

Response ID [REDACTED]

Submitted to Public Consultation - Review of the Food Standards Australia New Zealand Act 1991 - Impact Analysis
Submitted on 2024-04-10 16:50:19

Introduction

Have you read the Impact Analysis?

Yes

Demographics

What is your full name?

Full name:

Damian Maganja

Are you answering on behalf of an organisation?

Yes

What is the name of your organisation?

Organisation name::

The George Institute for Global Health

Which sector do you represent?

Research/Academic

Other: :

What country are you responding from?

Australia

Other: :

If we require further information in relation to this submission, can we contact you?

Yes

What is your email address?

Email address::

[REDACTED]

Section 3 - The problems to solve

Section 3 - The problems to solve (Methodology)

What are the issues with the current methodology? How should it be improved? Please provide justification.

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We remain concerned with the approach undertaken to identify and prioritise policy problems. While the problems have been updated since the draft Regulatory Impact Statement in early-2021, this has not been well documented. Little detail has been made available to explain processes, inputs and assumptions underpinning problem identification and prioritisation.

In particular, the continued exclusion of the main problem with the current food regulatory system, that people are not effectively protected from long-term health impacts and preventable diet-related diseases, must be justified. This is the primary objective of FSANZ, however is not mentioned in the IA at all and as a result the methodology completely fails to factor this in.

The current methodology is therefore flawed as it fails to identify a key policy problem that needs to be solved - that the Act in its current form does not enable the food regulatory system to meet its primary objectives of protecting public health, specifically long-term health and preventable diet-related disease, and the provision of adequate information to enable consumers to make informed choices, as raised by the majority of public health and consumer organisations in their submissions on the Draft Regulatory Impact Statement (2021). Instead, the current methodology, in policy problem 1, has focused simply on incorporating a definition of public health to minimise external stakeholder confusion about FSANZ's existing roles and operations.

Whilst this is a necessary step it is insufficient to deal with the actual policy problem. As a result, the entire IA fails to adequately address how FSANZ can and should address long-term health and preventable diet-related disease. This is evident in the analysis of each subsequent policy problem and in each option put forward for reform, including most significantly the risk-based framework and the cost benefit analysis. To help address this we propose that a Public Health Test be incorporated into the Act (see our response to the question in relation to other initiatives under component 2.1 for more details).

Policy problem 2 also fails to adequately include the problem that there are unnecessary time and cost burdens to consumers and governments as a result of FSANZ not undertaking more standard reviews and proposals and doing so in a timely manner

Are there other methodologies or evidence that the Impact Analysis should consider?

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As highlighted in Section 3, the Act is designed to “address negative externalities such as where the actions of some stakeholder groups create costs or harm for other people” and “address information asymmetries by ensuring that consumers have adequate information and consequently are able to make informed choices which promotes high quality production”. The Act should include responsibility for food systems security and their vulnerability to climate change via impact analysis. This feedback has been provided throughout the Review processes via expert stakeholders including academics and civil society organisations in Australia and New Zealand and is reflected in feedback outlined in Section 7 of the Impact Analysis. The food regulatory system has the opportunity to play an important role in ensuring Australia and New Zealand’s national and international obligations under the Paris Agreement and domestic Nationally Determined Contributions are fulfilled, and safeguarding food safety and security.

FSANZ, via the Act, is already equipped to undertake this work, having an established credible international reputation for food standards and safety, and its objectives regarding public health. FSANZ also has established relationships throughout the food system, including with experts, academics, civil society and other government agencies and departments. Through the expansion of FSANZ responsibilities via the Act, and increasing resources and internal expertise, FSANZ can be an effective agency to respond to the regulatory needs food security requires.

Section 3 - The problems to solve (Ratings)

Are the ratings assigned to each of the sub-problems and ultimately the problem appropriate?

No

Which rating(s) do you believe is inappropriately rated? What would be a fair rating for the problem? Please provide justification. (Free text)

Free text box, no character limit:

The sub-problems that are already having the largest impact on the health and wellbeing of Australians and New Zealanders should receive the highest possible impact ratings. These are:

- Policy Problem 1, sub-problem 1: Unclear definitions have created confusion about how FSANZ should consider short-and long-term risks to health when developing food regulatory measures;
- Policy Problem 2, sub-problem 2: Resourcing constraints have effectively preferenced piecemeal changes to food standards over holistic reviews;
- Policy Problem 3, sub-problem 2: Long-term decreases in funding have created significant resourcing pressure and are forcing FSANZ to focus on only a subset of its statutory functions.

We strongly disagree that the highest impact rating should be allocated to sub-problems that impact only the very small number of businesses making applications to FSANZ (Policy Problem 2, sub-problem 1), or refer to potential food safety risks which are currently extremely well managed (Policy Problem 4, sub-problem 3), as is currently proposed in the IA. These sub-problems are not of the same magnitude as widespread threats of harm to long-term health and should therefore not have equivalent or higher impact ratings than sub-problems dealing with those risks.

Policy Problem 1 | The purpose and objectives of FSANZ are not clear

This problem should be considered high magnitude (3) as the impact and extent of the risks posed by sub-problems 1 and 2 outweigh any other problems identified in the IA.

Sub-problem 1 | Unclear definitions have created confusion about how FSANZ should consider short-and long-term risks to health when developing food regulatory measures

We support the ratings for this sub-problem in the IA - high impact and large extent (3), given potential to undermine public health and safety but note that there are no reforms proposed under Option 2 that resolves the problem of ‘how’ FSANZ should consider long-term risks to health when developing food regulatory measures.

Sub-problem 2 | There remains some confusion about the factors to which FSANZ has given regard in its decision-making, and how this aligns with the objectives of the Act.

Ministers retain overall responsibility and accountability for the food regulatory system, if this is undermined in any way (particularly through not considering Ministerial policy guidance or not communicating effectively on consideration of guidance) then responsibility and accountability, ultimately public and stakeholder confidence, in the food regulatory system is diminished. The rating for this sub-problem should be higher - level of impact should be at least moderate (2) and extent of impact large (3). Note that nothing proposed under Option 2 will address this as there is no requirement to

prioritise compliance with Ministerial policy guidance above other considerations.

Sub-problem 3 | The Act is silent on the needs and commitments of government to First Nations and Māori Peoples

We support the ratings for this sub-problem in the IA but note that nothing proposed under Option 2 will necessarily address this, and meaningful improvements could be available under Option 1

Policy Problem 2 | Legislated processes and decision-making arrangements for food standards are cumbersome and inflexible

This problem should be considered low-moderate magnitude (1-2). The impact and extent of sub-problems 1, 2 and 4 are extremely limited as these are largely limited to FSANZ itself, affect only a very small number of products and businesses, and do not go to the object of the Act which is to ensure a high standard of public health protection as it relates to the quality and safety of food. There are no proposed reforms in the IA that will improve public health and consumer outcomes. We also recommend that sub-problem 3 be removed from this policy problem 2 and added to policy problem 3 as constraints due to inefficient resourcing relates to inefficiencies in operations.

Sub-problem 1 | Statutory processes are rules-based rather than outcomes-based

The IA acknowledges that the vast majority of applications are processed within timeframes but fails to acknowledge that the significant problem with delays lies in the processing of proposals. The reforms in Option 2 only act to make applications even more efficient, despite the majority already being completed within timeframes, and no reforms are proposed to address the delays in progressing proposals.

We consider the level of impact rating of high (3) given to this sub-problem inappropriate in reference to applications and suggest a rating of moderate-low (1-2) - the impact has not nearly the same magnitude as risks to short-and long-term health and should therefore not be rated as high. The extent of impact is extremely limited and should be given a rating of limited (1) in relation to applications as the problem only has significant negative implications for a small cohort of industry stakeholders. We note that nothing proposed under Option 2 will necessarily address claimed inefficiencies in resourcing, particularly as Option 2 proposes to only speed up some applications, most applications already assessed according to statutory timeframes, and applications are acknowledged by FSANZ as taking up minimal resources.

We would support these ratings for the purposes of reflecting the issues with progressing proposals but note that the framing of this problem does not encompass proposals.

Sub-problem 2 | Current requirements create barriers for Indigenous foods to be brought to market

The IA has not articulated how “diets and needs” are linked to “barriers to bringing traditional foods to market”. It has also not explained why traditional foods need to interact with novel food provisions of the Food Standards Code, demonstrate safety and be approved via an application as the vast majority of foods do not need to follow these processes to be bought to market. Given the absence of evidence and framing of the problem, the level of impact and extent of impact should both be low (1). We note also, that to the extent this is an issue, none of the reforms proposed under Option 2 will address this.

Sub-problem 3 | Resourcing constraints have effectively preferred piecemeal changes to food standards over holistic reviews

We support the ratings for this sub-problem in the IA - high impact and large extent (3), given potential to undermine public health and safety. However we note that this is not necessarily related to the Act, and resourcing constraints could also be overcome under Option 1. Option 2 presents only limited options to address this, and other options to address funding decreases (for instance an increase in substantive funding for FSANZ independent of cost-recovery mechanisms) exist under both Options 1 and 2.

Sub-problem 4 | FSANZ generally defaults to developing food standards, but other regulatory measures could be more efficient to create

‘Other regulatory options’ are available to FSANZ currently and no change is proposed under Option 2 that could not be done under Option 1. The non-use of other regulatory measures is in itself necessarily only a low impact and limited extent (should both be rated 1); rather, it is the impact of that use/non-use that is of relevance and this is covered elsewhere in the reform options.

Policy Problem 3 | Elements of FSANZ’s operations are inefficient

This problem should be considered moderate-high magnitude (2-3) as the impact on the Australian and New Zealand populations is significantly greater than suggested for sub-problem 2. This problem should also include sub-problem 3 (resourcing constraints) under policy problem 2, which would further increase the magnitude of this problem.

Sub-problem 1 | Current legislative provisions prohibit nominations and appointment processes for the FSANZ Board from adopting best practice

We agree with the ratings given.

Sub-problem 2 | Long-term decreases in funding has created significant resourcing pressure and is forcing FSANZ to focus on only a subset of its statutory functions

We agree that the level of impact of this problem is considerable and that the current rating of 3 is appropriate. However, the extent of the problem

extends far beyond implications for stakeholders and affects all Australians and New Zealanders, as such the extent should be rated 3. Option 2 presents only limited options to address this, and other options to address funding decreases (for instance an increase in substantive funding for FSANZ independent of cost-recovery mechanisms) exist under both Options 1 and 2.

Policy Problem 4 | Gaps and duplication of efforts challenge system agility

We support the rating of moderate magnitude (2) for this policy problem. We also support the sub-problem 1 and 2 ratings, noting that reforms proposed under Option 2 can all be done under Option 1 for each of these sub-problems.

Sub-problem 3 | Inconsistent interpretation and enforcement of food standards heightens costs for industry and enforcement agencies, while potentially undermining management of foodborne risks (Australia only)

Food safety risks are currently extremely well managed in Australia, as such the level of impact should only be rated as moderate (2). We suggest that a race to the bottom, in an effort to align requirements and minimise compliance costs for industry, is a real potential and will instead present further risks not considered in the IA and therefore suggest an extent of impact rating of large (3).

Section 5 - Options for reform

Component 2.1

Component 2.1.1

Would amending Section 3 and 18 of the Act to include a definition of public health and safety reduce confusion about how FSANZ considers short and long-term risks to health when developing food standards?

