

SUBMISSION

Tuesday, 9 April 2024

AMA Submission to Review of the Food Standards Australia New Zealand Act 1991- Impact Analysis

Submitted via survey: fsanzactreview@health.gov.au

Introduction

The AMA is pleased to make a submission into the Review of the Food Standards Australia New Zealand Act 1991 Impact Analysis.

The FSANZ Act Review commenced in July 2020, and is a comprehensive examination of the effectiveness of the FSANZ Act and the associated operations and responsibilities of Food Standards Australia New Zealand (FSANZ). The FSANZ Act is Australian legislation and underpins the Australia New Zealand Joint Food Regulatory System within which New Zealand participates as a partner under the bilateral Food Treaty.

Previously, the AMA has engaged with the review of the FSANZ Act, in a [submission](#) to the draft Regulatory Impact Statement in 2021, and subsequent consultation sessions with the consultancy firm engaged in the review, and the Australian Department of Health and Aged Care.

Through this work, the FSANZ Act Review has now identified 27 concepts across four themes for further investigation. These concepts have been consolidated into 20 components in the Impact Analysis due to alignment of several concepts and for easier analysis. The Impact Analysis outlines the cumulative costs and benefits of these components. Each of the 20 components are being considered individually, and it is expected that the final proposal considered by Food Ministers will be a combination of different components within the four themes. The overall cost benefit will depend on components considered.

Section 3 - The problems to solve (Methodology)

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

The Executive Summary of the Impact Analysis (IA) states that "The joint Australia-New-Zealand food standards system has an excellent reputation for safety, which also underpins the industry's economic prosperity" - given this, the main purpose of this review is unclear. The AMA believes that the main concern with the current system is that consumers are not effectively protected from long-term health impacts and preventable diet-related diseases. 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 AMA remains 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, the updates have not been well documented. The AMA is concerned that little detail has been made available to explain processes, inputs and assumptions underpinning problem identification and prioritisation to stakeholders more broadly.

The current methodology is 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).

Current methodology as it relates to policy problem 1 and 2

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, the AMA believes 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 the AMA proposes 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.

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 to the survey will reflect this, noting that many reform elements presented by the IA as part of Option 2, are similarly available under Option 1.

The AMA does not agree that Options 1 and 2 should be considered two independent options. Instead, there is considerable overlap between them as many of the problems highlighted under the status quo could be addressed without making significant legislative and operational reforms. Where this is the case, we ask that these elements are considered available under Option 1, and that the modelling and cost-benefit analysis reflects this. For example, any increased funding proposed under

Option 2 that does not require legislative change could also be applied under Option 1, and the benefit of this should be assessed independently.

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

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 (as well as other food shocks, such as experienced with COVID-19) via the 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 unique opportunity to play an important role in ensuring Australia and New Zealand's national and international climate 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, The AMA believes that FSANZ can be an effective agency to respond to the regulatory needs that food security requires.

Section 3 - The problems to solve (Ratings)

The questions on this page refer to the ratings listed in the Impact Analysis from page 30.

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

- Yes**
- No**
- Prefer not to respond/ I don't know**

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

The AMA recommends that 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 preferred 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.

The AMA strongly disagrees that the highest impact rating should be allocated to sub-problems that:

- impact on a very small number of businesses making applications to FSANZ (Policy Problem 2, sub-problem 1); or
- those food safety risks which are currently extremely well managed, suggesting less need for reform (Policy Problem 4, sub-problem 3),

As is currently proposed in the IA, these sub-problems are not of the same magnitude as widespread risks to long-term health. Therefore they should not have equivalent or higher impact ratings than sub-problems dealing with long-term health impacts.

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.

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. The AMA also recommends 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.

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.

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

The AMA supports the rating of moderate magnitude (2) for this policy problem.

Section 5 - Options for reform

Component 2.1

Component 2.1 relates to the *Purpose and objectives of FSANZ*. This section contains questions for Components 2.1.1 to 2.1.3 on pages 49 to 50.

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**
- No**
- Prefer not to respond/ I don't know**

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.

The AMA is concerned that missing from the IA and the reform options is 'how' public health and safety will be better addressed. Simply adding a definition will not reduce confusion about the processes that FSANZ will use to consider long-term risks to health when developing food standards. The AMA strongly recommends 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).

The AMA also recommends 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.

