree of change required

#### Option 3 requires some significant changes to legislation at all jurisdictional levels




While some components of this option require only minor changes to legislation, others require legislative changes at all jurisdictional levels (including referrals of powers to the Federal government from states and territories, and potentially New Zealand).

The establishment of a bi-national regulator would also be challenging to implement, with little precedent for such a model existing. The degree and complexity of change involved may not be uniform across Australian and New Zealand stakeholders and will need to be further explored during consultation.

#### Insights into what stakeholders have reported so far...

Stakeholders have given extremely different levels of support for this option; while some feedback has been positive and focused on the potential to transition to a stronger, more unified joint food standards system, others have indicated concern about losing power to regulate food at a jurisdictional level; as well as about the potential conflicts of interest inherent to FSANZ playing both standard-setter and enforcer.

#### Moderate change would be required to implement Component 1 (provide for FSANZ to instigate food incident responses)

Option 3 Component 1	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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#### Moderate to significant legislative changes are required to enable FSANZ to instigate food recalls or incident responses

FSANZ statutory functions (Section 13 1(k) of the Act) would be amended to provide for FSANZ, 'in consultation with the States and Territories, or on its own initiative' to coordinate action to recall food. It would also need the power to compel compliance.

Australian states and territories may all need to refer power to FSANZ to perform this function which would require changes to the Food Regulation Agreement. Were the option to be extended to New Zealand this would require further negotiation with New Zealand under the Food Treaty.

In this case, New Zealand would also need to implement significant legislative reform to its domestic food legislation.

#### This component would require moderate operational changes




There would be some operational changes as a result of this reform. These would be particularly significant for New Zealand. This change would add a level of agility into an existing operational response. However, it will require FSANZ to leverage its intelligence to identify risks and incidents early, to achieve the benefit of enabling FSANZ to instigate responses.

### Insights into what stakeholders have said so far...

There has been limited commentary to date on this component from stakeholders

A small number of stakeholders advised that the current system does work, but it is stilted by the legislative provisions for states and territories to initiate a request. Stakeholders who commented on food recalls were unanimous in their support for the work FSANZ does in this space and recognised its expertise to carry out this function effectively. Industry are supportive of an approach that brings consistent and correct messaging and minimises the financial impact of a food incident or food recall.

## Limited- to moderate- change would be required to implement Component 2 (FSANZ to provide more interpretive guidance)

Option 3 Component 2	Criterion 1: Extent to which option solves the policy problem 	Criterion 2: Degree of change required 	Criterion 3: Costs and benefits 
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### Minor legislative changes are required to enable FSANZ to issue interpretive advice

There would need to be some minor changes made to the Act for it to issue interpretive advice (most likely adding an additional function to Section 3 of the Act). This option does not require a referral of powers (including for New Zealand to recognise the sovereignty of FSANZ on this matter), but if a jurisdiction chose to challenge a FSANZ interpretation, the FSANZ guidance could be used to support any decision.

If this advice was to be binding however, this would likely present challenges in New Zealand, as a New Zealand court would be unlikely to reach outside its own jurisdiction to inform its ruling.

### FSANZ has the capability to issue advice

As the body developing food standards, FSANZ has the scientific and legal expertise to effectively provide advice and guidance on how these standards should be interpreted and enforced. They may require additional expertise and capacity in communications (as this would be a new function for which FSANZ has not previously delivered) so they can effectively distribute this advice to industry and jurisdictions.

### There is a private market of interpretive services that may potentially be disrupted

There is a mix of consulting services who currently operate in the market of interpreting standards and advice on behalf of regulated businesses. This market would potentially be disrupted if FSANZ were to provide interpretive guidance.

### Insights into what stakeholders have said so far...

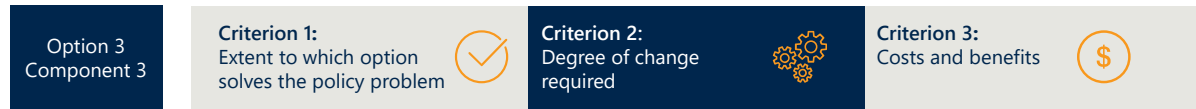
Stakeholders to date have expressed support for more interpretive certainty

Industry stakeholders to date have identified that they want less ambiguity in how to interpret standards. Interpretive certainty reduces variation of regulation between jurisdictions. Further, interpretive certainty allows industry to have greater confidence in a jurisdiction's review process, particularly as it relates to the cost and speed of an application. The opportunity cost of a slow application is overwhelmingly the greatest barrier to market entry expressed by industry.

For its part Government stakeholders broadly support improving regulatory certainty (after all it makes their schemes more effective) but expressed reservations about losing the implementation flexibility that gives rise to the interpretive uncertainty in the first place. For example, certain government stakeholders expressed that they wanted to retain the ability for Ministers to make their own interpretations within their own jurisdiction. In the absence of a referral of powers to the Australian Government to recognise FSANZ as having legal remit to interpret standards, some stakeholders

suggested there would be constitutional challenges in implementing this component because currently responsibility for monitoring and enforcing standards lies with jurisdictions.

### Significant change would be required to implement Component 3 (FSANZ to take on an enforcement role)



### Significant legislative changes would be required to provide FSANZ with enforcement powers

Enacting Option 2 of Component 3 would require significant legislative changes. The Act would need to be updated to include provisions on FSANZ's enforcement scope, activities and powers. These changes could only be enacted if states and territories agreed to a referral of power to the Australian Government and undertook relevant activities to achieve this, including redacting relevant sections of their own food acts. This would also have a significant impact on the Food Regulation Agreement (which includes model law provisions as an appendix).

An equivalent referral mechanism would need to be used in New Zealand if this were to be adopted as a joint measure through the Food Treaty. Such a reform would also require significant legislative change for New Zealand across a range of their domestic legislation (such as the Food Act 2014, Animal Product Act 1999 and Wine Act 2003). These changes could affect the nature of its verification, compliance and enforcement regimes which involve a wide network of third-party agencies.

### An enforcement function would represent a significantly new role for FSANZ

FSANZ would require investment in capability and capacity uplift if it were to establish an enforcement function, as this is not something it currently does.

Significant effort would also be required to establish an appropriate regulatory practice framework and regulatory strategy, supporting policies and procedures and governance arrangements.