Yes

Additional comments (optional):

Amending s3 and s18 of the Act to include a definition of public health and safety may address the minor issue that the Act itself should expressly include FSANZ's role in protecting against long-term risks to health, including diet-related disease, when developing food standards. This change is important but is not likely to result in any meaningful changes to FSANZ's work and approach to public health, as its role in protecting long-term health has been set out in a Ministerial Policy Statement and confirmed by both Ministers and the FSANZ Board, as noted in the IA. What is missing from the IA and the reform options is *how* this will be done. Simply adding a definition will not reduce confusion about *how* FSANZ is to consider long-term risks to health when developing food standards. We strongly recommend the inclusion of a Public Health Test in the Act to address this (see our response to the question in relation to other initiatives under component 2.1 for more details).

We also recommend that any confusion can also be alleviated by better communication by FSANZ of its consideration of short-and long-term risks to stakeholders.

We support an amendment to s3 of the Act to include a definition of 'protecting public health and safety' that encapsulates both acute and long-term health and the amendment of s18 to ensure it aligns with this definition.

We support the use of the definition in Ministerial Policy Statement on the Interpretation of Public Health and Safety in Developing, Reviewing and Varying Food Regulatory Measures with the following amendment (in capitals): "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, AND THE DIET-RELATED RISK FACTORS FOR THEM, as well as acute food safety concerns."

Do you anticipate that this clarification could materially impact the way that FSANZ approaches applications and proposals and the factors to which they give regard?

No

Additional comments (optional):

No. The Ministerial Policy Statement, which has been in effect for 10 years, already requires FSANZ to consider long-term health. The revised definition would simply reflect those requirements in the Act, where they should be. The inclusion of the definition simply clarifies categorically for external stakeholders FSANZ role and will not change the requirement that they consider long-term health.

We note the Cost Benefit Analysis includes the following as a qualified cost to industry of this reform "There is the risk that clarifying the definition of public health could inadvertently broaden FSANZ's remit in managing public health risks, potentially creating additional administrative burdens in the preparation of applications and creating barriers to trade." When discussing this cost, the IA says it may expand stakeholder expectations and put pressure on FSANZ to consider factors or take on roles outside its scope. We do not agree with this inclusion. We strongly disagree that confirming FSANZ's already legislated role in mitigating public health risks should be considered a cost to any stakeholder and ask that this be removed as a qualified cost.

Recommendation: The Act is amended to include a definition of public health as per the Ministerial Policy Statement on the Interpretation of Public

What would be the impact of clarifying the definition of 'protection of public health and safety' within the Act?

Positive

Additional comments (optional):

Component 2.1.2

Would revising the way FSANZ communicates its consideration of Ministerial Policy Guidance in developing food regulatory measures support greater transparency in the development of food regulatory measures?

Yes

How could the consideration of Ministerial Policy Guidance in the development of food regulatory measures be effectively communicated?

Free text box, no character limit:

Ministerial Policy Guidelines go through processes which already assess them against industry considerations (like those listed in s18(2)(a)-(d)) when they are developed. There is no need for FSANZ to undertake this exercise again when it is making its own determinations.

We strongly suggest that s18(2) of the Act is amended to ensure that FSANZ must make decisions in line with Ministerial Policy Guidelines and that the other items to which FSANZ must have regard, listed in s18(2)(a)-(d), are to be considered only once compliance with Ministerial Policy Guidelines is assured.

Compliance with Ministerial Policy Guidelines should be documented in a report and should clearly demonstrate how the Ministerial Policy Guidance has been complied with and the public health implications of compliance and non-compliance. This information should be publicly available on FSANZ's website.

We note that this would be in line with Best Practice Element 1 as outlined in the IA which states that "the objectives [of the regulator or standard setter] are clear and consistent, and factors considered by standard setters support such objectives". FSANZ objectives are very clear, as set out in s3 of the Act. The factors to be considered by FSANZ, however, do not currently support these objectives as Ministerial Policy Guidance is given the same weight as other considerations (those in s18(2)(a)-(d)).

Recommendation: The Act is amended to ensure Ministerial Guidelines have priority over other matters to which FSANZ must have regard when making decisions (as listed in s18(2)(a)-(d) of the Act).

Component 2.1.3

Would new provisions and/or language changes in the Act better support FSANZ to recognise Indigenous culture and expertise?

Prefer not to respond / I don't know

Free text box, no character limit:

We are supportive of a greater recognition of Indigenous food expertise in the Act and defer to the expertise of Indigenous-led organisations. Aboriginal, Torres Strait Islander and Māori people must be adequately consulted and involved in the changes in the Act provision and language changes, as it relates to their culture and health. We recognise the importance of cultural determinants of health for Aboriginal, Torres Strait Islander and Māori peoples, including the prioritisation of their knowledge and culture led approaches to health and wellbeing.

We note the program of work regarding six concepts to recognise Indigenous culture and expertise is being proposed by FSANZ. It is important for FSANZ to commence the co-design project they have outlined in this program of work (Figure 6) at Tier 3, to guide and support the work outlined in Tier 1 specifically relating to the Act, and in the Tier 2 work. The current level of consultation with Aboriginal, Torres Strait Islander and Māori people and experts, and lack of detail around the examples of new provisions and language changes, leaves us uncertain about the impact that component 2.1.3 will have on better recognising Indigenous culture and expertise.

We note that it is not sufficient to rely on a public submissions process for groups that are small, and have high demands for advice and consultation and specific consultation should be undertaken to ensure that changes in the Act reflect Aboriginal, Torres Strait Islander and Māori ways of being, knowing and doing and are appropriate to the regulation of food as it relates to their culture and health.

Finally, we urge the development and implementation of the Tier 2 and Tier 3 concepts, including through the detailed consultation mentioned above, as these may more meaningfully include and consider Indigenous cultures and expertises.

Recommendation: Specific consultation with Aboriginal, Torres Strait Islander and Māori people and experts needs to be undertaken as a matter of priority to ensure that proposed changes to the Act incorporate Indigenous culture and expertise.

What provisions or language changes could be included in the Act to promote recognition of Indigenous culture and expertise?

Yes

Free text box, no character limit:

We suggest FSANZ consult specifically with Aboriginal, Torres Strait Islander and Māori people and experts, to be guided on possible provisions and language changes that are culturally appropriate, and beneficial to broader promotion of Indigenous culture and knowledge within the food regulatory system. We recommend that the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) and Te Tiriti o Waitangi are referenced directly in the Act, to ensure accountability to the rights of indigenous peoples in the application of the Act. Alignment with the approach taken in Pae Ora (Healthy Futures) Act 2022 as to how to give effect to the principles of The Treaty of Waitangi is supported, but we note that the Māori language version of the Treaty, Te Tiriti o Waitangi, is more appropriate.

Component 2.1

Are there other initiatives that should be considered in Component 2.1?

Yes

Free text box, no character limit:

Clarification of the definition of public health as contemplated in the IA will not in and of itself ensure that the significant gap between the objectives of the Act, and the practical implementation of it in food standards is addressed. It is our view that despite the significant policy development included in ministerial policy statements, decisions of Food Ministers etc, the lack of clear and unambiguous guidance on how to achieve public health outcomes through food standards within the Act is a fundamental limitation.

The introduction of a definition must be accompanied by further guidance on how it should be implemented within the remit of food standards to ensure that the consideration of long-term public health outcomes cascades throughout FSANZ operations.

To ensure this, we strongly suggest that amendments are made to the Act to establish a set of considerations that FSANZ must take into account when setting priorities and when making decisions on proposals, applications, or standard reviews. The purpose of these considerations is to set clear and consistent expectations around how public health benefits and risks should be assessed in developing, reviewing, updating and adopting food standards.

We strongly support the Public Health Test as proposed by The George Institute for Global Health in their submission, as set out below.

The PUBLIC HEALTH TEST

Priority setting should consider:

- a) The burden of disease attributable to the food supply [1];
- b) Estimated benefit of change to the food supply from the work under consideration.

Decisions should:

- a) Discourage the development of foods with low or no nutritional quality, as defined by an appropriate nutrient classification scheme;
- b) Encourage patterns of healthy and sustainable eating, and discourage patterns of unhealthy and unsustainable eating, as defined in the Australian and New Zealand Dietary Guidelines [2];
- c) Reduce the quantity of ingredients and substances within foods that are known risk factors for chronic disease [3];
- d) Assess the impact on the burden of disease attributable to the food system;
- e) Include the benefits of improved public health outcomes and the costs of inaction on public health in any cost benefit analysis;
- f) Assess the cumulative impacts of the introduction of new foods on public health outcomes;
- g) Reduce availability of unhealthy foods targeted at children.

[1] Could be measured by the incidence of diet-related disease in the population and priority populations, as well as through vulnerability assessment of priority populations to diet-related disease.

[2] noting that updates are considering sustainability of the food supply

[3] for example added sugars, sodium and fats (trans fats, saturated fats) and additives with known health risks.

Recommendation: A Public Health Test, or set of considerations, that guides processes and decisions across the food regulatory system is introduced into the Act to set clear and consistent guidelines and expectations for how public health risks and benefits should be taken into consideration.

Component 2.2

Component 2.2.1

Would the introduction of a risk-based framework support FSANZ to be flexible and proportionate in handling of changes to the Food Standards Code?

No

Free text box, no character limit:

The IA provides extremely limited details about the risk-based framework, such that we cannot support this approach. There are both risks and opportunities to the introduction of a risk-based framework, however the IA does not explain exactly how it will be applied, who will make decisions and what appeals mechanisms there will be. The lack of detail means we are unable to support such an approach at this time.

From the information provided, the risk-based framework does not appear to produce an equivalent approach for public health and industry decisions. There is an apparent bias towards food industry/commercially driven decisions being assessed as 'low risk' and public health decisions always being assessed as 'high risk'. This would mean that commercial decisions can be made more quickly, without public scrutiny, including assessment of risk and provision of evidence. Meanwhile, public health related decisions would be open to the influence of commercially driven submissions from industry, require a higher evidentiary burden and take longer. The overall likely outcome of this is to worsen the existing disparity between the approach to public health and industry decisions under the Act, affecting both the time it takes for decisions to be made and the outcomes of those decisions.

Given claims that applications take up only a small fraction of FSANZ's resourcing, any moves to process some applications faster will likely not result in significant improvements to how FSANZ prioritises and resources work on activities to support public health and consumer objectives.

We have real concerns that this approach will negatively impact public health. The above, combined with the misleading conclusion from the Cost Benefit Analysis that all benefits under Option 2 are for public health while all costs are to industry, means we have strong concerns for the potential of a risk-based framework to negatively impact public health. This does not suggest a balanced approach for delivery of FSANZ's stated primary objective of a high standard of public health protection throughout Australia and New Zealand.

Noting our general concerns, if this component is to proceed we strongly support a separate, comprehensive public consultation on the risk-based framework to ensure the concerns for public health are addressed. Specifically, we request further consultation on:

- The risk criteria and assessment matrix
- The organisations whose assessments would be used as basis for minimal assessment approach
- What outcomes would be expected for public health from such an approach

This separate consultation should commence immediately and be developed simultaneously with the FSANZ Act Review.

Recommendation: That the development of the risk-based framework be brought forward so that it can be consulted on in detail, separately and simultaneously, with the FSANZ Act Review.

What criterion and/or evidence should be used to form the basis of a risk framework?

Free text box, no character limit:

The Public Health Test (see our response to the question in relation to other initiatives under component 2.1 for more details). The Public Health Test is the criterion; and then the risk framework should set out how likelihood and consequences will be assessed. The framework should also elaborate on the decision-making process and where the risk assessment will fit within that; delegation for risk assessment decisions; communication and appeals mechanisms.

What would be the impact of introducing a risk-based framework to guide development of food regulatory measures for you?