The AMA supports 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, **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?

- Yes**
- No**
- Prefer not to respond/ I don't know**

No, the AMA does not believe this clarification will materially impact the work of FSANZ. 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.

The AMA notes 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. The AMA does not agree with this inclusion. The AMA strongly disagrees 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.

The AMA recommends that The Act is amended to include a definition of public health as per the Ministerial Policy Statement on the Interpretation of Public Health and Safety in Developing, Reviewing and Varying Food Regulatory Measures, with the addition of diet-related risk factors.

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

- Positive**
- Neutral**
- Negative**
- Prefer not to respond/ I don’t know**

The AMA believes that legislative clarity about FSANZ role in long-term risks to health when developing food standards would be positive.

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**
- No**
- Prefer not to respond/ I don’t know**

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

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.

The AMA strongly suggests 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.

The AMA notes 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)).

The AMA recommends that 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?

- **Yes**
- **No**
- **Prefer not to respond/ I don't know**

The AMA is supportive of a greater recognition of Indigenous food expertise in the Act and defer to the expertise of Indigenous-led organisations. 1.3) 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 First Nations and Māori peoples, including the prioritisation of their knowledge and culture led approaches to health and wellbeing.

The AMA notes 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 First Nations 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.

The AMA notes 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 First Nations and Māori ways of being, knowing and doing and are appropriate to the regulation of food as it relates to their culture and health.

The AMA recommends that specific consultation with First Nations 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?

The AMA suggests that FSANZ consult specifically with First Nations 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. The AMA recommends 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**
- No**
- Prefer not to respond/ I don't know**

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 FSANZ 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, the AMA strongly suggests 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.

The AMA strongly supports 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.

The AMA also wishes to specifically mention the importance of recognising the impact that work of FSANZ has on children’s health. Nutrition affects human health, via epigenetic modifications, from conception, children are a particularly vulnerable group and deserve protection. Children deserve special consideration in relation to assessment of long-term benefits and risks to health when developing food standards. It should be a requirement that the impact of all food regulatory measures on children be considered, as the United Nations suggests under the Convention on the Rights of the Child, especially as it relates to the right to a healthy food environment (see: <https://www.unicef.org/media/96101/file/Protecting-Childrens-Right-Healthy-Food-Environment.pdf>).

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?

- Yes
- No
- Prefer not to respond/ I don’t know

The information given is too limited to support such an approach, given we cannot definitively answer this question, as the IA provides extremely limited details about the risk-based framework. 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 the AMA 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.

The AMA has 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.

The AMA would strongly support a separate consultation on the risk-based framework to ensure the concerns for public health are addressed. Specifically, we want 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.

The AMA recommends 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?

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.

The AMA suggests that the impact of food regulations on children be a specific criterion to be considered in a risk framework. Children should be explicitly considered in relation to assessment of long-term benefits and risks to health when developing food standards, due to the preventive ability of food regulations early in life, having the ability to impact the life-long health outcomes of Australian and New Zealand populations.

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

- **Yes**
- **No**
- **Prefer not to respond/ I don't know**

The information given is too limited to answer this question. The IA provides extremely limited information about the risk-based framework. The AMA thinks there are 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 the previous question 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?

- Yes
- No
- Prefer not to respond/ I don't know

- 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, the AMA supports this for public health measures and suggest non-conflicted bodies like the World Health Organization are included.

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?

- Yes
- No
- Prefer not to respond/ I don't know

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. What does 'enabling FSANZ to automatically recognise' mean? 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. The AMA suggests 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?

- Yes
- No
- Prefer not to respond/ I don't know

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?

- Yes
- No
- Prefer not to respond/ I don't know

The AMA believes that allowing FSANZ to create 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.

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

- Positive
- Neutral
- Negative
- Prefer not to respond/ I don't know

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. The AMA wishes to 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.

The AMA, and public health and consumer representatives, 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?

- Yes
- No
- Prefer not to respond/ I don't know

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, the AMA 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?

- Yes
- No
- Prefer not to respond/ I don't know

The AMA does 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?

The AMA 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?

- Positive
- Neutral

- **Negative**
- **Prefer not to respond/ I don't know**

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.

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?

- **Yes**
- **No**
- **Prefer not to respond/ I don't know**

The AMA suggests FSANZ consult specifically with First Nations and Māori people and experts to understand what they need and want from the food regulatory system.