FSANZ would need to create productive partnerships with existing jurisdictional enforcement agencies and implement a change management strategy to move all stakeholders onto the new, consistent regulatory approach (this could include establishing a memorandum of understanding (MOU) or service level agreements (SLA) to coordinate institutional arrangements going forward). It would need to do this without causing significant disruption to current services and being mindful not to lose what works well in each of the jurisdictions.

Adopting a Trans-Tasman enforcement function would also give FSANZ the opportunity to invest in new regulatory technologies that would deliver value to the system, and that capitalise on the economies of scale from a single, joint food standards system.

### Establishing a bi-national regulator would present considerable challenges for implementation

A bi-national regulator would be an unprecedented arrangement and as a result, the practicalities of establishing such a regulator would be complex and need to consider Australian, New Zealand and state and territory jurisdictional laws.

Jurisdictions would need to navigate how this new model would work within the context of the Trans-Tasman Mutual Recognition Act, and other Trans-Tasman elements of the existing model. There would be particular complexities to work through to consider how FSANZ would work alongside a New Zealand specific regulator to create synergies with enforcement of New Zealand specific standards (i.e. those that were created under the New Zealand Food Act in instances where New Zealand has opted out of a joint food standard). Potential operational inconsistencies between FSANZ's enforcement of joint food

standards and jurisdictional arrangements for the enforcement of the wider food system may also pose further challenges.

### **Careful organisational design work would be required to preserve FSANZ's independence and science-based approach**

Under the new model, FSANZ would perform functions including standards setting, project work, data collection and management (including existing surveillance work) and its additional regulator enforcement activities. These different functions will need to remain appropriately separate to minimise conflict of interest while still having strong internal streams of communications. Effective governance arrangements and systems would be required to operationalise all of FSANZ's functions and deliver confidence to the community that its independence has not been compromised.

#### Insights into what stakeholders have said so far...

##### **Stakeholders have reported mixed views about the value of FSANZ taking on enforcement activities**

Stakeholders – particularly industry – have recognised the value of a single enforcement agency that interprets and enforces food standards. Industry have noted that this would lead to a less burdensome regulatory system. Despite this support, several other concerns were raised.

All stakeholders consulted to date have been concerned about how FSANZ could maintain its independence when trying to both set standards and oversee enforcement. Some highlighted that FSANZ's independence as the 'standard setter' was one of its greatest strengths. There are, however, 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.

Jurisdictions indicated they value the ability to deliver food regulation under state, territory, and New Zealand acts. These concerns not only speak to the reticence to cede power to the Australian Government, but also the importance of regulatory schemes to be appropriate to local contexts. A bi-national regulatory approach attracts the risks of a less personalised approach to monitoring and enforcement.

New Zealand Government stakeholders have noted that the differences in regulatory schemes between Australia and New Zealand would make granting FSANZ an enforcement role challenging were that role also to be extended to the New Zealand context.

All stakeholders were concerned about how resourcing constraints would impact FSANZ's ability to deliver on a significantly expanded remit.

Of note, separate work is underway to surface key issues relating to jurisdictional inconsistencies in food regulation. Themes arising from this work are reported to include frustrations around how local food acts approach regulatory requirements around food safety systems, food safety supervisors and compliance requirements. These issues are reported to have been presented as a higher priority to the inconsistent interpretation of food standards and could also be meaningfully addressed through the revision of model law provisions in the FRA –noting however, that this has no application for New Zealand food businesses.

Further, government stakeholders have suggested that it is possible that FSANZ carrying out these functions as a non-domestic government agency would raise national security concerns for both Australia and New Zealand.



## Limited change would be required to implement Component 4 (clarify legislation so FSANZ can extend Australia and New Zealand's influence on the international stage)

Option 3  
Component 4

Criterion 1:  
Extent to which option  
solves the policy problem



Criterion 2:  
Degree of change  
required



Criterion 3:  
Costs and benefits



### Minor legislative changes are required to formalise FSANZ's role in this space

This change would require small changes to the act to formalise the role FSANZ already performs. Changes to s 18 of the Act could legislate the role of FSANZ in leading Australia and New Zealand's partnerships with other countries on matters relating to food safety.

### This amendment would build on FSANZ's existing international network and contributions

As this component is formalising work already occurring, it would not require material changes to existing operations.

#### Insights into what stakeholders have said so far...

#### Stakeholders recognised the value of FSANZ reputation and involvement in international collaborations views

Industry stakeholders, in particular, were encouraging of efforts that would lead to greater harmonisation of food standards, as well as any initiatives that might lead to new economic opportunities such as new trade agreements.

## 6.3.3 Costs and benefits

### This option presents some initial costs, but a less burdensome regulatory system in the longer term

This option presents some significant costs and benefits for all stakeholders, many of which have been challenging to quantify:

- For industry, there would be some compliance costs associated with understanding how to work with a new regulatory model, and potentially higher cost-recovery fees related to Component 4. This option would however deliver benefits for industry, including, reduced reputational damage (Component 1), increased economic opportunity and higher profits from a more consistent regulatory experience, and greater trade opportunities.
- For Government, this option would come with costs associated with legislative changes at the jurisdictional-level, and monetary and other organisational costs involved in implementation. The extent of costs would vary amongst jurisdictions including New Zealand. There could be reduced substantive compliance costs with generating interpretive advice. Benefits include reduced foodborne illnesses, more efficient and effective approaches to regulation, a strengthened joint food standards system, increased capacity to focus on most important matters, and more effective FSANZ presence in global dialogues on food standards.
- For consumers, this option would not present any substantive costs. Benefits include, an even safer joint food standards system (Component 1), and improved standards for consumers living in less-well enforced jurisdictions (Component 2).
- For FSANZ, this option would present some one-off establishment costs to set up new processes and arrangements (including a communication campaign of approximately AUD \$200,000 – AUD \$800,000

(NZD \$214,000 – NZD \$856,000) and ongoing operational costs associated with these new arrangements. Benefits are likely to include increased ability to take immediate action to food incidents resulting in a safer joint food standards system, greater influence interpretation of food standards, a more unified, bi-lateral system and greater influence on how to approach food standards harmonisation.

## Implementing Component 1 (provide for FSANZ to instigate food incident responses) is likely to deliver a net positive benefit

Option 3 Component 1	<b>Criterion 1:</b> Extent to which option solves the policy problem	<b>Criterion 2:</b> Degree of change required	<b>Criterion 3:</b> Costs and benefits
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### Giving FSANZ legislative powers to instigate recalls or incidents could mean risks and incidents are detected and acted upon earlier

FSANZ is already well placed to deliver this function and would require minimal costs to add slightly more resourcing capacity. The associated benefit of this component is a more efficient and consistent response to incidents and food recalls, particularly for those that cross jurisdictional borders. A timely response also benefits businesses, as it could minimise reputational damage and financial loss that arises from inefficient and inconsistent responses to food incidents or recalls. It was highlighted that for New Zealand, MPI currently performs this role effectively. Therefore, there is a risk that FSANZ becomes a redundant layer of hierarchy, resulting in a slower incident response.