Prefer not to respond / I don't know

Free text box, no character limit:

The information given is too limited to answer this question. The IA provides extremely limited information about the risk-based framework. There may be both risks and opportunities to the introduction of a risk-based framework, however the lack of detail about how the risk assessment would operate in practice means we are unable to estimate the benefits or risks with any certainty. Please see our response to previous questions for further details.

Component 2.2.2

Would enabling FSANZ to accept risk assessments from international jurisdictions support FSANZ to exercise risk-based and proportionate handling of applications and proposals? How so?

No

Free text box, no character limit:

- There is no assurance that accepting risk assessments from international jurisdictions would ensure standards would be aligned 'up' (to international standards that represent the best outcomes for public health and consumers) rather than 'down'. The IA does not provide assurance that public health considerations and impact has been properly assessed.
- Food standards should only be harmonised with international standards where those standards meet the Public Health Test (see our response to the question in relation to other initiatives under component 2.1 for more details).
- Public health considerations should also be able to be accepted through this mechanism. The apparent bias towards industry decisions being classified as 'low risk' and public health decisions being classified as 'high risk' means that public health decisions would likely fall out of this pathway. There may be examples where evidence from international jurisdictions lead to better public health outcomes- for example improvements to front-of-pack nutrition labelling that have been demonstrated to more appropriately consider health risks, better influence consumers, and improve governance. However there

appears to be no intention to accept risk assessment from international jurisdictions on broad public health measures.

- The IA states that the determinations of 'overseas bodies' could be adopted, we support this for public health-related measures and suggest bodies like the World Health Organization are included. Rigorous, transparent assessments and reporting of real, potential or perceived conflicts of interest of the assessing bodies, actors involved in assessments and the submitted evidence should be undertaken before these can be accepted.
- Should risk assessments be accepted from elsewhere, an additional layer of assessment relating to the Australian and New Zealand context, and particularly impacts on Aboriginal, Torres Strait Islander and Māori people, will be necessary to provide assurances that outcomes of risk assessments are appropriate for our populations, regardless of the technical qualities of those risk assessments

Would enabling (but not compelling) FSANZ to automatically recognise appropriate international standards support more risk-based and proportionate handling of applications and proposals and improve efficiency and effectiveness? How so?

No

Free text box, no character limit:

If a program of harmonisation with international standards proceeds, standards should be harmonised 'up' to international standards that represent the best outcomes for public health and consumers, rather than 'down' to standards that enable unhealthy foods to proliferate further in the marketplace. For this reason, food standards should only be harmonised with international standards where those standards meet the Public Health Test (see our response to the question in relation to other initiatives under component 2.1 for more details). The approach proposed in the IA risks further prioritising commercial decisions at the expense of public health. The assumptions made in Appendix D suggest that public health decisions would be classified as 'high risk' and therefore fall out of potential new pathways to amend food standards.

The types of standards automatically recognised are likely to be things that progress highly processed foods harmful to long-term public health onto the market.

It is also unclear how this would work in practice as 'enabling FSANZ to automatically recognise' remains ambiguous. The pathways described in the IA note that FSANZ would still need to go through some decision-making process and it is unclear what these processes would be. We suggest that a harmonisation program is developed and consulted on that sets out what should be harmonised and why, including consideration of the Public Health Test (see our response to the question in relation to other initiatives under component 2.1 for more details).

Would introducing a minimal check pathway for very low risk products help FSANZ exercise risk-based and proportionate handling of applications and proposals and improve efficiency and effectiveness?

No

Free text box, no character limit:

From the information provided, there appears to be no intention for the minimal check pathway to apply to proposals - only for applications. This risks further prioritising commercial decisions at the potential expense of public health, as risk assessments and evidence will not be open to public scrutiny during consideration of the application (i.e. before decisions are made), undermining the primary objective of the Act to protect public health.

Would introducing principles in legislation to allow FSANZ to create other pathways to amend food standards help FSANZ exercise risk-based and proportionate handling of applications and proposals?

No

Free text box, no character limit:

New pathways would remove public consultation. If FSANZ internal processes assess risk as low, then there is no public consultation step. The assumption is that the internal process would produce the same finding as the current public consultation step. The reform option does not outline how this would be demonstrated or assured. The decreased transparency prior to decision-making, and the removal of the potential for independent, critical oversight of process leading to decisions, remain of substantial concern.

What would be the impact of introducing new pathways to amend food standards for you?

Negative

Free text box, no character limit:

There is no evidence from the IA that any new pathways would apply to broader public health measures.

The assumptions made in Appendix D suggest that public health decisions would be classified as 'high risk' and therefore fall out of potential new pathways to amend food standards. This risks further prioritising commercial decisions at the expense of public health. We note also that there are no mechanisms in the proposed reforms to ensure that any efficiencies delivered result in more resources being directed towards processing public health proposals.

We would require further examination and publication of real (current and previous) applications and proposals against the draft criterion and decisions made to better assess the risk and benefits of this approach.

Are there other opportunities relating to new pathways to amend food standards that should be considered?

No

Free text box, no character limit:

As above, there is no evidence that new pathways to amend food standards would apply to public health measures, rather they currently point to these new pathways only being for commercially driven decisions leading to a greater availability of unhealthy foods on the market.

There are opportunities to improve public health, if consideration is given to expedite public health measures, and the risks of removing public consultation for commercially driven decisions are mitigated with the use of a Public Health Test (see our response to the question in relation to other initiatives under component 2.1 for more details). As noted in our response on other initiatives that should be considered under component 2.2, we also suggest there are statutory timeframes for proposals to ensure they are processed in a timely manner.

Component 2.2.3

Would increasing opportunities for decision making arrangements to be delegated support FSANZ to be more flexible and efficient? How so?

No

Free text box, no character limit:

We do not have enough information regarding the risk framework to support this option at present. Once consultation on the risk framework has been completed and the risk framework is finalised, we would be open to considering delegation arrangements of some low-risk decisions.

What factors should be considered when determining the level of risk for decision-making arrangements?

Free text box, no character limit:

We understand that the risk framework proposed under component 2.2.1 would also be used to determine which decisions could be delegated. As noted in our response on the risk framework, the Public Health Test (see our response to the question in relation to other initiatives under component 2.1 for more details) should be applied to assess risk. This is particularly important when determining the level of risk for decision-making arrangements. Consultation on the risk framework, should include specific questions about risk allocation for the purpose of decision-making delegation. Any new decision-making process should be subject to review after a period of operation.

What would be the impact of streamlining decision-making arrangements for you?

Prefer not to respond / I don't know

Free text box, no character limit:

If the proper consultation processes have been completed and risk has been determined accurately using the Public Health Test (see our response to the question in relation to other initiatives under component 2.1 for more details), then delegation of low-risk decisions could assist in streamlining decision making processes and reduce delays, meanwhile ensuring current processes are followed for decisions that are not low risk.

However, there is not enough information regarding the risk framework at present to identify how streamlining may impact public health.

What expertise should be considered when determining the delegation of decisions to an alternative person?

Free text box, no character limit:

Component 2.2.4

Would a one-off investment of time and resources to develop and publish a list of traditional foods or ingredients that have undergone nutritional and compositional assessments facilitate entry of traditional foods to market?

No

Free text box, no character limit:

We suggest FSANZ consult specifically with Aboriginal, Torres Strait Islander and Māori people and experts to understand what they need and want from the food regulatory system.

However, the purpose and benefit of this proposal remains uncertain, as traditional foods do not fall under the current scope of novel foods (Standard 1.1.2—8) and it can be assumed that any traditional foods that have already passed nutritional and compositional assessments would not be included as prohibited or restricted foods (Schedules 23 and 24). As such, it is unclear whether any other traditional foods would need to pass nutritional and compositional assessments to come to market. As there is no other identified need to interact with the Food Standards Code in the IA (beyond general provisions that apply to all/most foods e.g. labelling), this is unlikely to support increased entry of different traditional foods to market.

It also remains unclear what the extent of this one-off investment of time and resources would involve. As such, this option may be readily available to FSANZ already.

We note that without meaningful consultation there is a real risk of the commercialisation and potential for exploitation of traditional foods by non-Aboriginal, Torres Strait Islander or Māori peoples.

Would the development of further guidance materials on how traditional foods can be assessed for safety facilitate entry of traditional foods to market? How so?

Prefer not to respond / I don't know

Free text box, no character limit:

We suggest FSANZ consult specifically with Aboriginal, Torres Strait Islander and Māori people and experts, to be guided on whether guidance is necessary or how they may be better supported to engage with the food regulatory system more broadly. FSANZ must work with experts to better outline the traditional food assessment process, to ensure it is culturally appropriate and respectful of the food practices and knowledge of Aboriginal, Torres Strait Islander and Māori people. Guidance material that has been appropriately consulted on, co-designed and co-constructed has the potential to ensure that traditional foods can be safely assessed, and not enter the market in a way that is detrimental to Indigenous communities or the broader population. Further examples of the development process for guidance materials are needed, as with the current level of information provided we cannot agree as to whether this suggested development would help facilitate safe entry of traditional food to market. Furthermore, it remains unclear why traditional foods need to be assessed for safety in the first place; according to Standard 1.1.2—8, a “novel food means a non-traditional food that requires an assessment of the public health and safety considerations”, and a “non-traditional food means... a food that does not have a history of human consumption in Australia or New Zealand”.

Component 2.2.5

Would resourcing FSANZ to undertake more timely, holistic and regular reviews of standards allow FSANZ to be more strategic and consistent in changes to food standards?

Yes

Free text box, no character limit:

We suggest the Public Health Test (see our response to the question in relation to other initiatives under component 2.1 for more details) is used to determine which reviews are undertaken and how they are prioritised.

Additional resourcing does not require the adoption of Option 2 and is equally available under the existing Act and operations framework (Option 1). We recommend all components that propose additional funding that does not require significant legislative change be assessed separately, please see our response to the question on methodology.

Are there other initiatives that should be considered to drive more holistic consideration of food standards?

Yes

Free text box, no character limit:

There should be clear criteria outlined for how and when standard reviews will be undertaken. It should be clearly stipulated that both vertical standards (e.g. energy drinks) and horizontal standards (e.g. sugar labelling (i.e. that it flows throughout the Food Standards Code and affects all relevant products)) can be reviewed and reviews should be undertaken to support FSANZ primary objectives as set out in s3 of the Act.

Timelines for standard reviews should be implemented. We recommend a timeframe of 3 years from “decision to prepare” to “notification to FMM” with the potential for a one-year extension to be sought from FMM in exceptional cases where gathering the necessary evidence is taking longer than usual.

The IA proposes that Option 2 will result in up to 8 standard reviews a year but there is no mechanism to ensure this and no framework to govern how this would work in practice. There is also no justification for how FSANZ will be able to do this from a time and resource perspective.

Recommendation: The Act is amended to include statutory timeframes for standard reviews (3 years).

Component 2.2.6

Would the use of Codes of Practice and guidelines better support the implementation of the Food Standards Code and help to address issues that do not warrant the time and resources required to develop or vary a standard?

No

Free text box, no character limit:

FSANZ can already develop guidelines and Codes of Practice - no amendments to the Act are required to enable this. We do not support changes to the process and approval pathway for developing guidelines and Codes of Practice. Guidelines and codes of practice are non-binding and should only deal with matters of interpretation and application.

Can you provide an example of an issue that would have been/be better solved by a Code of Practice or guideline?

Free text box, no character limit:

How could the decision pathway for the development of a Code of Practice or guideline be incorporated into the risk framework outlined in Component 2.2.1?