The AMA notes that without meaningful consultation there is a real risk of the commercialisation and potential for exploitation of traditional foods by non-First Nations and non-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?

- **Yes**
- **No**
- **Prefer not to respond/ I don't know**

The AMA suggests FSANZ consult specifically with First Nations 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 First Nations 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.

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**
- No**
- Prefer not to respond/ I don't know**

The AMA suggests 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). The AMA recommends that 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**
- No**
- Prefer not to respond/ I don't know**

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. The AMA recommends 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.

The AMA recommends that 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?

- Yes**
- No**
- Prefer not to respond/ I don't know**

FSANZ can already develop guidelines and Codes of Practice - no amendments to the Act are required to enable this. The AMA does 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.

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

- Positive**
- Neutral**
- Negative**
- Prefer not to respond/ I don't know**

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 the AMA does 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**
- No**
- Prefer not to respond/ I don't know**

The AMA suggests that timeframes for proposals should be considered in component 2.2.

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 timelier manner.

The AMA strongly recommends 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. The AMA recommends 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.

The AMA recommends 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.

Component 2.3

Component 2.3 relates to *Efficient and Effective operations*. This section contains questions for Components 2.3.1 to 2.3.4 on pages 57 to 62.

Component 2.3.1

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

- Yes**
- No**
- Prefer not to respond/ I don't know**

The AMA supports 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 First Nations and Māori food and culture could be added to these additional skills we note that for adequate First Nations and Māori representation on the FSANZ Board specific positions for First Nations 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 First Nations 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?

- Yes**
- No**
- Prefer not to respond/ I don't know**

The AMA does 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**
- Neutral**

- **Negative**
- **Prefer not to respond/ I don't know**

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.

The AMA recommends that 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**
- **Neutral**
- **Negative**
- **Prefer not to respond/ I don't know**

The AMA notes 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. The AMA recommends that 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?

The AMA supports that this levy should only be applied to the largest food businesses, and supports the top 5000 as suggested in the IA.

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

- **Positive**
- **Neutral**
- **Negative**
- **Prefer not to respond/ I don't know**

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.

The AMA does 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?

- **Yes**
- **No**
- **Prefer not to respond/ I don't know**

The AMA does 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 2.4

Component 2.4 relates to *Improving system agility*. This section contains questions for Components 2.4.1 to 2.4.7 on pages 62 to 66.

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?

- Yes
- No
- Prefer not to respond/ I don't know

How would this need to be implemented to be successful?

The AMA supports 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?

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?

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
- No
- Prefer not to respond/ I don't know

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?

FSANZ needs to be better resourced to ensure it can undertake its core functions, including regular standard reviews and efficient processing of proposals. This would 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 as it would already have been done.

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**
- No**
- Prefer not to respond/ I don't know**

The AMA supports this and strongly encourage that this database be publicly available. Data linkage and sharing with Australian Bureau of Statistics and Australian Institute of Health and Welfare should be ensured as a step of maintaining this database.

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

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.

The AMA recommends 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.

Component 2.4.4

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

- Yes**
- No**
- Prefer not to respond/ I don't know**

The AMA supports the sharing of information to support the development of the Food Standards Code.

What should be the focus of such information sharing arrangements?

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 the AMA opposes. 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?

- Yes**
- No**
- Prefer not to respond/ I don't know**

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?

- Yes**
- No**
- Prefer not to respond/ I don't know**

There is 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**
- No**
- Prefer not to respond/ I don't know**

The AMA supports the amendment of the Act to ensure First Nations and Māori peoples are properly consulted on FSANZ work, with the creation of consultation guidelines. Food expertise of First Nations 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 First Nations 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. The AMA recommends a deeper consultation process with First Nations 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 First Nations and Māori stakeholders.

Component 2.4.7

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

- Yes**
- No**
- Prefer not to respond/ I don't know**

The AMA is supportive 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?

- Yes**
- No**
- Prefer not to respond/ I don't know**

Section 6 - Net Benefit

This section refers to questions in *Section 6 - Net benefit* within the Impact Analysis, commencing on page 68.

Section 6 - Net Benefit (Option 1)

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

- Yes**
- No**
- Prefer not to respond/ I don't know**

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 Cost Benefit Analysis reflect this, noting that many reform elements presented by the IA as part of Option 2, are similarly available under Option 1.