### Economic costs and benefits for different stakeholder groups have been identified

The costs and benefits for this component of Option 3, by stakeholder group, are shown in Table 17.

**Table 17 | Costs and benefits of Component 1, Option 3 (FSANZ to take a lead role in recalls and food incidents)**




Stakeholder	Costs or benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>Some risk of greater financial damage for New Zealand businesses due to a slower incident response as a result of added layer of FSANZ in food incident/recall response</li> </ul>
Industry	Benefits	<ul style="list-style-type: none"> <li>Reduced reputation damage in instance of delayed food recall and food incidents</li> <li>Potentially minimised financial damage from food recalls and food incidents due to more efficient and coordinated response. (For example, an independent report to FSANZ (not publicly available) on the economic impact of the incident determined the apparent residual impact to be -8.6% reduction in market value, equivalent to AUD \$24.7 million, see section 3.4.1).</li> <li>An even safer joint food standards system, with more timely notification of recalls and food incidents</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Costs	<ul style="list-style-type: none"> <li>Costs associated with legislative changes to jurisdiction-level legislation to refer appropriate powers to the Australian Government to enable FSANZ to take lead on food incidents</li> </ul>

Stakeholder	Costs or benefits	Description of costs or benefits
Governments (Australia and New Zealand, including jurisdictions)	Benefits	<ul style="list-style-type: none"> <li>• Reduced foodborne illness due to earlier identification and responsiveness to problems</li> <li>• More timely identification and management of food risks resulting in a more effective response</li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Consumers	Benefits	<ul style="list-style-type: none"> <li>• Reduced foodborne illness due to earlier identification and responsiveness to problems</li> <li>• An even safer joint food standards system, with more timely notification of recalls and food incidents</li> <li>• Clearer and more consistent messaging during food incidents and recalls</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>• Increased ability to take action based on available data and insights</li> <li>• An even safer joint food standards system, with more timely notification of recalls and food incidents</li> </ul>

#### Discussion questions related to the assessment of Option 3, Component 1

36. Would the impact of pursuing Option 3, Component 1 represent a positive, negative or neutral outcome for your sector?
37. Are you aware of any quantified costs that food businesses have borne as a result of a food incident or recall?
38. Is FSANZ coordinating food recalls /incident response a function that would be equally valuable for Australia and New Zealand? Why

#### Implementing Component 2 (FSANZ to provide more interpretive advice) is likely to deliver a net positive benefit

Option 3 Component 2	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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#### Greater interpretive advice would reduce compliance costs for industry and for jurisdictional regulators

Providing interpretive advice would reduce compliance costs for industry (leading to higher profits and increased producer surplus), as the standards would only require interpretation once, across all jurisdictions. This could also level the playing field for food businesses operating in jurisdictions where the compliance burden is currently higher. In the example of egg producers in section 3.4.2 for instance, this could reduce costs for businesses operating in Queensland and Western Australia.

This would be particularly important for businesses operating across states and territories or the Trans-Tasman; and small businesses for whom interpretive costs would be a significant burden

Furthermore, compliance costs for jurisdictions would be reduced. Currently, each jurisdiction has dedicated staff interpreting and subsequently enforcing the standards. If FSANZ provides interpretive advice, this would reduce substantive compliance costs for each jurisdiction. Without data on the current costs of these services/FTE figures, FSANZ cannot quantify this.

### **There are likely to be some costs to set up and communicate new arrangements**

The set-up of these new arrangements will come with some establishment costs for jurisdictions and new businesses. Both these groups of stakeholders will need to set up new processes and policies to recognise and act on FSANZ guidance. FSANZ would also need to run an awareness campaign so stakeholders are aware of this change. This campaign could cost approximately AUD \$200,000 – AUD \$800,000 or NZD \$214,000 – NZD \$856,000 (for campaign budget and/or FTEs).<sup>88</sup>

As interpretive advice would focus on new standards (rather than existing standards), establishment costs for FSANZ would be minimal.

### **Economic costs and benefits for different stakeholder groups have been identified**

The costs and benefits for this component of Option 3, by stakeholder group, are shown in Table 18.

**Table 18 | Costs and benefits of Component 2, Option 3 (provide for FSANZ to give greater guidance on food standards)**

Stakeholder	Costs or benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>Some initial substantive compliance costs to understand changes in policies and processes and complete appropriate internal training</li> <li>Offset by reduced ongoing substantive compliance costs to operate across jurisdictional boundaries and from less need for interpretive advice</li> <li>Administrative costs to meet any new, higher standards</li> </ul>
Industry	Benefits	<ul style="list-style-type: none"> <li>Increased economic opportunity and higher profits (producer surplus) to operate or trade in jurisdictions that have previously adopted interpretations of food standards that incur higher compliance costs</li> <li>Increased economic opportunity and higher profits (producer surplus) for smaller businesses who have needed to pay for interpretive services</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Costs	<ul style="list-style-type: none"> <li>Reduced substantive compliance costs associated with generating interpretive advice for application within their own jurisdictions</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Benefits	<ul style="list-style-type: none"> <li>More efficient and effective approaches to regulation based on a common interpretation of food standards</li> <li>Increased compliance with regulatory obligations, with consistent enforcement across jurisdictions, for example, greater compliance with general health claim requirements.</li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>N/A</li> </ul>




<sup>88</sup> This range has been calculated considering estimates provided by FSANZ (lower end of range) and other RIS proposing a national regulator (upper end of range).

Stakeholder	Costs or benefits	Description of costs or benefits
Consumers	Benefits	<ul style="list-style-type: none"> <li>Consumers living in less-well enforced jurisdictions would move up to the national standard</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>One-off establishment costs to set up processes and policies for new function, deliver appropriate training for staff and conduct education awareness campaign</li> <li>Ongoing operational and administrative costs associated with undertaking new activities</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>Greater influence to ensure interpretation of food standards align with the original policy intent</li> </ul>

#### Discussion questions related to the assessment of Option 3, Component 2

39. Would the impact of pursuing Option 3, Component 2 represent a positive, negative or neutral outcome for your sector?
40. Are you aware of any data to demonstrate the current impost on industry from interjurisdictional inconsistencies in the enforcement of standards?
41. Is the notion of FSANZ taking on enforcement activities equally valuable for both Australia and New Zealand? Why / why not?