Free text box, no character limit:

What would be the expected impact if Codes of Practice and guidelines were developed for industry, by industry?

Negative

Free text box, no character limit:

Voluntary, self-regulated, co-regulated and industry-led guidelines and codes of practice have consistently been shown to be ineffective, unenforced and to risk public safety, health and confidence in the food system and we do not support this.

See:

• Ngqangashe, Y., S. Friel, and A. Schram, The regulatory governance conditions that lead to food policies achieving improvements in population nutrition outcomes: a qualitative comparative analysis. *Public Health Nutr*, 2021. 25(5): p. 1-11.

• Ngqangashe, Y., et al., A narrative review of regulatory governance factors that shape food and nutrition policies. *Nutrition Reviews*, 2021. 80(2): p. 200-214.

Component 2.2

Are there other initiatives that should be considered in Component 2.2?

Yes

Free text box, no character limit:

Timeframes for proposals.

The reform options in the IA will not result in more proposals being progressed; the summary of Option 2 of Section 6 of the IA notes the FSANZ will continue to “deliver three proposals per year”. In addition, the reform options in the IA do not ensure that proposals are processed in a more timely manner.

We strongly recommend that statutory timeframes for proposals are introduced into the Act. We acknowledge that proposals are broader, more complex and require more nuanced consultation than applications, but this should not result in proposals extending over many years. Currently there is a wide range of completion times for proposals, with an average completion time of 3.5 years. We recommend a stipulated timeframe for completing proposals to create an incentive and a more balanced approach to progressing these important reforms. This should allow sufficient time for FSANZ to identify, and if necessary, generate, evidence to support decision-making, particularly if new or other resources can be dedicated to this and/or other sources of data and expertise can be drawn upon.

We recommend a timeframe of 3 years from “decision to prepare” to “notification to FMM” with the potential for a one-year extension to be sought from FMM in exceptional cases where gathering the necessary evidence is taking longer than usual.

Recommendation: The Act is amended to include statutory timeframes for proposals (3 years).

Component 2.3

Component 2.3.1

Would amending the compositional requirements of the FSANZ Board increase flexibility and reflect contemporary governance processes?

Yes

Free text box, no character limit:

We support the addition of additional skills that would support good governance and oversight of the Act as per the recommendations of the 2014 review, noting that the requirements for expertise (as currently set out in the Act) must be retained.

In relation to the suggestion that expertise in Aboriginal, Torres Strait Islander and Māori food and culture could be added to these additional skills we note that for adequate Aboriginal, Torres Strait Islander and Māori representation on the FSANZ Board specific positions for Aboriginal, Torres Strait Islander and Māori people should be created. This will help to increase knowledge of Indigenous food and culture within the FSANZ Board (as is Tier 1 in Figure 6), by ensuring that decisions that impact Aboriginal, Torres Strait Islander and Māori people, are being made by members of their communities. This amendment will aid the board in adequately achieving contemporary governance processes, allowing decisions to match the intent of the Act as it relates to Indigenous knowledge and culture. It is not appropriate for board members to be deemed knowledgeable on cultural matters when they themselves are non-Indigenous.

Would amending the nomination process for the FSANZ Board to be an open market process increase efficiency and support a better board skill mix?

No

Free text box, no character limit:

We do not support changing the current nomination process to an open market one. As stated, we strongly oppose any decision that may reduce the number of public health positions on the board. Not only would an open market process risk reducing public health positions on the board, but an open market process might also reduce the quality of public health nominees. That is, particularly given that there are no details as to what such a process would look like, there is a real risk that former industry representatives with health backgrounds may qualify. By keeping the nomination abilities among public health organisations, this issue can easily be avoided. This helps ensure management of real/perceived conflicts of interest.

Component 2.3.2

What would be the expected impact of removing the option for applications to be expedited?

Positive

Free text box, no character limit:

Expedited applications pose a real risk of regulatory capture and a pathway for larger industry actors to have their applications processed ahead of the queue, particularly smaller businesses. Removing expedited pathways would ensure there is a level playing field for all those making applications.

Recommendation: The Act is amended to remove the expedited applications process.

Component 2.3.3

What would be the expected impact of the implementation of an industry-wide levy?

Positive

Free text box, no character limit:

We note that funding is a key issue for FSANZ. An industry wide levy will provide a reliable source of known funding for FSANZ on an ongoing basis. It would also result in a level playing field for industry who receive vast benefits from FSANZ work as outlined in the IA in the discussion on component 2.3.3.

Recommendation: The Act is amended to implement an industry wide levy.

How could eligibility criteria for a levy be set so that it is fair, consistent and feasible to administer?

Free text box, no character limit:

We support that this levy should only be applied to the largest food businesses, and we support the top 5000 as suggested in the IA.

What do you think could be an acceptable range for a levy rate? Please provide your response in Australian Dollars.

Free text box, no character limit:

What would be the expected impact of compulsory fees for all applications?

Negative

Free text box, no character limit:

Compulsory fees will not result in a level playing field for all of industry and will result in the risk of industry capture. Compulsory fees are also not as financially sound as an industry wide levy for resourcing FSANZ.

We do not think there should be any option to expedite applications under any fee structure – this favours big businesses and puts small businesses at a distinct disadvantage.

Are there specific entrepreneurial activities that FSANZ should be considering charging for to build up a more sustainable funding base?

No

Free text box, no character limit:

We do not support cost recovery from industry initiated entrepreneurial activities. We note that Best Practice Element 3 of the IA highlights that cost recovered services frequently represent a minority funding stream for standard-setters and we support that this is appropriate to ensure FSANZ is independent. Furthermore, it is also not FSANZ's role to assist with entrepreneurial activities.

Component 2.3.4

Would imposing a food recall coordination levy imposition contribute to a more sustainable funding base and support FSANZ to rebalance its workload priorities by addressing resourcing pressures? How so?

Prefer not to respond / I don't know

Free text box, no character limit:

How could eligibility criteria for a levy be set so that it is fair, consistent and feasible to administer?

Free text box, no character limit:

Would charging jurisdictions to add additional proposal or project work to FSANZ's workplan meaningfully support FSANZ to rebalance its workload priorities by addressing resourcing pressures? How so?

Prefer not to respond / I don't know

Free text box, no character limit:

What would be the expected impact of imposing a food recall coordination levy on jurisdictions?

Prefer not to respond / I don't know

Free text box, no character limit:

How would this need to be implemented to be successful?

Free text box, no character limit:

Would it be better to charge a levy per recall, or an annual levy?

Not Answered

Free text box, no character limit:

What would be the expected impact of charging jurisdictions a fee to add additional proposal work to FSANZ's workplan?

Negative

Free text box, no character limit:

How would this need to be implemented to be successful?

Free text box, no character limit:

Component 2.3

Are there other initiatives that should be considered in Component 2.3?

Prefer not to respond / I don't know

Free text box, no character limit:

Component 2.4

Component 2.4.1

Would establishing mechanisms to enable FSANZ and FMM to undertake periodic joint agenda setting lead to a shared vision of system priorities?

Prefer not to respond / I don't know

How would this need to be implemented to be successful?

Free text box, no character limit:

We support FSANZ working with Food Ministers to set a joint agenda and strategic direction for the food regulatory system but note that this already occurs. FSANZ attends the FMM and there is a standing agenda item to discuss FSANZ workload and priorities. This mechanism is all already in place and available to FSANZ under Option 1.

What factors should be considered as part of the joint prioritisation matrix?

Free text box, no character limit:

The Public Health Test (see our response to the question in relation to other initiatives under component 2.1 for more details) should be used to guide the prioritisation of all FSANZ work, as public health remains the priority objective of the Act.

In what ways could FSANZ and FMM work together in a more coordinated way?

Free text box, no character limit:

As noted, priority setting between FSANZ and FMM is already a standing agenda item. Provided FSANZ are doing regular standard reviews as core work and progressing proposals efficiently, and are resourced to perform these essential tasks, this should be sufficient.

Component 2.4.2

Would more routine engagement between FSANZ and the FRSC reduce duplication of effort and missed opportunities to manage risk? How so?

Yes

Free text box, no character limit:

FSANZ already meets regularly with jurisdictions at the FSANZ jurisdictional forum and attends the FRSC policy development working group meetings, this should be continued. These mechanisms are all already in place and available to FSANZ under Option 1 and any enhancement of them is available under both options.

What approaches could be used to improve collaboration between FSANZ, the FRSC, and the FMM?

Free text box, no character limit:

FSANZ needs to be better resourced to ensure it can undertake its core functions, including regular standard reviews and efficient processing of proposals. This may relieve the need for FRSC and FMM to direct FSANZ work to ensure the Food Standards Code is up to date and reflects changes in the market.

Component 2.4.3

Would FSANZ assuming a role as a database custodian for Australia meaningfully improve intelligence sharing across the regulatory system? How so?

Yes

Free text box, no character limit:

We support this and strongly encourage that this database be publicly available. We note data linkage and sharing with Australian Bureau of Statistics and Australian Institute of Health and Welfare should be ensured.

What types of data would be most useful for FSANZ to curate?

Free text box, no character limit:

Collection of data is critical to monitor the work of the food regulatory system and the overall impact of nutrition on public health outcomes. Data can help in identifying priorities, the development of policy options and the evaluation of implementation. Importantly, consumption data will be critical in the assessment of proposals and applications, especially in ensuring public health is addressed. It is essential to driving better health outcomes for Australians and New Zealanders.

We recommend the development of a routine and comprehensive nutrition monitoring and surveillance system in both Australia and New Zealand. In New Zealand, a food consumption survey should be included as part of the regular Health survey conducted by the Ministry of Health.

Data that should be collected and curated includes data on:

- Food supply including composition
- Sales data
- Dietary intake (consumption data)
- Nutrition related health outcomes, as they relate to broader burden of disease.

The George Institute has significant expertise and experience in collecting, processing, analysing and preparing for public dissemination a range of

relevant data, and we suggest that any future efforts in this area be informed through dedicated engagement with us and other experts.

We further note that concerns with the coverage, reliability and accessibility of the food composition database used for the Five Year Review of the Health Star Rating system prompted a recommendation, subsequently supported by Food Ministers, to develop a comprehensive database of branded food products that could be publicly reported. We remain concerned with the progress of FSANZ's Branded Food Database, the close involvement of food industry and exclusion of public health and consumer stakeholders in its development and implementation, and more generally with the strong potential for coverage, reliability and accessibility to not be assured.

Component 2.4.4

Would establishing information sharing arrangements with international partners reduce duplication of effort and missed opportunities to manage risk?

Yes

Free text box, no character limit:

What should be the focus of such information sharing arrangements?

Free text box, no character limit:

The information sharing should only form part of the initial background research required during standard development. Information sharing for this purpose is acceptable practice and differs greatly to the earlier questions regarding enabling FSANZ to automatically recognise appropriate international standards (which we oppose). Consideration for the Australia and New Zealand context is also required.

Component 2.4.5

Would introducing Statements of Intent into food standards meaningfully improve consistent interpretation and enforcement of food standards? How so?

Prefer not to respond / I don't know

Free text box, no character limit:

What should a Statement of Intent include to benefit industry and enforcement agencies to understand and consistently apply food standards?

Free text box, no character limit:

Component 2.4.6

Would FSANZ being resourced to develop, update and maintain industry guidelines improve consistent interpretation and enforcement of food standards? How so?

Prefer not to respond / I don't know

Free text box, no character limit:

There may be some benefit in FSANZ being able to provide additional interpretive guidance to industry.

Would amending the Act to allow FSANZ to develop guidelines in consultation with First Nations or Māori peoples support cultural considerations being taken into account in the food standards process?