The costs and benefits to consumers and governments need to be more specific and detailed and the assumptions clearly articulated. The AMA strongly suggest that the Cost Benefit Analysis include:

- Costs and benefits for all impacted stakeholders (industry, consumers, and governments) for each of type of FSANZ work separately (i.e. costs and benefits to consumers from applications,

costs, and benefits to consumers from proposals and costs and benefits to consumers from standards reviews) - these are not equal and should not be treated in the same way.

- The Cost Benefit Analysis should clearly state what is meant by 'public health benefits', is this a decrease in non-communicable disease rates, reduced body mass index, based on dietary patterns (a mixture of these things)? Separate definitions of short-term public health benefits and long-term public health benefits should be set out.
- Short (primarily safety) and long-term (chronic disease) benefits should be separately noted for each element of the Cost Benefit Analysis, for both consumers/governments.
- Health, healthcare system and associated social and economic impacts should all be quantified clearly for both costs and benefit for both consumers and governments.

The AMA recommends that 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?

The AMA does not have expertise in this area. We strongly recommend consultation with peak bodies for Aboriginal and Torres Strait Islander, and Māori peoples.

What are the current delay costs to industry?

The AMA does not consider it reasonable for delayed profits to a for profit industry to be considered at the equivalent level to real health system costs borne by governments and consumers.

The Cost Benefit Analysis notes that there are delay costs to industry due to the inefficient processing of both applications and proposals.

In relation to proposals: we are not aware of any delay costs to industry as a result of the timing of proposals and the IA does not note any. Any delay costs as a result of proposal timing should be clearly set out, detailed and quantified.

In relation to applications: more specificity and detail about delay costs should be provided. Are the industry costs presented in the Cost Benefit Analysis 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?

In respect of the amount specified as the delay costs to industry these are based on costs provided by the processed food industry, this is not independent or verifiable and we recommend that independent economic data is used that is applied to real world figures. The AMA note the requirement in the Australian Government Guide to Regulatory Impact Analysis (2020) that data sources and calculation methods used to calculate regulatory compliance burden must be transparent and that any gaps or limitations in the data are discussed and that assumptions are disclosed. The AMA does not consider that the delay costs noted in the Cost Benefit Analysis currently meet that requirement.

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

- Yes
- No

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. The AMA recommends a significant effort be dedicated to identifying and engaging with these experts and organisations.

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**
- No**
- Prefer not to respond/ I don't know**

The costs and benefits to consumers and governments need to be more specific and detailed and the assumptions clearly articulated. The AMA strongly suggests that the Cost Benefit Analysis include:

- Costs and benefits for all impacted stakeholders (industry, consumers, and governments) for each of type of FSANZ work separately (i.e. costs and benefits to consumers from applications, costs, and benefits to consumers from proposals and costs and benefits to consumers from standards reviews) - these are not equal and should not be treated in the same way.
- The Cost Benefit Analysis should clearly state what is meant by 'public health benefits', is this a decrease in non-communicable disease rates, reduced body mass index, based on dietary patterns (a mixture of these things)? Separate definitions of short-term public health benefits and long-term public health benefits should be set out.
- Short (safety) and long-term (chronic disease) benefits should be separately noted for each element of the Cost Benefit Analysis, for both consumers and governments.
- Health, healthcare system and associated social and economic impacts should all be quantified clearly for both costs and benefit for both consumers and governments.
- The Cost Benefit Analysis should clearly articulate how a 'risk-based' approach improves public health. This approach is less rigorous than the current approach, is the benefit because it allows extra time for FSANZ to do proposals (when no additional proposals are anticipated to be completed each year)? Where is the quantification of the cost of FSANZ being less rigorous in the Cost Benefit Analysis?

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

- Yes**
- No**

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. The AMA recommends a significant effort be dedicated to identifying and engaging with these experts and organisations.

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

- Yes**

- **No**
- **Prefer not to respond/ I don't know**

The summarised outcome of the Net Benefit section is that Option 2 is more cost effective than Option 1 in delivering public health benefits – the AMA does not agree that this conclusion can be drawn from the data or proposed reforms presented. The Cost Benefit Analysis states that public health represents the main driver of benefits under Option 2, but there is insufficient detail to determine whether these benefits will be realised. This is highlighted by the absence of consideration of the burden of disease throughout the Cost Benefit Analysis and the key assumption that all applications, standard reviews, and proposals only lead to public health benefits. It is important for example, that the impact of reform options is modelled to show costs as a result of poor health, to both the healthcare system and consumers.