#### Implementing Component 3 (FSANZ to take on an enforcement role) could achieve a positive outcome, for a significant investment

Option 3 Component 3	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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#### Significant investment would be required to stand up an enforcement function, but there would be ongoing administrative saving

Establishing an enforcement function within FSANZ would require some significant upfront investment. This investment would likely include:

- Organisational design and implementation (development of new policies, procedures, systems, structures and governance arrangements and appropriate internal training)
- As with Component 2, this reform would require a communications campaign. Nous anticipates that this would require no additional costs to what was budgeted in Component 2.

There would also be costs in drafting new legislative changes, requiring significant engagement across jurisdictions due to the nature of the change. All jurisdictions would then need to pass their own legislation to refer relevant powers to the federal government.

There would be a freeing of capacity at jurisdictional levels by consolidating policy setting roles into one FSANZ team. To date, Nous has not been able to access data on the combined regulators FTE workforce size (and spend on policy setting roles) across jurisdictions and so cannot estimate what capacity would unlock at the jurisdictional level. However, the RIS that proposed reforms to create a national approach to

maritime safety regulation for commercial vessels estimated under a slightly similar model that administrative savings would be approximately 15%.<sup>89</sup>

The sector can also achieve operational efficiencies in the long term through best regulatory practice and by leveraging regulatory technologies.

### **Industry would see some initial compliance costs but also a less burdensome and more consistent regulatory environment**

There will likely be some initial compliance costs for businesses associated with understanding changes in the regulatory environment. There is also a risk that a new enforcement mechanism could reduce continuity between jurisdictions and industry which could have implications for food standards compliance.

However, once understood these changes will ultimately lead to a reduced regulatory burden on business (particularly for those operating across jurisdictional boundaries) and a more consistent experience. This will lower businesses costs, leading to higher profits. To date, no quantitative data has been accessible to characterise the costs to industry of inconsistent interpretation of food standards across jurisdictions.

### **Economic costs and benefits for different stakeholder groups have been identified**

The costs and benefits for this component of Option 3, by stakeholder group, are shown in Table 19.

**Table 19 | Costs and benefits of Component 3, Option 3 (position FSANZ to take on enforcement role)**

Stakeholder	Costs or benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>Compliance costs to understand changes in policies and processes and complete appropriate internal training</li> <li>Offset by reduced compliance costs to operate across jurisdictional boundaries</li> </ul>
Industry	Benefits	<ul style="list-style-type: none"> <li>More consistent experience of regulation, thus higher profits, when operating or trading across borders</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Costs	<ul style="list-style-type: none"> <li>Costs associated with legislative changes to jurisdiction-level legislation to refer appropriate powers to the Australian Government to enable FSANZ to exercise enforcement powers</li> <li>Potential duplication of costs and inefficiencies associated with FSANZ overlaying a bi-national regulatory approach over enforcement arrangements that are already relatively effective (for example, MPI, which provides a consistent regulatory experience for food businesses in New Zealand)</li> <li>Potential risk that failure to understand new enforcement mechanisms could result in greater non-compliance with food standards in the short term</li> </ul>




<sup>89</sup> National Approach to Maritime Safety Regulation: Regulation Impact Statement, April 2009. This RIS identified a saving of 28 FTE in a workforce of 191.39 FTE, equating to a saving of 15%.

Stakeholder	Costs or benefits	Description of costs or benefits
Governments (Australia and New Zealand, including jurisdictions)	Benefits	<ul style="list-style-type: none"> <li>Increased capacity for jurisdictions to focus on other high-impact food policy/regulatory matters, not captured within FSANZ's regulatory remit</li> <li>More effective management of non-compliance by better leveraging capacity and expertise across the system</li> <li>Strengthening of the bi-national nature of the scheme</li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>Increased regulatory compliance costs could be passed onto consumers through the price of products</li> </ul>
Consumers	Benefits	<ul style="list-style-type: none"> <li>N/A</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>One-off establishment costs to set up regulatory functions, deliver appropriate training for staff and conduct education awareness campaign</li> <li>Ongoing operational and administrative costs associated with undertaking new activities</li> <li>Risk of perceived conflict of interest between 'standard setting' and 'enforcement body', which could diminish trust in FSANZ</li> </ul>

#### Discussion questions related to the assessment of Option 3, Component 3

42. Would the impact of pursuing Option 3, Component 3 represent a positive, negative or neutral outcome for your sector?
43. Are you able to provide detail on the costs or resources each jurisdiction invests into enforcement activities?

### Implementing Component 4 (clarify legislation so FSANZ can extend Australia and New Zealand's influence on the international stage) could create new economic opportunities for businesses

Option 3 Component 4	<b>Criterion 1:</b> Extent to which option solves the policy problem 	<b>Criterion 2:</b> Degree of change required 	<b>Criterion 3:</b> Costs and benefits 
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#### There would be some small costs associated with legislative change, but a much greater benefit for industry and stakeholders

There would little in associated costs for this change. These would be limited to ongoing costs of building and maintain the international collaborations.

These costs would be superseded by the benefits for industry and jurisdictions, as it would extend Australia and New Zealand's influence on the world stage. Furthermore, greater collaboration around food standards will lead to greater harmonisation; reduced compliance costs for food businesses exporting to other countries, making our product more competitive in international markets.

Finally, harmonisation of standards would increase Australia and New Zealand's access to foreign markets. This could make both countries more attractive options as manufacturing locations.



As with Component 2, for Component 4 There is some risk that by expanding FSANZ's role beyond 'standard setting' to include food policy; could compromise its independence. This risk could be managed through appropriate governance channels and structures.

### Economic costs and benefits for different stakeholder groups have been identified

The costs and benefits for this component of Option 3, by stakeholder group, are shown in Table 20.