Yes

Free text box, no character limit:

We support the amendment of the Act to ensure Aboriginal, Torres Strait Islander and Māori peoples are properly consulted on FSANZ work, with the creation of consultation guidelines. Food expertise of Aboriginal, Torres Strait Islander and Māori peoples should be recognised, and we support a broader consideration of the impact of the food regulatory system, and of individual food regulatory measures, on Aboriginal, Torres Strait Islander and Māori peoples. Consultation is imperative to ensuring the food regulatory system is inclusive of diverse needs of the community, as it relates to nutrition, culture, food security, and public health.

To date this consultation has not been sufficient in reviewing the Act with Indigenous perspectives in mind. We recommend a deeper consultation process with Aboriginal, Torres Strait Islander and Māori groups to determine their specific requirements and that FSANZ considers co-developing culturally tailored compliance guidelines. This process will require a significant investment in time and resources to develop relationships with the most appropriate Aboriginal, Torres Strait Islander and Māori stakeholders.

Component 2.4.7

Would FSANZ collaborating with jurisdictional enforcement agencies improve inconsistent interpretation and enforcement of food standards?

Yes

Free text box, no character limit:

Yes, we support enhanced collaboration between FSANZ and jurisdictional enforcement agencies. Particularly if it leads to improved enforcement of standards that promote better public health outcomes.

Component 2.4

Are there other initiatives that should be considered in Component 2.4?

No

Free text box, no character limit:

Section 6 - Net Benefit

Section 6 - Net Benefit (Option 1)

Are there other costs and benefits that have not yet been qualified or quantified?

Yes

Free text box, no character limit:

The Australian Government Guide to Regulatory Impact Analysis (2020) requires that data sources and methods used to calculate regulatory compliance burden are transparent, that any gaps or limitations in the data are discussed, and that assumptions are disclosed. We do not consider that the cost benefit analysis, as set out in the IA, meets those requirements. Inputs and assumptions that are provided independent of commercial conflicts of interest and are verifiable must be detailed. In particular, we note that the evidentiary basis for certain assigned costs and benefits to industry appears to be considerably less transparent and rigorous than that applied to the assessment of public health impacts.

The quantified outcomes of cost benefit analyses are likely to be influential to the perspectives of stakeholder groups, and particularly when results are presented to decision-makers. However, we have considerable concerns with the inclusions/exclusions, inputs and assumptions feeding into the current cost benefit analysis, as well as the framing and presentation of results. Given this, as well as our feedback on proposed reform components above, we do not consider that the outcomes of or conclusions drawn from the cost benefit analysis, as presented in the IA, can reliably be presented to decision-makers.

The current approach to the cost benefit analysis and framing of the options precludes an appropriate consideration of the relative costs and benefits associated with each component and for each stakeholder group. This is important given the actual outcomes reforms may lead to, and the purposes of the costs and benefits implicated, are diverse; the costs to public good of private benefits from measures to improve commercial outcomes, in terms of diet-related burden of disease and associated impacts on health, social and economic systems, may be considerable, and governments must be advised of these differential impacts to appropriately consider the implications. Widespread public health impacts and isolated, individual business impacts are not equal and should not be treated in the same way.

Finally, we note the summary statement that "Option 1 maintains high costs to industry and FSANZ to achieve public health benefits". We consider this an acceptable and valid outcome for government, given the potential threat to population health posed by the alternatives proposed.

We provide detailed feedback below. Without addressing these items, there is a significant risk that confidence in these analyses and their implications and uses will continue to be undermined.

Common to cost benefit analyses of both Option 1 and Option 2:

- Assumptions, inputs and the data and evidence underpinning them must be more clearly detailed with regard to both quantified and qualified costs and benefits.
- All benefits that are listed as quantified must report explicit figures, to facilitate assessment.
- What is meant by "public health benefits" should be clearly articulated, and short-term and long-term public health impacts should be distinguished.
- The impacts on diet-related burden of disease and associated health, social and economic effects of proposals, standards reviews and applications must be separately considered and quantified, including by stakeholder group (particularly consumers and governments). The IA notes this was "a broad generalisation given the diversity of proposals and applications processed by FSANZ"; this must be adequately explored and detailed.
- The analysis of public health impact must acknowledge harm from food regulatory system actions and activities, both actual (e.g. approved components/products or other permissions which have the potential to cause harm) or delayed (e.g. the lengthy period for development and implementation of folic acid fortification, iodine fortification and alcohol pregnancy warning labels), as well as any possible public health-based actions not undertaken by the food regulatory system (e.g. rigorous and mandatory compositional limits).
- It is inappropriate to suggest that all FSANZ's work has benefits to public health when applications are typically made for commercial reasons, standards reviews are inadequately described in the IA (i.e. there is no rationale stipulated for the assumption that each standard review results in a public health benefit), and some proposals may adversely affect health outcomes (e.g. proposed explicit permission to display added sugar and carbohydrate claims on alcohol, which has been identified by FSANZ as having the potential to mislead consumers, may lead to increased alcohol consumption and thus harm).

- Proposals and standards reviews must be separated in analysis and reporting as they may have different effects. We note with concern that under Option 2 “increase in public health benefits is generated from more standard reviews while continuing to deliver three proposals per year”, given the claimed benefits from freeing/increasing resources to focus on proposals.
- It is assumed that resourcing limitations are preventing FSANZ from completing proposals in a timely way; however it is likely that the contentious nature of some proposals is also a significant factor, and this should be reported in the analyses.
- We note that the current figure applied for public health benefit is derived from an 14-year old outcome and is extremely limited and speculative besides. This proxy used to quantify public health impact may therefore not be appropriate. An alternative proxy measure with quantifiable public gains could be used (e.g. decreased consumption of alcohol by pregnant women and impact on alcohol-related harms).
- A unit cost/benefit from applications and from standards reviews also need to be distinctly set out, with the rationale detailed.
- It is difficult to agree that the food industry derives no quantifiable benefits from the current (and continuing) features of the food regulatory system, particularly as applications are typically made for commercial reasons.
- Claimed delay costs to industry must be better evidenced; “Sourced from industry consultations” is insufficient.
- The assumption that delay costs to industry from processing applications are passed on to consumers must be better tested, as there is no apparent reason to assume quicker resolution of applications would result in lower prices to consumers.
- New products introduced as a result of approved applications detract from sales and therefore revenue of other, existing products; a new product, regardless of whether it is required to be assessed by FSANZ or not, does not add to total demand for food.
- There are quantifiable benefits to FSANZ and governments more broadly of FSANZ’s work regarding food safety and public health; it is difficult to agree that governments derive no quantifiable benefits from the current (and continuing) features of the food regulatory system.
- The assumptions underpinning Aboriginal, Torres Strait Islander and Māori food industry value add are “Based on current industry growth projections”. That is, these projections are explicitly based on the current food regulatory system, and not the recently proposed reformed food regulatory system. Therefore, these benefits should be noted under Option 1. Any other potential impacts on this sector from proposed reforms are not mentioned. The sensitivity analysis is also insufficiently detailed to assist with evaluation of the impact of the assumed growth rate.
- It remains unclear whether and to what extent activities listed as currently occurring under Option 1 (Table 12), other than an increase to the number of standards reviews, would continue under Option 2. It is also unclear what “a subset of [FSANZ’s] functions” refers to, and what functions are missing from Table 12.
- Extra funding independent of any proposed reforms is assumed for Option 2, without basis. This must also be included for Option 1, or removed entirely.
- A qualified cost to FSANZ, governments and the food industry must be a lack of confidence in the healthiness of the food supply.

Specific to cost benefit analysis of Option 1:

- In Appendix C, Option 1 assumptions, it is noted that only “3 proposals and reviews per year” are included in the analysis for Option 1 yet Table 12 specifies 3 proposals and 1 standard review are conducted per year.
- The potential for products/components to be approved by the Australian and New Zealand food regulatory system, and then exported elsewhere, must be explored as a benefit.
- Public health benefits would be better described as a quantified benefit to consumers. This may have been incorrectly titled as a quantified cost.
- A cost to consumers is stated as “Reduced consumption on food items due to increased costs from cost recovery initiatives”. Given the small number of applications approved each year this is very unlikely to meaningfully affect consumption on a population or even individual level, given the considerable range of options in the current food supply.

Recommendation: The Cost Benefit Analysis must appropriately reflect public health costs and benefits and the design, conduct, analysis and interpretation must be redone to achieve this.

What are the growth expectations of the First Nations and Māori food sector?

Free text box, no character limit:

We do not have expertise in this area. We strongly recommend consultation with peak bodies for Aboriginal and Torres Strait Islander and Māori peoples. Please note our concerns with the inconsistent application of benefits from this item, as above; current growth expectations are based on the current regulatory system therefore are a benefit from the current regulatory system.

What are the current delay costs to industry?

Free text box, no character limit:

We do not consider it appropriate for delayed revenue to a for-profit industry making commercial decisions to be considered at the equivalent level to real burden of disease and health, social and economic system costs borne by governments and consumers. In addition, it would be reasonable to assume that industry should factor in the maximum timeframe of regulatory approvals when considering costs i.e. there should not be a need to consider delay costs.

As noted above, more transparency and detail about delay costs should be provided. It remains unclear whether industry costs presented in the cost benefit analysis are lost potential costs or lost real costs, i.e. lost potential revenue from a not yet developed product or lost revenue from a developed and ready for market product which is unable to be transferred to market and sold.

The amount specified as the delay costs to industry are based on costs provided by the industry. Given the lack of detail provided, this is not independent or verifiable and we recommend that independent data is used and applied to real world applications

Do you have any additional data that would be useful in characterising the costs and benefits of current regulatory settings?

Yes

Free text box, no character limit:

Data and expertise are available across Australia and New Zealand to support a Cost Benefit Analysis that appropriately reflects the costs and benefits to public health, particularly amongst public health and consumer groups. We recommend a significant effort be dedicated to identifying and engaging with these experts and organisations. Previous efforts to engage with relevant stakeholders have been demonstrably inadequate or entirely lacking. Public health organisations have offered expertise several times but these offers have not been taken up.

Any other comments regarding the Option 1 information in the Net Benefit section?

No

Free text box, no character limit:

Section 6 - Net Benefit (Option 2)

Are there other costs and benefits for different stakeholders that have not yet been qualified? What are they?

Yes

Free text box, no character limit:

The Australian Government Guide to Regulatory Impact Analysis (2020) requires that data sources and methods used to calculate regulatory compliance burden are transparent, that any gaps or limitations in the data are discussed, and that assumptions are disclosed. We do not consider that the cost benefit analysis, as set out in the IA, meets those requirements. Inputs and assumptions that are provided independent of commercial conflicts of interest and are verifiable must be detailed. In particular, we note that the evidentiary basis for certain assigned costs and benefits to industry appears to be considerably less transparent and rigorous than that applied to the assessment of public health impacts.

The quantified outcomes of cost benefit analyses are likely to be influential to the perspectives of stakeholder groups, and particularly when results are presented to decision-makers. However, we have considerable concerns with the inclusions/exclusions, inputs and assumptions feeding into the current cost benefit analysis, as well as the framing and presentation of results. Given this, as well as our feedback on proposed reform components above, we do not consider that the outcomes of or conclusions drawn from the cost benefit analysis, as presented in the IA, can reliably be presented to decision-makers.