Given the burden of diet related non-communicable diseases grows annually, there needs to be some quantification in the Cost Benefit Analysis of the proportion increase in products which cause public health harm each year and the total public health cost of the increasing supply of these products as facilitated by FSANZ within the food regulatory system - this needs to be modelled under Option 1 and Option 2.

In relation to the analysis on proposals / applications / standard reviews specifically:

Proposals

- The proxy used to quantify public health impact is not appropriate for proposals as a whole.
- The Option 2 discussion notes that FSANZ will be able to process proposals in a 'more timely manner' - this needs to be quantified - as noted in our responses above, the AMA recommends that there is a time limit set for completion of proposals (3 years), this should be used as that measure for proposals and then reflected in the Cost Benefit Analysis.
- Delay in processing proposals has not been accounted for under Option 2 and should be.

Applications

- Applications are largely for commercial benefit and not public health outcomes - this needs to be reflected in the Cost Benefit Analysis.
- It should not be assumed that every application has a consumer benefit.
- A unit cost/benefit for consumers for applications specifically needs to be set out (not the \$1.3m used for proposals) and the rationale for that amount articulated.

Standard reviews

- A unit cost/benefit for consumers for standard reviews specifically needs to be set out (not the \$1.3m used for proposals) and the rationale for that amount articulated.
- There is no rationale stipulated for the assumption that each standard review results in a public health benefit.

Industry costs

The AMA strongly disagrees 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.

Section 8 - Best option and implementation

This section refers to questions in *Section 8 - Best option and implementation* within the Impact Analysis, commencing on Page 87.

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?

- Yes
- No
- Prefer not to respond/ I don't know

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 analysis of whether Option 2 solves the policy problems has resulted in a distortedly 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?

- Yes
- No
- Prefer not to respond/ I don't know

The AMA notes 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.

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.

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).

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?

- Yes
- No
- Prefer not to respond/ I don't know
- Bundling components for reform into themes does not enable accurate assessment of the risks with each component. The AMA strongly recommends 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?

- Yes
- No
- Prefer not to respond/ I don't know

The IA summarises that Option 1 was deemed on average much riskier than Option 2. The AMA suggests that this is reassessed according to our recommendations below:

The IA in section 8.2.2 states that the consequences of the risks of unsafe food or introducing higher risk to population health (i.e. unhealthy food) is major and gives each of these a consequence rating of 1 (major). We strongly support this rating and note that we do not consider any other risks identified as consequential as these and such, no other consequences 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.

The AMA notes that many of the risks found under Option 1 can be addressed under the status quo, and Option 2 doesn't necessarily resolve those risks - there needs to be equal treatment of this ability 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 professionally 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).

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. The AMA strongly disagrees 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.*

The AMA agrees 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 2

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

The AMA agrees 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.*

The AMA agrees 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.*

The AMA strongly disagrees 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,*

The AMA supports the risk rating for this risk.

Theme: efficient and effective operations

Option 1

- *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.*

The AMA strongly disagrees 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: Application of a levy on select industry participants could contribute to financial stress in a sector that is already feeling overwhelmed.*

The AMA strongly disagrees 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. The AMA recommends 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).

Section 9 - Evaluation of the preferred option

This section refers to questions in *Section 9 - Evaluation of the preferred option* within the Impact Analysis, commencing on Page 104.

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

- Yes**
- No**
- Prefer not to respond/ I don't know**

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

- Yes**
- No**
- Prefer not to respond/ I don't know**

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 of some source. Governments should be adequately funding FSANZ to perform its functions. The AMA strongly suggests 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. The AMA acknowledges 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.

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

The AMA wishes to highlight 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 30-year opportunity to ensure FSANZ's role in improving the food supply and the resulting public health outcomes needs to be taken. 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

The AMA notes that the IA does not accurately or adequately represent public health and consumer organisations' feedback from previous consultations in the 'Summary of stakeholder feedback' section. More significantly, this feedback 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, their FSANZ 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.

The AMA disagrees 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. The AMA remains 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 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 the AMA strongly recommends that these are reflected in the next steps for reform.

Contact

president@ama.com.au