**Table 20 | Costs and benefits of Option 3, Component 4 (clarify legislation so FSANZ can extend Australia and New Zealand's influence on the international stage)**

Stakeholder	Costs or benefits	Description of costs or benefits
Industry	Costs	<ul style="list-style-type: none"> <li>Higher cost-recovery fees for FSANZ costs that are recovered from industry (i.e., for paid applications)</li> </ul>
Industry	Benefits	<ul style="list-style-type: none"> <li>Potential for greater harmonisation of food standards and improved economic trade opportunities for Australian and New Zealand businesses</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Costs	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Governments (Australia and New Zealand, including jurisdictions)	Benefits	<ul style="list-style-type: none"> <li>Greater presence of Australia and New Zealand in the global dialogue about food and associated increased influence over the world's overarching policy direction</li> <li>Greater attractiveness for Australia and New Zealand as a manufacturing location, from harmonised standards.</li> </ul>
Consumers	Costs	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Consumers	Benefits	<ul style="list-style-type: none"> <li>N/A</li> </ul>
FSANZ	Costs	<ul style="list-style-type: none"> <li>Ongoing costs associated with building and maintaining international collaborations. While in the first instance, this cost of going to more international conference junkets is borne by FSANZ, some of these costs may be passed on to the industry through cost-recovery arrangements.<sup>90</sup></li> <li>Risk of perceived conflict of interest between 'standard setting' and 'policy influencer', which could diminish trust in FSANZ</li> </ul>
FSANZ	Benefits	<ul style="list-style-type: none"> <li>Greater influence over how harmonisation of food standards is approached</li> </ul>

### Discussion questions related to the assessment of Option 3, Component 4

44. Would the impact of pursuing Option 3, Component 4 represent a positive, negative or neutral outcome for your sector?

<sup>90</sup> Australian Government Cost Recovery Guidelines (RMG 304), Department of Finance, 2020. Available at: <https://www.finance.gov.au/publications/resource-management-guides/australian-government-cost-recovery-guidelines-rmg-304>

#### Discussion questions related to the assessment of Option 2

45. Are there other costs and benefits (qualitative or quantitative) that should be measured in relation to Option 3? If so, who would bear these costs and benefits?
46. What activities or functions within Option 3 do you think could be supported through cost recovery mechanisms?

## 7 Discussion questions

Stakeholders are invited to provide written feedback on the discussion questions that have been distributed throughout the draft RIS and are consolidated below. Feedback will be collected via *the Australian Department of Health Consultation Hub*, with the consultation period closing on Tuesday 18 May 2021.

Government, industry, public health consumer groups and individual stakeholders are all welcome to respond.

### Policy Problems

1. Aside from the three key Policy Problems identified in this RIS, are there other key Policy Problems that should be considered as part of this regulatory impact analysis? If so, what are they and do they manifest differently in Australia and New Zealand?
2. What examples or issues are you aware of in the food regulatory system regarding food sustainability?
3. What examples or issues are you aware of in the food regulatory system regarding recognition of indigenous culture and food expertise?

### Option 1

4. Would the impact of pursuing Option 1 represent a positive, negative or neutral outcome for your sector?
5. What are the key risks borne by different stakeholder groups for this option? What is the likelihood of these risks, and what would be the magnitude of consequence if they occur?
6. Do you have any data on hand that will help to quantify the cost of delays when bringing products to market through the current process? If so, please provide these data.
7. Are there other costs and benefits (qualitative or quantitative) that should be considered as part of this impact analysis? If so, who would bear these costs and benefits?
8. Are you aware of any data that may assist in quantifying the magnitude of these costs and benefits? If so, please provide these data.
9. What risks are borne by your sector as a whole and by different stakeholders under Option 1 (i.e., retain the status quo)?
10. (For jurisdictional regulators) What resources (FTE) do you dedicate to monitoring and enforcement of food standards? What are the costs associated with these arrangements?

### Option 2

11. Would the impact of pursuing Option 2, Component 1 represent a positive, negative or neutral outcome for your sector?
12. If FSANZ's objectives were broadened to include sustainability, how should sustainability be defined? For example, do you support a limited definition of sustainability (i.e., environmental impacts) or a broad definition of sustainability (i.e., environmental, health, economic and social impacts)?
13. What economic opportunities might arise for Australian and New Zealand industry from a greater focus on sustainability?

14. How can FSANZ's activities better recognise indigenous culture and food expertise? Is this the right framing? What differences between the Australian context and the New Zealand context are important to consider? What changes are required to the FSANZ Act to enable this?
15. What economic opportunities might arise for indigenous businesses from bringing traditional goods to the broader market?
16. Would the impact of pursuing Option 2, Component 3 represent a positive, negative or neutral outcome for your sector?
17. Do you think this Component should also include the ability for the Food Ministers' Meeting to delegate to the FSANZ Board for decision-making? If so, for what decisions should this delegation include?
18. What types of issues do you think can be appropriately dealt with in codes of practices or guidelines?
19. Can you provide data to quantify the administrative burden on industry associated with compiling the required evidence base to support a comprehensive risk assessment by FSANZ?
20. Are you aware of any data to demonstrate the potential savings for industry if FSANZ had the statutory ability to recognise and adopt international risk assessments?
21. Would the impact of pursuing Option 2, Component 3 represent a positive, negative or neutral outcome for your sector?
22. What are examples of novel food products and ingredients and new technologies used in the production and testing of food products that could be appropriately and safely introduced using regulatory sandboxes?
23. Would the impact of pursuing Option 2, Component 4 represent a positive, negative or neutral outcome for your sector?
24. Should a function for FSANZ's to collect, consolidate and communicate food safety data be legislated?
25. Would the impact of pursuing Option 2, Component 5 represent a positive, negative or neutral outcome for your sector?
26. Would stakeholders (including universities, expert food safety bodies or industry) be willing to pay for data or data-linkages services from FSANZ?
27. Would the impact of pursuing Option 2, Component 6 represent a positive, negative, or neutral outcome for your sector?
28. What are the key risks borne by different stakeholder groups for this option? What is the likelihood of these risks, and what would be the magnitude of consequence if they occur?
29. Are there other costs and benefits (qualitative or quantitative) that should be measured in relation to Option 2? If so, who would bear these costs and benefits?
30. Are you aware of any data that may assist in quantifying the magnitude of these costs and benefits? If so, please provide these data.
31. Should the Act provide for more of its work with industry to be offset through cost recovery mechanisms? For example, should FSANZ seek to broaden the types of applications for which it charges fees; should the provision of interpretative advice attract fees; or are there other activities for which FSANZ should cost recover?
32. What would be the impact on industry (especially small to medium businesses) or consumers of FSANZ cost-recovering for a broader range of activities?