The current approach to the cost benefit analysis and framing of the options precludes an appropriate consideration of the relative costs and benefits associated with each component and for each stakeholder group. This is important given the actual outcomes reforms may lead to, and the purposes of the costs and benefits implicated, are diverse; the costs to public good of private benefits from measures to improve commercial outcomes, in terms of diet-related burden of disease and associated impacts on health, social and economic systems, may be considerable, and governments must be advised of these differential impacts to appropriately consider the implications. Widespread public health impacts and isolated, individual business impacts are not equal and should not be treated in the same way.

Finally, we note the summary statement that “Option 1 maintains high costs to industry and FSANZ to achieve public health benefits”. We consider this an acceptable and valid outcome for government, given the potential threat to population health posed by the alternatives proposed.

We provide detailed feedback below. Without addressing these items, there is a significant risk that confidence in these analyses and their implications and uses will continue to be undermined.

Common to cost benefit analyses of both Option 1 and Option 2:

- Assumptions, inputs and the data and evidence underpinning them must be more clearly detailed with regard to both quantified and qualified costs and benefits.
- All benefits that are listed as quantified must report explicit figures, to facilitate assessment.
- What is meant by “public health benefits” should be clearly articulated, and short-term and long-term public health impacts should be distinguished.
- The impacts on diet-related burden of disease and associated health, social and economic effects of proposals, standards reviews and applications must be separately considered and quantified, including by stakeholder group (particularly consumers and governments). The IA notes this was “a broad generalisation given the diversity of proposals and applications processed by FSANZ”; this must be adequately explored and detailed.
- The analysis of public health impact must acknowledge harm from food regulatory system actions and activities, both actual (e.g. approved components/products or other permissions which have the potential to cause harm) or delayed (e.g. the lengthy period for development and implementation of folic acid fortification, iodine fortification and alcohol pregnancy warning labels), as well as any possible public health-based actions not undertaken by the food regulatory system (e.g. rigorous and mandatory compositional limits).
- It is inappropriate to suggest that all FSANZ’s work has benefits to public health when applications are typically made for commercial reasons, standards reviews are inadequately described in the IA (i.e. there is no rationale stipulated for the assumption that each standard review results in a public health benefit), and some proposals may adversely affect health outcomes (e.g. proposed explicit permission to display added sugar and carbohydrate claims on alcohol, which has been identified by FSANZ as having the potential to mislead consumers, may lead to increased alcohol consumption and thus harm).
- Proposals and standards reviews must be separated in analysis and reporting as they may have different effects. We note with concern that under Option 2 “increase in public health benefits is generated from more standard reviews while continuing to deliver three proposals per year”, given the claimed benefits from freeing/increasing resources to focus on proposals.
- It is assumed that resourcing limitations are preventing FSANZ from completing proposals in a timely way; however it is likely that the contentious nature of some proposals is also a significant factor, and this should be reported in the analyses.

- We note that the current figure applied for public health benefit is derived from an 14-year old outcome and is extremely limited and speculative besides. This proxy used to quantify public health impact may therefore not be appropriate. An alternative proxy measure with quantifiable public gains could be used (e.g. decreased consumption of alcohol by pregnant women and impact on alcohol-related harms).
- A unit cost/benefit from applications and from standards reviews also need to be distinctly set out, with the rationale detailed.
- It is difficult to agree that the food industry derives no quantifiable benefits from the current (and continuing) features of the food regulatory system, particularly as applications are typically made for commercial reasons.
- Claimed delay costs to industry must be better evidenced; "Sourced from industry consultations" is insufficient.
- The assumption that delay costs to industry from processing applications are passed on to consumers must be better tested, as there is no apparent reason to assume quicker resolution of applications would result in lower prices to consumers.
- New products introduced as a result of approved applications detract from sales and therefore revenue of other, existing products; a new product, regardless of whether it is required to be assessed by FSANZ or not, does not add to total demand for food.
- There are quantifiable benefits to FSANZ and governments more broadly of FSANZ's work regarding food safety and public health; it is difficult to agree that governments derive no quantifiable benefits from the current (and continuing) features of the food regulatory system.
- The assumptions underpinning Aboriginal, Torres Strait Islander and Māori food industry value add are "Based on current industry growth projections". That is, these projections are explicitly based on the current food regulatory system, and not the recently proposed reformed food regulatory system. Therefore, these benefits should be noted under Option 1. Any other potential impacts on this sector from proposed reforms are not mentioned. The sensitivity analysis is also insufficiently detailed to assist with evaluation of the impact of the assumed growth rate.
- It remains unclear whether and to what extent activities listed as currently occurring under Option 1 (Table 12), other than an increase to the number of standards reviews, would continue under Option 2. It is also unclear what "a subset of [FSANZ's] functions" refers to, and what functions are missing from Table 12.
- Extra funding independent of any proposed reforms is assumed for Option 2, without basis. This must also be included for Option 1, or removed entirely.
- A qualified cost to FSANZ, governments and the food industry must be a lack of confidence in the healthiness of the food supply.

Specific to cost benefit analysis of Option 2:

- It is unclear how quantified benefits for consumers and FSANZ are related and costed. For consumers, a quantified benefit is listed as: "As reforming standard-setting enables FSANZ to process more proposals and reviews, the associated public health benefit increases, the associated public health benefit increases, extrapolating to an additional AUD \$10.7 million (NZD \$11.4 million) in public health benefits per year". For FSANZ, quantified benefits include: "As streamlined standard-setting processes free up capacity and as FSANZ is resourced to undertake more reviews of standards, the number of proposals/reviews processed per year is estimated to increase by eight" and "An increase in FSANZ resourcing to support the development and implementation of all its components will create more sustainable funding arrangements for FSANZ to deliver public health benefits". These outcomes appear to be overlapping or at least very similar. Explicit clarification, including of how these differ and are separately counted, will be extremely important given how this would affect outcomes of the cost benefit analysis. It is also indicated that the number of proposals is not expected to increase. It is difficult to see therefore how the uplift in resources will make any improvement to the number or timeliness of proposals.
- The risk assessment applied in the assumptions for Option 2 must be detailed, and it should be clearly noted that this may or may not be relevant to outcomes of the actual risk framework implemented. We suggest that one example from "an application" to determine changes to processing time is insufficient for its assumption and broad application.
- The number of assumed proposals and standards reviews must be clearly distinguished, given the lack of clarity around what standards reviews may involve and the in-text note that it is anticipated only 3 proposals will continue to be completed each year. "As streamlined standard-setting processes free up capacity and as FSANZ is resourced to undertake more reviews of standards, the number of proposals/reviews processed per year is estimated to increase by eight" is unclear.
- As noted previously, we disagree that "There is the risk that clarifying the definition of public health could inadvertently broaden FSANZ's remit in managing public health risks", given the IA and FSANZ already acknowledge this role, and that it should be considered a cost to industry; the implication of this assumption is that FSANZ's actual, existing role to manage public health risks is a threat to the food industry.
- For reasons previously noted, a "risk-based approach" increases the risk of harm by introducing a less rigorous approach with fewer controls, and this is also noted in section 8 of the IA. It cannot improve public health as assumed in this cost benefit analysis. This risk and cost to consumers, FSANZ and governments must be quantified.
- As discussed previously, there are no mechanisms to ensure that "reforming standard-setting enables FSANZ to process more proposals and reviews", and the detail provided does not support this assertion. As such it is inappropriate to assume and incorporate increased public health benefits from this measure, also noting other concerns with relevant assumptions and inputs.
- The two points under "Unchanged benefits compared to Option 1" for quantified benefits for industry are listed as qualified benefits for industry in the cost benefit analysis for Option 1.
- As noted previously, it is inappropriate to assume additional funding independent of any proposed reforms; this must be excluded as it is equally valid for Option 1.
- The assumptions or evidence underpinning the claimed cost to industry "Removing paid applications may mean that industry can no longer reliably predict when they may take a product to market. This could increase costs associated with product development, inventory management, and marketing campaigns. An unpredictable timeline might also deter potential international food companies from operating in Australia" must be provided. Industry and international food companies will still be able to reliably predict when they may take a product to market, but they will simply no longer be able to expedite it. Any associated costs with product development, inventory management and marketing campaigns can be adequately managed as this is still refers to known, maximum timeframes. As such this should not be considered a cost to industry.

Recommendation: The Cost Benefit Analysis must appropriately reflect public health costs and benefits and the design, conduct, analysis and interpretation must be redone to achieve this.

Do you have any additional data that would be useful to characterising the costs and benefits of proposed initiatives?

Yes

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Data and expertise are available across Australia and New Zealand to support a Cost Benefit Analysis that appropriately reflects the costs and benefits to public health, particularly amongst public health and consumer groups. We recommend a significant effort be dedicated to identifying and engaging with these experts and organisations. Previous efforts to engage with relevant stakeholders have been demonstrably inadequate or entirely lacking. Public health organisations have offered expertise several times but these offers have not been taken up.

Any other comments regarding the Option 2 information in the Net Benefit section?

Yes

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We note that the combined impact of the proposals is, according to the current cost benefit analysis in the IA, to significantly increase costs for governments and consumers for no to relatively little benefit to those stakeholders, respectively, while halving costs and greatly increasing benefits for the food industry. This also significantly alters the Benefits Cost Ratio for each stakeholder group. According to Table 14 and 16:

- FSANZ – costs will increase by ~\$35m (+27%) and benefits will increase by ~\$112m (+503%). Benefits Cost Ratio increases from 0.17 to 0.80, from Option 1 to Option 2, a 4.8 fold increase.
- Other government – costs will increase by ~\$44m (+291%) and there are no benefits under either Option 1 or Option 2. Benefits Cost Ratio cannot be calculated.
- Industry – costs will decrease by ~\$35m (-54%) and benefits will increase by ~\$116m (from no benefits under Option 1). Benefits Cost Ratio under Option 2 calculated as 3.97.
- Consumers – costs will increase by ~\$68m (+944%) and benefits will increase by ~\$83m (+40%). Benefits Cost Ratio decreases from 28.64 to 3.84, from Option 1 to Option 2, a 7.5 fold decrease.
- Overall – costs will increase by ~\$112m (+51%) and benefits will increase by ~\$310m (+136%). Benefits Cost Ratio increases from 1.05 to 1.63, from Option 1 to Option 2, a 1.6 fold increase.

However, these are entirely predicated on the current inputs and assumptions. As noted above, we remain extremely concerned about these, particularly with regard to inclusions and exclusions and where inconsistencies may have been introduced. For instance, the extra costs to public health necessarily introduced by a framework that increases risk of harm would significantly alter these calculations; this is most concerning given the cost benefit analysis states that public health represents the main driver of benefits under Option 2. In addition, it is inappropriate to assume additional government funding for FSANZ independent of any reforms and to include this only in the analysis for Option 2, when the rationale for this and the reasons why this cannot be added to the analysis for Option 1 are unclear; this will obviously distort results.

We also remain concerned with the potential impact of unrealised but assumed benefits to FSANZ. That is, if FSANZ do not receive increased funding (from whatever source, as is stated to be required) and staff (as is stated to be required), it will continue to not be able to meet its current legislated objectives and functions and/or any new objectives and functions.

Section 8 - Best option and implementation

Section 8 - Best option and implementation (Solving policy problems)

Does the approach to assessing the degree to which an option solves a policy problem make sense? How so?

No

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The IA presents two options as available for consideration – Option 1 being to ‘retain the status quo’ with no changes to the Act or to FSANZ’s operations, and Option 2 being to ‘modernise regulatory settings’ by adopting the entire package of reforms. Presenting the options as polarised in this way creates an artificial distinction between Options 1 and 2. Problems are characterised as features of Option 1, with Option 2 framed as a package of solutions, even though many of the identified problems could be addressed without changing the Act or operational framework. Presenting the reforms as two distinct ‘all or nothing’ options does not accurately reflect the changes that genuinely require significant legislative and operational reform, and those that require changes to FSANZ’s resourcing, strategic direction and prioritisation. The approach taken presents a conclusion of overall significant benefit to Option 2, even though it is acknowledged that not all components of Option 2 may ultimately proceed, and some benefits could apply equally under Option 1.

Our responses on the best option and implementation reflect this, specifically:

- Criterion 1 of the methodology (extent to which the options and their components solve policy problems) has no application at all for Option 1 because Option 1 proposes no changes to current arrangements. This zero rating for each policy problem under Option 1 weights the solution strongly in favour of Option 2 with no real basis. In addition, the subjective assessment of whether Option 2 solves the policy problems has resulted in an inappropriately high total score for Option 2 under criterion 1.
- Many of the reforms suggested under Option 2 would already be available to FSANZ under the status quo and should therefore not receive a positive rating where they are considered for Option 2 (see our response below for more details).

Is the rating assigned to each of the sub-problems appropriate? If not, why?

No

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We note that the negative impact rating of policy problem 1 is inconsistent in the IA, with both a rating of 3 (high) and 2 (moderate) noted on page 89 of the IA. We refer to our response in Part 3 above and note that we support a negative impact rating of 3 (high) for policy problem 1.

Option 2 is given a rating of 3 - majority resolution - for solving Policy Problem 1. We would argue that the rating should be 0 (not-at-all) or 1(low) at best. Sub-problem 1, Policy Problem 1

Option1: Option 1 could address Policy Problem 1- the confusion about how FSANZ should consider short-and long-term risks to health when developing is one that sits with stakeholders not FSANZ itself - the FSANZ Board have confirmed FSANZ role in long-term health risks. FSANZ simply needs to communicate this better and has the ability to do so under Option 1. As such this sub-problem has no negative impact.

Option 2: As above. Whilst the inclusion of a definition may address the unclear definition issue of this sub-component the more important element of this sub-component is 'how' FSANZ should consider short- and long-term risks to health when developing standards. There has been no attempt in Option 2 to include mechanisms for how FSANZ is to do this nor to separate out how FSANZ considers these risks. We would consider there is no resolution of this element of the policy problem.

Sub-problem 2, Policy Problem 1

The solution presented in the IA for the confusion about the factors to which FSANZ has given regard in its decision making is simply communication - this is equally available to FSANZ under Options 1 and 2 and therefore each option should have an equal rating for this sub-problem. There is no resolution of this policy problem under each option as no reforms are proposed.

Sub-problem 3, Policy Problem 1

The proposed changes merely add language into the Act in relation to Aboriginal, Torres Strait Islander and Māori Peoples, much like language already exists in relation to 'public health' and we do not consider that sufficient and genuine engagement and consultation has been conducted with Aboriginal, Torres Strait Islander and Māori Peoples to ensure that these changes are in the best interests of those groups. These words, do not in and of themselves result in commitment of government to Aboriginal, Torres Strait Islander and Māori Peoples, and respect for their culture and knowledge. We would consider this a minimal resolution of this policy problem, if any. Acting on the Tier 2 and Tier 3 solutions would make a meaningful difference and we strongly suggest these are included at this stage of the reforms.

Option 2 is given a rating of 2.5 - moderate-high resolution - for solving Policy Problem 2. We would argue that the rating should be 1 (low) at best.

Sub-problem 2 - we do not consider that Option 2 provides any reforms that actually remove barriers for Indigenous foods to be brought to market, it simply is the creation of a list of 'safe' traditional foods. These foods don't need any interaction with the novel foods provisions of the FSC and therefore the relevant importance and impact is limited. As such there is no resolution of this sub-problem in Option 2 and that ratings given to Options 1 and 2 should be the same.

Sub-problem 3 - Option 2 does not 'require' FSANZ to do any holistic reviews at all so there is no resolution of this sub-problem. Increased resourcing under Option 1 could equally have the same impact on holistic reviews and Options 1 and 2 should therefore be rated the same.

Sub-problem 4 - FSANZ already has the capacity to develop guidelines and codes of practice and as there is no suggestion that FSANZ is required to do these under Option 2 it provides no more resolution of this policy problem than Option 1. As such Options 1 and 2 should be rated the same.

Option 2 is given a rating of 2.5 - moderate-high resolution - for solving Policy Problem 3. We would argue that the rating should be 1.5-2 (moderate).

Sub-problem 1 - whilst the addition of additional skills will benefit FSANZ, open market nominations would not result in better, more efficient, effective decision making and we would therefore not rate this sub-problem as completely resolved.

Sub-problem 2 - decreases in funding could be resolved under both Options by changes to substantive funding arrangements to FSANZ. Under Option 2 cost recovery mechanisms could be used to address some of the deficit, this could partially resolve this sub-problem.

Option 2 is given a rating of 2.5 - moderate-high resolution - for solving Policy Problem 4 and Option 1 is given a 0 - no resolution. We would argue that the rating should be the same for both options as the proposals under all three sub-problems for Options 1 are operational and FSANZ has the ability to undertake them under current arrangements. As such both Options 1 and 2 resolve this sub-problem equally and should have the same rating.

Section 8 - Best option and implementation (Delivery risks)

Do you think the delivery risks have been appropriately identified and categorised within the Impact Analysis?

No

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- Bundling components for reform into themes does not enable accurate assessment of the risks with each component. We strongly recommend that each component is assessed separately. This is particularly important as not all components will necessarily be implemented, it is imperative that the risks of each component are clear so that the combined impact of components that are taken forward can be accurately assessed.
- Confusion around the public health objective and poor management of risk related to long-term health should be considered as separate risks and not bundled together.
- Both the risk-framework and new pathways have potential to impact short-term health outcomes (food safety) and long-term health outcomes, this must be specified and the risk for each assessed separately.
- Without a requirement to dedicate resources to proposals (e.g. through legislated timeframes) there is no guarantee that FSANZ resources will be used

to progress these, this has not been factored in as a risk itself, nor into the assessment of related risks.

- Without a requirement to dedicate resources to standard reviews (e.g. through legislated timeframes) there is no guarantee FSANZ resources will be used to progress these, this has not been factored in as a risk itself, nor into the assessment of related risks.
- Reallocation of resources and new sources of funding are insufficient to adequately support FSANZ's organisational capacity to manage its current workload and address and manage risks relating to long-term health impacts in a timely manner. This should be clearly identified as a risk under both Options 1 and 2.

Are the delivery risk ratings assigned to each of the sub-problems appropriate?

No

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The IA summarises that Option 1 was deemed on average much riskier than Option 2. As noted previously, it is inappropriate to report all proposed reforms under Option 2 as one package, given some, all or none of these components may be introduced and many of them do not require changes to the Act. The individual impacts of each component will be important to consider.

We suggest that this section is reassessed according to our recommendations below:

In section 8.2.2 it is stated that the consequences of the risks of unsafe food or introducing higher risk to population health (i.e. unhealthy food) is major (consequence rating of 1). We strongly support this rating and note that we do not consider any other risks identified as consequential as these, i.e. no other consequences, particularly those which only potentially impact a small number of businesses that are required to interact with the applications process each year, should receive a rating of 1 (major) as they are not on the same scale of harm.

The risks and impacts of businesses not entering the market or bringing products to market should not be overstated. This does not reflect the market in which vast numbers of products enter the market each year and only a very small percentage of them require approval via applications through FSANZ.

We note that many of the risks noted under Option 1 can be addressed under the status quo, i.e. without legislative changes, and Option 2 doesn't necessarily resolve those risks while opening other, more consequential risks - there needs to be equal consideration of this when assessing risks under each option.

Theme: purpose and objectives

Option 1

- Identified risk: Confusion around the objectives and scope of FSANZ will perpetuate, meaning that risks relating to public health and safety – particularly long-term health – are not well managed.

Consequences of “confusion” should be rated as minimal (3), given it is acknowledged that FSANZ “should already” and is “already empowered” to consider long-term health impacts. Likelihood for stakeholder confusion only remains high if FSANZ does not communicate effectively, which could be rectified under Option 1. Nothing proposed under Option 2 will better support FSANZ's ability to consider risks to long-term health, in fact many of the proposed reforms will remove oversight and actually work to heighten risk. As such the likelihood is negligible (3).

- Identified risk: The FSANZ Act remains out of step with contemporary expectations and obligations to recognise Indigenous culture and expertise.

Consequences and likelihood are actually both minimal (3), given the limited engagement with Act by stakeholders and the public. Terminology in Food Standards Code could be updated to recognise Indigenous culture and expertise through routine Food Standards Code management at any time. Nothing proposed under Option 2 to address this.

Option 2

- Identified risk: Alignment of definitions could inadvertently widen the scope for FSANZ and its role in managing public health risks.

Consequences and likelihood of “clarification” are both minimal (3), given it is acknowledged that FSANZ “should already” and is “already empowered” to consider long-term health impacts. We strongly disagree that confirming FSANZ's already legislated role in mitigating public health risks should be considered a risk. The hypothesised impacts noted are extremely speculative and not supported by evidence.

- Identified risk: Improving visibility of First Nations and Māori culture and expertise could draw attention to the lack of focus on other population groups.

We agree that the consequences of this risk are minimal and the likelihood not high, however it is entirely inappropriate to suggest that appropriate, if nominal, recognition of Aboriginal, Torres Strait Islander and Māori culture and expertise would exclude the broader population, particularly when almost all indicators relevant to the food regulatory system are worse amongst Aboriginal, Torres Strait Islander and Māori people.

Theme: reformed standard-setting

Option 1

- Identified risk: FSANZ's organisational capacity will continue to be used in a way that does not make best use of its expertise, as proposals and applications will continue to be processed in a manner agnostic to risk

We do not support the risk rating of major for this risk and recommend this is rated 2 (moderate). We support that the likelihood rating but note that the risk of this continuing under Option 2 remains high as it is not resolved by any of the reforms presented in the IA as there are no mechanisms proposed

to ensure the FSANZ better uses its expertise.

- Identified risk: Ongoing capacity constraints will reinforce an effective focus on processing applications, at the expense of proposals and other high-value work

We disagree that the consequence is high given applications only use a minor portion of FSANZ resources. As such, reallocation of those resources is unlikely to meaningfully affect progress on other work, especially when no mechanisms require focus on other work. The consequence and likelihood should therefore be rated as minimal/unlikely (3). This risk is not addressed in Option 2.

- Identified risk: Australia and New Zealand will continue to be markets that international food companies choose not to enter, given the high regulatory burden associated with amending food standards - particularly where safety has been established elsewhere.

No evidence has been presented that international food companies are choosing not to enter the ANZ market due to regulatory burden. Overwhelmingly products do not need to lodge applications to be introduced into the ANZ market so any impact of international food companies not entering the market as a result of this is limited in any event. Consequences and likelihood should both be rated minimal (3). Other hypothesised impacts noted are extremely speculative and not supported by evidence.

Option 2

- Identified risk: Applying a risk framework to guide process and decision-making may lead to unsafe foods entering the market.

We agree that any potential harm from this risk is massive and support the rating of major (1) for this risk. We strongly disagree however that the likelihood of this is moderately likely-unlikely (2.5). The likelihood of risk due to less oversight and scrutiny under the proposed risk-framework is necessarily heightened. Routine assessments of the effectiveness of the risk framework are not proposed in the reforms, and will not necessarily be effective in mitigating the risk posed by this reform, as acknowledged in the IA itself. As such the likelihood rating should be high (1).

- Identified risk: Establishing new pathways to amend foods standards could reduce the level of oversight and scrutiny of products in the pre-market phase, introducing higher risk to population health and safety.