33. How often do you currently engage with the food regulation system through making applications to change food standards?
34. What are the most significant barriers that you or your organisation faces when trying to engage with the food regulation system?
35. Would you be more likely to engage with the food regulation system through the new pathways proposed in this regulatory impact statement? If so, which pathways would you be most likely to use and why?

### Option 3

36. Would the impact of pursuing Option 3, Component 1 represent a positive, negative or neutral outcome for your sector?
37. Are you aware of any quantified costs that food businesses have borne as a result of a food incident or recall?
38. Is FSANZ coordinating food recalls /incident response a function that would be equally valuable for Australia and New Zealand?
39. Would the impact of pursuing Option 3, Component 2 represent a positive, negative or neutral outcome for your sector?
40. Are you aware of any data to demonstrate the current impost on industry from interjurisdictional inconsistencies in the enforcement of standards?
41. Is the notion of FSANZ taking on enforcement activities equally valuable for both Australia and New Zealand? Why / why not?
42. Would the impact of pursuing Option 3, Component 3 represent a positive, negative or neutral outcome for your sector?
43. Are you able to provide detail on the costs or resources each jurisdiction invests into enforcement activities?
44. Would the impact of pursuing Option 3, Component 4 represent a positive, negative or neutral outcome for your sector?
45. Are there other costs and benefits (qualitative or quantitative) that should be measured in relation to Option 3? If so, who would bear these costs and benefits?
46. What activities or functions within Option 3 do you think could be supported through cost recovery mechanisms?

## 8 Next steps

This draft RIS will be open for public submissions from Tuesday 6 April to Tuesday 18 May 2021. Submissions received will be considered and thematically analysed to further refine the issues and potential reform ideas identified.

Findings from written submissions and additional consultation will be collated into a final Regulatory Impact Statement, which will be used to inform any amendments to the Act. The final RIS will build on this draft RIS by answering three additional questions:

1. Who did you consult and how did you incorporate their feedback?
2. What is the best option from those you have considered?
3. How will you implement and evaluate your chosen option?

Information on the preferred reform option will include greater detail in defining the legislative implications and costs and benefits, drawing on the feedback and submissions to this draft RIS. Discussion of implementation and evaluation of the preferred option will include consideration for undertaking further legislative reviews of the Act to ensure that it remains fit-for-purpose, effective and future-proof given the substantial changes to food regulation, government priorities, consumer preferences and industry practices that are anticipated to continue in the future.

The Department of Health, in collaboration with New Zealand Ministry for Primary Industries, will lead the legislative amendment process.

# Appendix A Terms of Reference

Table 21 provides the full Terms of Reference for the Review.

Table 21 | Review Terms of Reference

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).
<u>Scope</u>	
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:
	<ul style="list-style-type: none"> <li>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</li> <li>revision of the interface between the regulator and business, i.e. the digital or paper systems used to support the assessment.</li> </ul>
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 22 outlines membership of the FSANZ Act Review Steering Committee.

Table 22 | FSANZ Act Review Steering Committee members

Organisation
Australian Government Department of Health (Chair)
Australian Government Department of Agriculture, Water and the Environment
New Zealand Ministry for Primary Industries
Food Standards Australia New Zealand
Department of Prime Minister & Cabinet
Department of Industry, Science, Energy and Resources

## Appendix C Review consultation plan

This draft RIS is informed by extensive stakeholder consultation.

Consultation on the Review commenced in June 2020 and took place over three stages:

1. Stage 1 (June) | Understanding the issues and risks in the current regulatory system
2. Stage 2 (July – October) | Identifying possible solutions to those issues
3. Stage 3 (October – November 2020) | Testing reform ideas and understanding the potential regulatory impact they might have, including public consultation on a scoping paper that described 25 reform ideas.

Consultation has been well attended, and the Review has received input from a broad variety of stakeholders from across Australia and New Zealand. A snapshot is provided at Figure 23.

Figure 23 | Overview of consultation activities to date



# Appendix D Impact analysis assumptions

This Appendix details the assumptions underpinning the impact analysis of the reform options including:

- Overarching assumptions informing the analysis
- Assumptions underpinning estimates of impact of reforms on regulatory burden for industry, applying the Australian Government's *Regulatory Burden Measurement Framework*
- Assumptions underpinning other quantitative components of impact analysis.

Each is described in turn.

All new regulations or changes to existing regulations need to have the increase or decrease in regulatory costs imposed on businesses, community organisations and individuals quantified using the Regulatory Burden Measurement framework.<sup>91</sup> Additionally, all Regulation Impact Statements (RISs) need to be accompanied by a regulatory costing.

The framework includes consideration of the following regulatory costs:

Compliance costs:

- i. administrative costs
- ii. costs incurred by regulated entities primarily to demonstrate compliance with the regulation (usually record keeping and reporting costs)
- iii. substantive compliance costs
- iv. costs incurred to deliver the regulated outcomes being sought (usually purchase and maintenance costs).

Delay costs:

Expenses and loss of income incurred by a regulated entity through:

- v. an application delay
- vi. an approval delay.

The following costs are excluded from the Regulatory Burden Measurement framework and are not required to be considered when quantifying an estimate of regulatory burden.

- vii. Opportunity costs (unless they relate to a delay)
- viii. Business-as-usual-costs
- ix. Non-compliance and enforcement costs
- x. Regulatory impacts related to the administration of courts and tribunals
- xi. Indirect costs (costs that may arise indirectly from the impacts of regulatory changes, including changes to market structure and competition impacts)
- xii. Direct financial costs
- xiii. Costs of international obligations imposed as a pre-requisite for participation in international markets

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<sup>91</sup> Guidance for policy makers: Regulatory Burden Measurement (2020), Department of Prime Minister and Cabinet. Available at: <https://www.pmc.gov.au/regulation/guidance-policymakers/regulatory-burden-measurement>

xiv. Government-to-government regulation (includes all regulation imposed by Commonwealth on Australian Government, state and territory government, local government and foreign government departments or agencies).

## Scope of application

- The RBMF is applied to Options 2 and 3 for businesses under the administrative cost category.
- The RBMF is applied in relation to changes to processes and decision-making arrangements for amending food standards, in particular the addition of new pathways, streamlining of existing pathways and changing of evidentiary requirements (by drawing on international evidence-base).
- Questions for consultation outlined in Section 7 include questions for industry to substantiate the impact of delay costs under the current legislative arrangements and proposed reform options; that is, the extent to which delays in processing and approving applications lead to foregone economic opportunities for businesses selling food products for which entry to the Australian and New Zealand markets is delayed under current arrangements.

## Assumptions

- Labour cost associated with making applications uses the 'default work-related and non-work-related labour rate' proposed by the RBMF. This provides an economy-wide value for employees of AUD \$41.74 (NZD \$44.66) per hour, scaled up using a multiplier of 1.75 to account for non-wage labour on costs, resulting in a scaled-up rate of AUD \$73.05 (NZD \$78.16).<sup>92</sup>
- The calculations assume that the applications received by FSANZ will increase at historical rates over the next ten years (20 in 2021, up to 31 in 2030). It is assumed that the distribution of applications (by procedure) will continue over this period.
- Time spent on applications by industry applicants uses the maximum variable hours for each type of procedure (as set out in FSANZ's Application Handbook<sup>93</sup> (a legislative instrument under s 23(1) of the Act which is available online). High-level assumption (for Option 1 – status quo) is that an applicant spends two hours on an application for every one hour spent by FSANZ processing the application.
- Under Option 2, it is assumed that 50% of total applications (that have been noted as straightforward or low-risk in submissions to this Review) would be subject to a streamlined and/or new pathway. It is assumed that these applications would be subject to a low-risk pathway. This uses the legislated 'minor procedure' as a guide, which has maximum variable hours for FSANZ of 100 hours (relative to 240 hours for level 1 – general procedure and 380 hours for level 2 – general procedure).
- Under Option 2, it is assumed that 25% of total applications (or 50% of the low-risk applications determined above) would be subject to the industry self-substantiation pathway. This assumes zero administrative hours for businesses involved in making application (as this provides an alternative process to applications).
- Our projections of industry burden of FSANZ application delays are based on data that FSANZ approved 15 applications in the financial year 2019-2020.
- All dollar values initially derived in AUD and converted to NZD at a ratio of 1 : 1.07 on 26.2.21.

<sup>92</sup> Regulatory Burden Measurement Framework Guidance Note, available at:

<[https://www.pmc.gov.au/sites/default/files/publications/Regulatory\\_Burden\\_Measurement\\_Framework.pdf](https://www.pmc.gov.au/sites/default/files/publications/Regulatory_Burden_Measurement_Framework.pdf)>, p. 18

<sup>93</sup> FSANZ Application Handbook 2016, available at:

<<https://www.foodstandards.gov.au/code/changes/Documents/Application%20Handbook%20as%20at%201%20March%202016.pdf>>

## D.1 Assumptions underpinning other quantitative analysis

### Governance costs

- The following assumptions underpin the estimates of efficiencies through a smaller (8-person) Board:
- Costs for regular face-to-face meetings (4 per year) for 12-person Board amount to AUD \$104,930 (NZD \$112,275) comprising:
  - AUD \$25,350 (NZD \$27,125) for each Australia meeting
  - AUD \$29,000 (NZD \$31,000) for New Zealand meeting
  - AUD \$280 (NZD \$300) for teleconference costs.
- Costs for regular face-to-face meetings (4 per year) for 8-person Board would amount to AUD \$67,870 (NZD \$72,620), including:
  - AUD \$16,080 (NZD \$17,200) for each Australia meeting
  - AUD \$19,750 (NZD \$21,100) for New Zealand meeting
  - AUD \$280 (NZD \$300) for teleconference costs.
- In particular, it is estimated that moving to a virtual by default model for board meetings would save FSANZ AUD \$25,000 – AUD \$30,000 (NZD \$26,750 – NZD \$32,100) per meeting.
- In practice, this equates to at least AUD \$100,000 – AUD \$120,000 (NZD \$107,00 – NZD \$128,400) in reduced costs per year; AUD \$1 million – AUD \$1.2 million (NZD \$1.07 million – NZD \$1.28 million) over a 10-year period. Salary cost reduction for 8-person Board would amount to 4 x AUD \$42,960 (NZD \$46,000) p.a. (each Board member remuneration). Board chair remuneration, the Finance, Audit, and Risk Management Committee (FARMC) Chair and FARMC member remuneration would remain constant across options.<sup>94</sup>

### FSANZ operational costs and capacity

The impact assessment estimates the organisational capacity (in terms of dollars and labour hours) that could be made available at FSANZ through changes to processes and decision-making arrangements. This provides an indication of resources that could be deployed to higher impact and priority issues through changes to the regulatory framework to support more flexible and risk-proportionate approaches. It should not be interpreted to suggest that current resourcing levels could (or should) be reduced.

- FSANZ's workload (in terms of applications and proposals) will continue at recent historical growth rates over the next ten years. Capacity will be freed up through changes to times in processing applications. Time to assess proposals will remain the same.
- The maximum hours for different procedures in FSANZ's Application Handbook is used as guidelines for time spent on each application. Cost per hour uses OBPR's labour-cost (AUD \$41.74 (NZD \$44.66) x 1.75 = AUD \$73.05 (NZD \$78.17)) for consistency.
- Under Option 2, 50% of total projected applications over 10-years (n=128) will be subject to a more streamlined pathway (excluding industry self-substantiation pathways) with faster processing times. Labour time for streamlined pathways assumes current minor procedure approach (maximum of 100

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<sup>94</sup> FSANZ submission to this Review (governance position paper); data on Board member remuneration also available in FSANZ Annual Reports0.

hours). This amounts to a 140-hour saving per streamlined application (level 1) and 280-hour saving per streamlined application (level 2).

- Under Option 2, 25% of total projected applications over 10-years (n=64), or 50% of streamlined applications from dot point above, will be subject to the industry self-substantiation pathway. Labour time for FSANZ is assumed to be zero hours (excluding greater role in post-market surveillance and monitoring). This amounts to a saving of 240 hours (for streamlined level 2 applications) and 380 hours (for streamlined level 3 applications).
- The total funding for FSANZ between 2017 and 2020 was approximately AUD \$60 million (NZD \$64.2 million), AUD \$20 million (NZD \$21.4 million) per annum following a decrease of almost a third since 2011. Assuming that total FSANZ funding remains stable, total funding over the next ten years is estimated to be AUD \$200 million (NZD \$214 million).

# Appendix E Summary of comparable international food regulatory systems

The food regulation systems of Canada, the United States, the European Union, and the United Kingdom have undergone recent modernisations. Common changes have included:

- Affirming food safety as the core objective of any modernisation efforts
- Extending the regulatory system's scope to include the whole food chain
- Focusing on preventing rather than responding to issues
- Integrating risk-based decision making
- Consolidating institutional arrangements
- Better leveraging international reviews and risk assessments of food products
- Establishing shared food standards.

## **Canada's modernisation efforts have partly focused on increasing opportunity for industry and subsequent reviews have introduced ideas around research and development**

Canada has recently undertaken a significant modernisation project to update the food regulatory system. *The Safe Food for Canadians Act 2018* and the *Safe Food for Canadians Regulations (2018) (SFCRs)* were designed to make the overall joint food standards system safer by focusing on prevention and improving emergency response capabilities. The legislation consolidates food provisions now administered and enforced by the Canadian Food Inspection Agency (CFIA) under four statutes into the *Safe Food for Canadians Act* to strengthen oversight of food commodities being traded inter-provincially or internationally. The Act focuses on three important areas:

1. Improving food safety oversight to better protect consumers
2. Strengthening and streamlining legislative authorities
3. Enhancing international market opportunities.

The SFCRs are a series of outcomes-based regulations intended to make the whole food regulatory system more agile, especially the monitoring and enforcement requirements. Supporting the SFCRs, the CFIA is rolling out a series of non-regulatory initiatives over the coming years to consolidate the modernisation program. This includes an integrated risk-management scheme derived from greater use of data and surveillance, and a digitisation of the system to ensure that both regulators and the regulated are leveraging the best available technology to protect the safety of Canadian people.

Canada has recently commenced a modernisation review of their food regulatory system:<sup>95</sup>

"As stakeholders seek to benefit from the increased growth potential that comes with globalization, they face challenges with a regulatory system that has not kept pace with change in the sector. Further, stakeholders emphasize the importance of a system that supports global competitiveness, including

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<sup>95</sup> Canadian Food Inspection Agency. (2019). Targeted Regulatory Review: Agri-food and Aquaculture Roadmap. [online] Available at: <https://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/forward-regulatory-plan/agri-food-and-aquaculture-roadmap/eng/1558026225581/1558026225797>

through harmonization with trading partners, shared setting of standards, and reduced regulatory barriers to trade. Regulated parties have identified opportunities to make the current system more efficient (for example, by reducing approval times), modern (for example, through changes to processes, platforms and tools) and consistent".<sup>96</sup>

- As part of the modernisation review,<sup>97</sup> Health Canada has developed an Agri-food and Aquaculture Roadmap which will further explore options to:
- Modernise food regulations to enable innovative and safe foods for Canadians
- Increase Canadian participation and influence in international standard setting bodies
- Use of foreign reviews and joint risk assessments to bring innovative food products to the market for Canadians
- Provide clarity to industry approaches to novel products of biotechnology
- Develop a food labelling coordination strategy, including considering a regular cycle for labelling changes
- Develop a framework to conduct clinical trials on infant formulas in Canada.

### **The United States gave important powers to its Food and Drug Administration but failing to increase its funding commensurately undermined the new systems effectiveness**

The US recently passed the 2011 *Food Safety Modernization Act* (FSMA) which was designed to modernise the regulatory system and provide the Food and Drug Administration (FDA) with more effective tools to enforce the law. Broadly, the FSMA adopted a principles-based design and changed the objective of the regulatory system from responding to public health matters to preventing them. The changes followed a series of foodborne illness outbreaks in the early 2000's and were supported by industry.

The FSMA:

- Expanded the FDA's authority to conduct mandatory recalls of contaminated food products
- Enhanced surveillance systems to investigate foodborne illness outbreaks
- Established new preventative controls and food safety plans at some food processing facilities and farms
- Enhanced the FDA's traceability capacity within the nation's food distribution channels
- Increased inspection frequencies of high-risk food facilities (both domestic and foreign facilities)
- Expanded the FDA's authority and oversight capabilities with regard to foreign companies that supply food imports to the US.

The tangible changes enacted by the FSMA have been introduced gradually and many have only recently come into force. There is not yet a consensus on the overall impact of the modernisation project. There is some evidence that the FSMA has achieved one of the intended goals of giving domestic producers and suppliers a relative advantage over importers. Conversely there are concerns that funding has not increased proportionately to the increased responsibilities given to the FDA. Resources are tighter than ever, and the FDA is failing to meet a number of key metrics related to inspection volumes.<sup>98</sup>

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<sup>96</sup> Canadian Food Inspection Agency. (2019). Targeted Regulatory Review: Agri-food and Aquaculture Roadmap. Available at: <https://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/forward-regulatory-plan/agri-food-and-aquaculture-roadmap/eng/1558026225581/1558026225797>

<sup>97</sup>Ibid.

<sup>98</sup> FDA hasn't been doing enough FSMA inspections. (2017). [online] Available at: <https://www.fooddive.com/news/report-fda-hasnt-been-doing-enough-fsma-inspections/506072/>



## **The European Union employs a multi-national unified regulatory model to deliver food safety outcomes across dozens of jurisdictions**

The European Union employs a multi-national unified regulatory model. The EU issues international directives and legislated regulations in the form of harmonised standards which cover the entire food production and processing chain within the EU, as well as imported and exported goods. The EU manages legislative policy through Regulations and Directives. Regulations have binding legal force throughout every Member State and enter into force on a set date throughout the Union. For example, when the EU wanted to ensure that all member states were protected by common safeguards for goods imported from outside the EU, the Council adopted a regulation - REGULATION (EU) 2015/478 – to have binding effect on all jurisdictions. Directives by contrast outline certain results that must be achieved by each member state but unlike regulations, each Member State is free to decide how to transpose directives into national laws. One example is the EU consumer rights directive, which strengthens rights for consumers across the EU, for example, by eliminating hidden charges and costs on the internet and extending the period under which consumers can withdraw from a sales contract. In both cases, states are under no obligation to implement these outcomes through a specific model law or similar instrument. Rather, member states are free to employ any legislative tool that suits their context, provided it achieves the outcomes stated in the directive.

While individual countries implement legislation to reflect the standards and establish controls to enforce them, the EU audits the application and effectiveness of those laws and controls, and also provides training to the responsible EU and international authorities.

The EU also employs other non-binding instruments to achieve regulatory outcomes. The EU can make recommendations, which are non-binding suggestions for member-states to undertake certain actions (for example improve their use of videoconferencing to help judicial services work better across borders). There are no legal implications associated with a recommendation, but they nonetheless allow EU institutions to make their positions explicitly known.

EU institutions can also issue opinions. Like recommendations they are non-binding and have no legal effect, but nonetheless can be used when laws are being made so that stakeholders understand the views of different organisations on proposed legislation.