We agree that any potential harm from this risk is large and support the rating of major (1) for this risk. We strongly disagree however that the likelihood of this is moderately likely (2). The likelihood of risk due to less oversight and scrutiny under the proposed new pathways is necessarily heightened. The IA does not provide any information on how comparable standard-setting bodies would be 'carefully selected' and as such we do not agree that this risk can be managed well based on information provided. As such the likelihood rating should be high (1).

- Identified risk: Less direct oversight of food standards by the FMM and FSANZ Board would reduce scrutiny and diminish oversight and accountability over the standard setting system.

We strongly disagree that the consequence of this is only moderate-minimum (2.5), this has the potential to undermine public confidence in the food regulatory system. This should be considered a risk of major consequence (1). We support a likelihood rating of 2.

- Identified risk: Increased use of Codes of Practice and guidelines could create enforcement obligations for jurisdictions to which Ministers have not agreed,

We support the risk rating for this risk.

Theme: efficient and effective operations

Option 1

- Identified risk: Nomination and appointment processes would continue to be relatively laborious endeavours and perpetuate the risk that the Board will not have the necessary skills to provide effective governance

We disagree that the consequence of this is moderate (2), it is minor (3). It is also not very likely (rating 3 rather than current 1) given current scope and flexibility for appointments.

- Identified risk: FSANZ will continue to focus on only a subset of its statutory duties, effectively creating gaps in the regulatory system where risks and opportunities are not managed as well as they could be.

We strongly disagree that the consequence of this risk is major (1) and that the likelihood of its occurrence is very likely (1) given applications only use a minor portion of FSANZ resources. As such, reallocation of those resources is unlikely to meaningfully affect progress on other work, especially when no mechanisms require focus on other work. This risk is not addressed in Option 2. The consequence and likelihood are both minimal (3).

Option 2

- Identified risk: The Board could be less efficient and well equipped to consider sectoral interests under new nomination arrangements

We support the risk rating for this risk.

- Identified risk: Expanded cost recovery mechanisms borne by industry could create new barriers to entry for businesses seeking to vary food standards, reducing accessibility of the scheme

Cost recovery methods do not inhibit engagement with FSANZ. We note the CBA analysis assumes any costs would be passed on to consumers, as such the consequence of this should be low (3 not 2) and the likelihood unlikely (3 not 2). Overwhelmingly products do not need to lodge applications to be introduced into the ANZ market so any impact of cost recovery mechanisms linked to applications is limited in any event.

- Identified risk: Application of a levy on select industry participants could contribute to financial stress in a sector that is already feeling overwhelmed.

We strongly disagree that the consequence of this should be comparable to unsafe foods entering the market or the introduction of higher risk (i.e. unhealthy food) to population health, as there is no risk of harm to population health. We recommend the consequence rating should be 3 (not 1). The IA only proposes a levy on large organisations, hence the likelihood of this risk is unlikely (3).

- Identified risk: An industry-wide levy could contribute to regulatory capture

Any cost recovery mechanism risks regulatory capture, not just a levy, so this is a risk for all cost recovery mechanisms proposed in the IA. Cost recovery mechanisms that expedite applications (as under Option 1) are much more risky, as are paid applications as a whole (as under Option 2) as this only benefits big food who can afford to regularly participate in the application process. As such, the consequence and likelihood of this reform should be considered as moderate (2) at most.

- Identified risk: Imposing a food recall coordination levy could increase the risk of non-engagement with FSANZ by jurisdictional enforcement agencies, resulting in less well managed foodborne risks

We do not agree that the consequence of this is major and this risk should be rated (2-3), food recall is currently managed more than adequately and any indication that there is a serious widespread incident will be acted on immediately. We also think this risk is unlikely (3) as no jurisdiction will allow harm to come to people, industry and government from inaction.

Theme: improving system agility

Option 1

- Identified risk: Efforts to align policy and regulatory work across the system will continue to be frustrated

We support the rating for this risk but note that all reforms proposed under Option 2 to address this are available to FSANZ under Option 1 also as they are operational in nature. The likelihood for stakeholder confusion only remains high if FSANZ and FMM/FRSC continue to not communicate priorities and needs effectively.

- Identified risk: Inconsistencies in interpretation and enforcement will continue to be an issue, particularly for Australian businesses and enforcement agencies, generating undue regulatory burden

Consequences and likelihood demonstrably minor given cross-country penetration of products/companies and necessary jurisdictional-based approach to enforcement. We note that reforms proposed under Option 2 to address this are available to FSANZ under Option 1 also as they are operational in nature. We propose ratings of consequence (3), likelihood (2).

Option 2

- Identified risk: Greater collaboration across the system could put at risk FSANZ's independence, if not done well

Collaboration across the system is already being undertaken with adequate checks and balances. The reforms proposed under Option 2 are available to FSANZ under Option 1. As such we suggest a likelihood rating of 1 as this collaboration is sure to continue.

- Identified risk: Systematising data collection and curation of databases work could actually create perverse incentives for data custodians to share their data

The consequence of this would not be dissimilar to current arrangements and we suggest a rating of 3. This is very likely however and should have a likelihood rating of 1 - this has been demonstrated by slow progress on combining jurisdictional databases and slow uptake of Branded Food Database and HSR 5 year review.

Section 9 - Evaluation of the preferred option

Are there any other factors that should be captured in a future evaluation?

Yes

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The impact on the burden of disease of any proposals, as well as associated costs to individuals, governments and the economy, will be critical to understand. However, this must be rigorously assessed; significant expertise is available across Australia and New Zealand to support this.

As noted throughout this submission, the costs, benefits, impacts and risks of components must be assessed individually and reported by stakeholder group individually to facilitate an appropriate consideration of the relative merits of each component.

Other comments

Is there anything else you want to share with us on the Impact Analysis?

Yes

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Resourcing of FSANZ

The IA is clear that FSANZ is insufficiently resourced and that it must be adequately resourced to deliver on its current legislated responsibilities, in addition to any new functions proposed in the reform options.

The IA clearly sets out that FSANZ operating budget has declined in real terms and that over 90% of this comes from government funding. Governments should be adequately funding FSANZ to perform its functions, regardless of any changes to the FSANZ Act itself. We strongly suggest that one of the key enablers for FSANZ is a commitment from all governments to better fund FSANZ to undertake its functions, which could be undertaken under the status quo. We acknowledge that this is out of scope for the FSANZ Act Review and support the suggestion that FSANZ's substantive funding arrangements should be considered as part of the broader work in relation to the joint food standards system. Noting that it is out of scope, but also available under the status quo, it is inappropriate to assume additional core funding for FSANZ under Option 2 in the IA.

Inclusion of sustainability in the act

To achieve FSANZ purpose of long-term health outcomes for Australians and New Zealanders, the Act must ensure a food regulatory system that is healthy, sustainable and secure. There is a clear and urgent need to reorient the food regulatory system to safeguard food security for all people living in Australia and New Zealand. The Review of the Act provides an opportune moment to address the gap in legislative and regulatory frameworks that safeguard food security, and to respond to the climate change policy landscape in Australia and New Zealand which have made international commitments to food security (see UAE declaration on sustainable agriculture, resilient food systems, and climate action COP28 Declaration on Food and Agriculture).

Expanding the objectives of the Act in Section 3, 13 and introducing a related provision in Section 18(2), would give clear responsibility for FSANZ to promote food security. Such a change would enable FSANZ to consider issues that promote or threaten sustainability (particularly as it relates to food security) in its deliberations about food regulatory measures.

Public health support for this approach was provided throughout earlier stages of the Review. Since this time, Australia's policy landscape has changed, with clear commitment from the Commonwealth Government to address food security in the face of climate change. The release of the National Health and Climate Strategy (see: National Health and Climate Strategy | Australian Government Department of Health and Aged Care) clearly demonstrates this with Actions that address food security (Ref Actions 3.1, 3.3, 3.5, 3.6, 3.7, 3.8, 4.15, 4.16, 4.3, 5.3, 5.4, 6.6, 6.7 and 7.5). Many of these Actions must have the support of the food regulatory system to be realised. The next iteration of the Australian Dietary Guidelines will include a focus on sustainability. New Zealand has a Climate Change Response (Zero Carbon) Amendment Act 2019 that provides a framework by which New Zealand can develop and implement clear and stable climate change policies.

Currently there is a lack of interdisciplinary collaboration and engagement between environmental science, agricultural science, health and nutrition science in the pursuit of an evidence base to underpin food system policy in Australia and New Zealand. There is a great need for this to occur, and quickly. Food policy involves several government departments and agencies, each with a different perspective on the issue. These bodies must work collaboratively to implement the significant changes needed to move toward a sustainable food system required to support the health of Australia and New Zealand.

FSANZ's role in the food supply

We note that the IA fails to highlight FSANZ's role in improving and shaping the food supply. We recognise that FSANZ is only one mechanism within the food regulatory system for this, but it is an important one. The potential impact of FSANZ making full impact assessments that adequately explore public health effects on a regular basis, and its ability to shape product formulation and labelling across the available food supply, has a scale of impact on diet-related diseases that most other mechanisms do not. This is a 30-year opportunity to ensure FSANZ's role in improving the food supply and the resulting public health outcomes. However, taken together, the combined impact of the reforms in Option 2 of the IA will further compromise the capacity of FSANZ to meet its two legislated, priority objectives – to protect public health and safety, and to support consumers to make informed choices.

Representation of public health and consumer stakeholder voice

We note that the IA does not accurately or adequately represent public health and consumer organisations' feedback and suggestions from previous consultations in the 'Summary of stakeholder feedback' section. More significantly, this has not been reflected in the policy problems and solutions proposed in the IA.

Public health and consumer stakeholders were clear in their feedback in previous consultations that the reform options (then presented under options 2

and 3 of the Draft Regulatory Impact Statement) would not enable, and would in fact further undermine, FSANZ's ability to meet its two legislated, priority objectives – to protect public health and safety, and to support consumers to make informed choices. At that time public health and consumer submissions noted:

- that whilst the status quo is a negative outcome it is better than options 2 and 3 (16/19 (84%) public health organisations and 3/3 (100%) consumer organisations)
- the policy problem of the FSANZ Act not meeting its primary goal of public health, specifically in relation to long-term health and preventable diet related disease (in addition to other policy problems) was missing from the analysis (18/19 (95%) public health organisations and 1/3 (33%) of consumer organisations).

The public health community's perspectives on FSANZ operations, FSANZ's role in the food supply and the FSANZ Act Review have, since the first public consultation in 2020, been consistently communicated but are not reflected in the IA.

We do not agree with all the characterisations of the feedback the public health and consumer community has provided over the past three and a half years of this Review as presented in section 7. We also disagree with the statement made in section 7.1 of the IA, that “the IA has evolved significantly. Characterisation of the problems to solve, and the options to solve these has changed dramatically since the RIS was published for consultation in 2021” and suggest that the fundamental approaches, principles, proposals and intended outcomes remain largely the same. We remain concerned that the combined impact of the reforms proposed under Option 2 will negatively impact the health and wellbeing of Australians and New Zealanders.

The IA represents a further development of some of the reforms previously proposed under options 2 and 3 of the Draft Regulatory Impact Statement, however with no additional reforms to protect and promote public health and consumer interests. Our submission proposes measures that will safeguard public health and consumer interests, and we strongly recommend that these are reflected in the next steps for reform.

Privacy and Confidentiality

Do you want this submission to be treated as confidential?

No.

If you want all or parts of this submission to be confidential, please state which parts and why.

Free text box, no character limit: