

Introduction

Have you read the Impact Analysis?

Yes

Demographics

What is your full name?

Full name:
Food Safety Standards and Regulation

Are you answering on behalf of an organisation?

Yes

What is the name of your organisation?

Organisation name::
Queensland Department of Health (AWAITING CLEARANCE)

Which sector do you represent?

Government

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.

Free text box, no character limit:

An overall impact rating for each sub-problem has been calculated by combining a rating out of three for the level of impact and the extent of impact of the problem. While the report gives broad descriptors for each rating of impact, it does not indicate how these were determined for each sub-problem.

In the previous draft Regulation Impact Statement, consideration of costs and impacts of various problems and their solutions was almost exclusively focused on industry, with little consideration of public health impacts or benefits, which can ultimately lead to cost savings to the health system. It will be important to see an assessment of the public health impacts for each component, with consideration of the overall net effect on the protection of public health and safety. Proper and due consideration must be given to the assessment of long-term public health impacts for each component. This is a significant oversight and should be given the priority it deserves, especially given the priority objective of the food regulatory system is ‘to protect public health and safety’, with other objectives being listed in descending order of priority.

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

Free text box, no character limit:

No comment

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:

Certain sub-problems listed under each of the four Policy Problems do not adequately capture the issues raised in earlier sections of the document. The implications are that the reforms may not adequately address the problems that have been identified. For example:

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

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

Unclear definitions about FSANZ's need to consider short- and long-term risks to health are not the issue and have not been an issue since 2013 when the Ministerial Policy Statement on the Interpretation of Public Health and Safety in Developing, Reviewing and Varying Food Regulatory Measures clearly defined FSANZ's role. This was reaffirmed by the Food Ministers' Meeting (FMM) in 2022.

Rather, the confusion highlighted in Policy Problem 1 relates to the inadequate reflection of the primary objective to protect public health and safety throughout the Act and FSANZ's functions, including in decision-making. Inadequate funding of FSANZ to perform its functions has been a contributing factor.

Including a definition of 'protection of public health and safety' in the FSANZ Act might be a useful first step. However, it will not address how this objective is implemented by FSANZ. The described friction around the extent to which standards should be used to just establish a safe food supply, vs underpinning a food system that promotes a safe and healthy food supply, fails to consider that a healthy food supply and a safe food supply are inextricably linked. For example, toxins or chemicals found in food, such as aflatoxin from mould, acrylamide from baking processes, or excess levels of certain additives can contribute to chronic diseases such as cancer. Other food characteristics or components can contribute to obesity, which also contributes to cancer. Therefore, these health and safety issues should not be considered distinct from each other.

To adequately address Sub-problem 1, the sub-problem could be better described as: Unclear definitions of protection of public health and safety, and inadequate reflection of these throughout the Act and FSANZ's functions, have created confusion about how FSANZ should consider short-and long-term risks to health when developing food regulatory measures. This should be rated 3 for both level and extent of impact.

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

This issue extends beyond confusion and relates to sub-problem 1, where FSANZ's decision-making processes need to better reflect the Act's primary objective of protection of public health and safety. NOUS raises the example of factors under Section 18(2) that are considered with equal weighting, including Ministerial Policy Guidelines and ensuring a competitive food industry. NOUS indicates that there is confusion regarding the extent to which FSANZ must 'have regard to' Ministerial Policy Guidelines. Almost all these guidelines have been developed for instances where it has been recognised that special consideration needs to be given to protecting health and safety for certain products, labelling or in certain situations. This ties the guidelines directly to FSANZ's primary objective in developing food regulatory measures. These guidelines have been subject to formal regulatory impact processes, which consider industry impact, and failure to adequately meet the guideline is grounds for the FMM to request a review of a proposed change to the Food Standards Code. For FSANZ to consider health-related Ministerial Policy Guidelines with equal weighting to industry factors is problematic and conflicts with the overarching purpose and objectives of the Act. To ensure the protection of public health and safety is reflected in decision-making, the Act should acknowledge that where Ministerial Policy Guidelines directly support this primary objective, a corresponding weighting to them will be applied.

NOUS also makes the point that tensions arise when Ministerial guidelines are at odds with the desirability of an efficient and internationally competitive food industry and provides infant formula as an example. NOUS states the challenges in progressing changes to infant formula have been due to political tensions over the merits of infant formula vs breastfeeding. These have been due to applications not adequately considering or addressing the risk of new ingredients for infants. Infants are vulnerable and often dependent on formula as the sole source of nutrition during a unique period when food consumed significantly impacts both short- and long-term health and developmental outcomes. The Ministerial Policy Guideline on infant formula was developed as Ministers recognised the greater level of risk to be managed with infants (and felt this was not being adequately considered by FSANZ). Therefore, the regulatory framework for infant formula should be commensurate with this level of risk. Confusion over the weighting of the Ministerial Policy Guidelines against industry factors has led some to believe applying the greater level of risk management outlined in the guideline was not necessary, while others expected the guideline principles to be considered as part of the primary objective to protect public health and safety. It should also be noted that this applies to the example given later for FSANZ Application A1155 (addition of an oligosaccharide to infant formula) that NOUS indicates was delayed despite being 'fully approved in several comparable foreign jurisdictions'. Most of the other jurisdictions only permitted the ingredient in infant formula, at half the level being proposed, and no safety tolerance studies at the higher levels were provided. The applicant could also not demonstrate that adding the ingredient would be of benefit to infants; a principle incorporated in the infant formula Policy Guideline as an additional surrogate for safety given the influence of infant formula consumption on long-term development. If the Policy Guideline had been given greater consideration by the applicant, the delays may have been avoided.

Given the delays caused by this confusion and inadequate weighting of the Ministerial Policy Guidelines in line with the primary objective, this sub-problem should be rated 3 for both the level and extent of impact.

In terms of the relative importance of the sub-problems under Policy Problem 1, sub-problem 1 and 2 are considered to have the greatest impact, followed by sub-problem 3 (that the Act is silent on commitments to First Nations and Maori Peoples), noting the need for this to also be addressed.

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

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

It is suggested that the overall impact should be higher than 6. Both level and extent of impact should be 3. The under-resourcing of FSANZ is cited as the key reason that holistic reviews of standards are not undertaken, and proposals, some of which have been underway for 10-20 years, are not being completed in a timely manner. This has a significant impact on the protection of public health and safety of the population. For example, the review of sports foods has been on hold for many years despite recognition of the inadequate regulation of sports foods on the market, with associated health and safety impacts. Given FSANZ is significantly underfunded compared with similar overseas jurisdictions, as outlined in the NOUS report, it is crucial this be considered a priority.

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

Sub-problem 1 | The lack of a shared vision of system priorities between FSANZ and the FMM limits the effectiveness of the broader food regulatory system

The overall impact of this sub-problem is rated 4, however it should be lower. Priority setting discussions between FSANZ and the FMM are important and already occur. Much of the workload requested of FSANZ by the FMM is for the review of out-of-date standards or public health and safety issues, which should be part of FSANZ's core functions. Reducing requests from the FMM would be better addressed under Policy Problem 1.1 by ensuring the protection of public health and safety (according to the Ministerial policy definition) is reflected in FSANZ's functions, and under Policy Problem 3.2 by ensuring FSANZ is adequately funded to conduct regular reviews of out-of-date standards.

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):

The Impact Analysis written by Nous Group indicates that stakeholders are confused about the definition of public health and safety. This is despite the Ministerial Policy Statement on the Interpretation of Public Health and Safety in Developing, Reviewing and Varying Food Regulatory Measures (2013) that clarifies FSANZ's role and the FSANZ Board's clarification that FSANZ's objectives are intended to make a positive contribution to longer-term public health objectives.

Thus, whilst the inclusion of a definition would be useful, on its own and without other measures to support the implementation of a definition in practice, it would be unlikely to have much impact from a public health point of view and the ability to reduce any confusion that may or may not exist is questioned. Long-term health outcomes require a multi-faceted approach which recognises the importance of influencing consumer behaviour.

Clearly defining 'protecting public health and safety' may enhance stakeholders' understanding of FSANZ's role, as well as how food standards can support public health objectives. It should be noted that FSANZ's risk assessment of applications and proposals to amend the Food Standards Code includes an assessment of food safety and short- and long-term public health effects.

The risk of having a broad definition is stakeholders may interpret this as meaning that all issues can be addressed by the Food Standards Code. If a comprehensive definition was used, there would need to be clear communication that food regulation may not be the most appropriate intervention to affect change for all food-related public health issues.

The Ministerial Policy Statement definition is the most suitable and reflects the interrelated nature of short- and long-term public health and safety. The instrument which legislates for a high standard of public health protection in the domestic food supply should encompass all food-related illness, not just short-term food safety issues. Defining 'protecting public health' may ensure that longer term health outcomes (including prevention of diet-related chronic disease and conditions) are properly considered within FSANZ's remit.

It is noted that in the Nous Group's outline of the objective of this reform work (page 42), and what a strong regulatory framework should contribute - protection of public health is noticeably absent. This highlights that a definition on its own is insufficient if the object of the Act in Section 3 (to ensure a high standard of public health protection) and the primary objective of standard setting in Section 18 (the protection of public health and safety) are not reflected further in this reform work (such as in decision making and other functions).

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

Additional comments (optional):

Clarifying the meaning of protection of public health and safety may help reduce any role confusion. However, such clarification is unlikely to have a material impact on the approach to applications and proposals unless these objectives are reflected in other FSANZ functions, including decision-making (which includes the weighting given to Ministerial Policy Guidelines).

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

Positive

Additional comments (optional):

Clarifying the definition of 'protection of public health and safety' within the Act may remove any doubt that FSANZ should consider public health and safety broadly from both a short- and long-term perspective, including both communicable and non-communicable food-related illness. However, as previously stated, unless the clarification of the definition is accompanied by practical change in FSANZ's functions, there is potential that it will have little impact.

In both the draft regulatory impact assessment and this Impact Assessment, the importance of retaining the protection of public health and safety as the primary objective has been highlighted. However, collectively, it appears the proposed actions to date would result in a reduction in public health and consumer protections overall. To prevent these reforms from having a net negative impact on public health and safety, both the problems and actions proposed need to reflect the protection of health and safety as the legislated primary food regulatory objective.

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:

It is noted that in the FSANZ Application Handbook, applicants are already advised to address any relevant Ministerial Policy Guidance material within their applications. In call for submission papers for applications and proposals, FSANZ also provides an assessment of how the Policy Guideline has been addressed. This indicates that there may need to be greater communication on the role of policy guidance in the process of decision-making.

Additionally, it should be considered as to whether the FSANZ Act should recognise that policy guidelines have been developed to provide specific guidance on the protection of public health and safety in relation to certain situations or foods, and thus should be incorporated as part of the prioritised primary objective, rather than something that FSANZ must 'have regard to' and in equal measure to industry factors.

It is also important to note that Ministerial Policy Guidelines have already been subject to regulatory impact assessments and their merits against industry interests have previously been assessed.

Component 2.1.3

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

Yes

Free text box, no character limit:

It is suggested that this would need to be determined in consultation with First Nations stakeholders. Currently, dietary assessments undertaken to assess the effect on public health of a potential change to the Food Standards Code, e.g. new processing aid or higher pesticide residues, do not take into account differences in consumption patterns of the general Australian and New Zealand population and First Nations Peoples.

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:

Further consideration of relevant changes to the Act to promote recognition of First Nations culture and expertise, in consultation with relevant stakeholders would be welcome. This is particularly important because of the significant disparity between the health of First Nations peoples and other populations in Australia and significantly more work is required to close this gap.

Recognition of Indigenous cultures and food expertise could be much broader than bringing 'bush tucker' to market. It may also include for example the impacts of proposed changes to the Food Standards Code on Aboriginal and Torres Strait Islander health outcomes; it could also consider public health

issues highly relevant to Aboriginal and Torres Strait Islander peoples, such as access to healthy, affordable food in remote communities.

Consideration should also be given to including the impacts of proposed food regulatory changes on the public health of First Nations groups. Currently, traditional foods are considered by the FSANZ Advisory Committee for Novel Foods which consults local Indigenous community leaders to assess traditional use. A dedicated Indigenous Advisory Committee for Indigenous foods may be a worthwhile consideration, in addition to a list of pre-approved Indigenous foods. Further consideration of how a 'history of safe use' may be better determined for these foods is encouraged however it is suggested that any changes in this area need to be guided by these groups. It is important however that Indigenous foods are subject to the same regulatory scrutiny as any other food which is new to the market.

Further, initiatives that recognise and support First Nations People, their culture and expertise, including food-related enterprises should be supported. However, FSANZ may not be best placed to do this.

Component 2.1

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

Yes

Free text box, no character limit:

1. Market failures, which can impact on trade as well as public health and consumer confidence, include outbreaks associated with microbiological contamination, excessive chemical residues, foreign objects in food and misleading information.

- Maintaining consumer confidence is a function of both the food regulatory system and Australian Consumer Law.
- Addressing market failures does not rest solely with governments. Good regulation prevents market failures and should be implemented in partnership with industry and other stakeholders.
- The scoping paper makes very few references to market failure. The strawberry tampering incident is an example of market failure which may have been mitigated by the implementation of a primary production and processing standard for horticulture.

2. Consideration of culturally and linguistically diverse population groups and their culture and traditions surrounding food. Whilst these groups are not Indigenous to Australia or New Zealand, they make up a significant proportion of the population in Australia.

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

Free text box, no character limit:

The introduction of a risk-based framework, such as the indicative one proposed, may assist in assessment of some standard setting and decision making, provided that both short- and long-term public health is considered. It will also be important to demonstrate how this would be applied to longer term public health issues (for example health claims) or situations where changes to the Food Standards Code are proposed to meet the objective regarding the provision of adequate information to enable consumers to make informed choices.

Streamlining the review of low-risk amendments (e.g. processing aids) from select international regulatory systems (e.g. Codex, USFDA) with the minimal check pathway would create efficiencies. It could allow resources of jurisdictions, FSANZ and the Food Ministers' Meeting (FMM) to be directed to higher priority proposals and issues. This may serve to ensure work in these areas can also be progressed.

However, it is important to note that a risk-based framework that is solely focused on acute food safety risk is likely to negatively impact the community if these public health issues are continuously considered low-risk and deprioritised.

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

Free text box, no character limit:

A broad approach to risk should be considered including the primary three food regulatory objectives to protect public health and safety, provide adequate information and prevent misleading or deceptive conduct, all of which are listed in descending priority order in the Act.

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

Negative

Free text box, no character limit:

Food regulation already operates under a risk-based framework.

However, if an alternate risk-based framework is introduced that does not consider the three priority objectives under Section 18(1), (the protection of public health and safety; provision of adequate information; and the prevention of misleading or deceptive conduct) this could result in the deprioritisation of important regulatory measures needed to address issues under these objectives.

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

Free text box, no character limit:

Adopting risk assessments from overseas jurisdiction and Codex has the potential for realising efficiencies for FSANZ and stakeholders in the standard setting process, promoting industry innovation and reducing data requirements for applicants. However, food standards can be used as technical barriers to trade by our trading partners, and consequently, may not always solely based on science. Applicability to the Australian/NZ situation needs to be assessed.

It is noted that this process is already possible under the current provisions of the FSANZ Act and has already occurred with Health Canada and the assessment of certain genetically modified foods. This process could support FSANZ's approach but should be subject to verification, consideration of local characteristics and assessment against relevant Ministerial Policy Guidelines. It is extremely important that any such provisions do not allow any weakening of public health protections.

Questions relating to the applicability to Australia and New Zealand include:

- Will all overseas assessments be regarded as having equivalent scientific merit or only those from selected regulators and or assessment agencies?
- What criteria should be used to benchmark overseas regulators/assessment agencies and their assessments?
- What will be done if there is divergence of scientific opinion?
- Will FSANZ evaluate overseas assessments, even those from comparable agencies?

Further, have the risk assessments incorporated Australia New Zealand-specific variables? For example, in relation to maximum residue limits of agvet chemicals and maximum limits for contaminants, dietary consumption values, such as potato consumption from an Asian country, may not reflect our diets.

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:

Australia is highly reliant on the export of agricultural commodities for its economic prosperity and has strongly contributed to international standard setting over many years. However, Australia has not had an official policy of accepting standards such as Codex. This is even though we have encouraged other countries to adopt those standards to support Australian trade. Consequently, there are good trade reasons to adopt relevant international standards.

However, there needs to be careful articulation of the implication of the adoption of Codex MRLs as limits in Australia. In Australia, compliance with food standards MRLs is only part of the regulatory regime associated with the use of agricultural and veterinary chemicals. This is not an unreasonable outcome given that there are other areas of risk that are managed by the APVMA approved instructions. However, it does require some clear articulation of the reasons for the situation.

The APVMA assesses risks to public and the environmental health and trade and sets appropriate use instructions to manage the risks. The APVMA also sets MRLs that are associated the approved uses in Australia. The adoption of Codex MRLs into the Food standards Code means that the MRLs set can be different to those in the APVMA MRL Standard. In most Australian states, agricultural producers must comply with the APVMA MRLs. Therefore, it sets up an anomalous situation that overseas producers.

While a current FSANZ function highlights the need for consistency, a key tenant of this is based on the best available scientific evidence, as well as the overarching priority of the protection of public health and safety. To uphold these two latter criteria, it is understood the intent is that it will be checked.

A mechanism to enable FSANZ to adopt international standards could have benefits for domestic food producers who export and are currently required to adhere to more than one standard (i.e. domestic and export standards).

It is considered appropriate that the introduction of such a provision would need to be clarified that international standards can be considered only where they have undergone a similar scientific and risk assessment to what would be undertaken by FSANZ during the application process.

The adoption of international standards by default may create challenges if the standard is contrary in design to those in the Food Standards Code, is over-prescriptive, does not take into account related domestic standards (both those within and outside the food regulatory system, such as environmental standards for chemical MRLs) or is not suitable for the Australian and New Zealand context, both from a public health and social policy perspective.

It is also unclear whether this would also involve automatic adoption of changes or even revocation of standards or permissions should the international jurisdiction amend these regulations. In principle the streamlining of the application process is supported, however consideration needs to be given to drafting, implementation and some rigour placed around what is an acceptable overseas standard.

Queensland continues to support a scientific and risk-based approach to standards development and therefore the automatic adoption of new standards is not supported due to:

- the limited engagement between the Commonwealth Government bodies and jurisdictions regarding international standards development processes, and
- the lack of an implementation period to enable industry, regulators and consumers to prepare for the change to the Food Standards Code.

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?

Prefer not to respond / I don't know

Free text box, no character limit:

Issues with the current application/proposal system are:

- FSANZ's technological and safety assessments of new additives and GM food/ingredients take up resources which could be better used in strategic work. This trade-off needs to be explored especially in cases where the substance has been approved for use by Codex or in other countries.
- It is time consuming for stakeholders, involving review of one or two Call for Submission papers and an Approval paper, making a submission to FSANZ when warranted, and, in the case of government stakeholders, briefing of the lead Minister on how to vote on a proposed amendment.
- Related applications about a family of substances, e.g. steviol glycosides, are considered individually, rather than as a group. Many of the elements of the safety assessment are the same for each substance.
- Technical, risk-based assessments of minor application changes should not require the need for extensive consideration. Ministers may become fatigued when considering an amendment about a processing aid sourced from a GM microorganism, both with unpronounceable names, but would be more engaged when considering policy issues, including those with a strong social policy consideration.
- Technological justification for an amendment is often not well articulated in the Call for Submissions paper and supporting document. There is an underlying policy issue as to whether any substance which is safe should be permitted in a food, or only permitted if there is a technological justification for its presence.
- The lack of statutory timeframes for proposals has resulted in significant delay, and prioritised industry applications over more strategic policy issues.
- One proposal is P1028 (Infant Formula) which commenced in 2013, and following this there have been applications (e.g. A1155) from industry seeking permission for additional substances in infant formula. There have been diverse views from stakeholders and some issues have been deemed out-of-scope for A1155. If P1028 had been progressed in a timely manner, some of these controversial or out-of-scope issues may have already been resolved.

The process could be expedited by:

- combining Call for Submissions and Approval stages for an application for a food additive or GM ingredient that has already been approved for the same use by Codex Alimentarius or regulatory agency of another country (e.g. UK Food Standards Agency, US Food and Drug Administration, European Food Safety Authority and US Food and Drug Administration, Canadian Food Inspection Agency)
- excluding applications involving food additives (includes processing aids) and GM ingredients or foods from Ministerial approval unless FSANZ's risk assessment indicated a safety or public health issue, similar to how the APVMA is able to change the Maximum Residue Limits standard of the Food Standards Code directly, without oversight of the Forum.
- Approval by the FSANZ Board would be sufficient for these types of low risk, routine technical approvals, however, some safeguards could be built in, such as the FSANZ being able to defer to the FMM on Food Regulation higher-risk matters.

It is suggested that a broadening of the application process should have been considered. This approach would allow for the pre-market approval of health claims. The Code amendment process would relieve the regulatory burden on jurisdictions as the accuracy of claims would need to be verified via a pre-market approval, prior to any regulatory oversight, rather than the self-substantiation process that does not require pre-approval. It would reduce the use of unsubstantiated claims, which may be in the marketplace for some time before regulatory action is taken. Part of the consideration of this option would be to gain an understanding of the barrier for industry when applying for Code amendments. For example, there may be concerns about cost, or timeframes, or the opportunity to protect their commercial information.

The current process prohibits a business from using a relationship that has been notified by another food business. As such, a food business wishing to make a general level health claim based on a relationship that is already on the list must undertake its own systematic review and notify FSANZ of the relationship. It is suggested this approach places burdens on regulators to continue to review and consider the merits of potentially similar food-health relationships. An underlying reasoning for this approach appears to be the protection of a business's commercial development efforts.

Whilst this is of course important for business, it may need to be reassessed whether it is the role of FSANZ or jurisdictional food regulators to be concerned about whether a business's competitor may 'springboard' as a result of the notification of food-health relationships. It is suggested business have a variety of protections under laws relating to intellectual property and obligations of confidence which could be utilised to safeguard their commercial interests.

Any consideration of the options for managing the process for notifying a food health relationship, should consider the difficulties with the removal of claims which are not able to be substantiated.

There are reservations about industry self-substantiated pathways for very low risk products. It requires FSANZ and/or jurisdictions to take on enhanced post market monitoring and surveillance roles, requiring additional resourcing, including, potentially, acquisition of specialist knowledge. With the industry self-substantiation pathway, there is a risk, albeit low, that unsafe products may be in the market for some time before regulatory action is taken.

Minimal check pathways would need to continue to deliberate on local characteristics, assessment against relevant Ministerial Policy Guidelines and ratification by government. This would ensure the ongoing separation of powers between the risk assessors and risk managers and the oversight of legislation by elected officials for each jurisdiction. Further discussion should also occur around what might be considered comparable regulatory systems, being those with independent pre-market assessment, rather than industry self-assessment or self-regulatory processes.

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

Free text box, no character limit:

The general principle of recognising categories of risk to allow FSANZ to expedite routine or low-risk amendments while focusing limited resources to carefully consider and assess high risk amendments that may have wide ranging food safety, social or economic impacts is agreed.

The triaging system used to risk rate applications/proposals should be simple and reproducible. applications involving a food additive already approved in Codex or other international food systems could automatically be categorised as low risk and triaged as a minor variation, without the need for FMM approval.

An application or proposal that aligns with a strategic priority of FSANZ should be triaged as a major variation. Amendments that have broad-ranging political, social and economic consequences are likely to be of key interest to Ministers (e.g. pregnancy warnings on alcohol) and will require their approval.

Whether rejection is an option for an application/proposal that falls outside FSANZ's area of expertise and does not align to strategic priorities should be considered.

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

Positive

Free text box, no character limit:

FSANZ's technological and safety assessments of new additives and GM food/ingredients take up resources which could be better used in strategic work. Further it can be time consuming where briefing of the lead Minister is concerned on how to vote on the proposed amendment.

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

Prefer not to respond / I don't know

Free text box, no character limit:

No comment.

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:

It is considered that the FMM is a law-making body which is designed to create efficiencies in decision making by replacing parliamentary process in adopting food laws into members' jurisdictions. Existing processes adopted to streamline decision-making further have included the FMM making out-of-session decisions for low-risk changes to the Code. Further delegating these law-making functions to unelected officials is a significant step as it may remove Ministerial oversight. Other reforms that create efficiencies may have a more tangible effect than removing ministerial oversight as without policy guidance it may be difficult to achieve the overarching aim of protecting health and safety, both in the short-term and long-term.

Although this may be a good long-term aspiration, especially for applications where there is a strong and relevant evidence-base, the system is not mature enough yet to allow for ministerial delegation to the FSANZ board for decision-making. Ministers are advised by their own jurisdictional officers and accountable to their constituents. This independence and accountability would be lost if Minister's were to delegate to the FSANZ Board without oversight and sign-off.

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

Free text box, no character limit:

It should be considered that an issue that might be low risk for one stakeholder, may be higher risk for another. A range of factors should be considered including the level of public health and safety risk, the impact on the reputation of the domestic food supply and the level of interest to the public of the proposed change.

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

Positive

Free text box, no character limit:

FSANZ's technological and safety assessments of new additives and GM food/ingredients take up resources which could be better used in strategic work. Further it can be time consuming where briefing of the lead Minister is concerned on how to vote on the proposed amendment.

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

Free text box, no character limit:

No comment.

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

Free text box, no character limit:

Domestic and international trade opportunities may arise for Indigenous businesses bringing traditional foods to the broader market, especially if these foods have nutritional or therapeutic benefit e.g., Kakadu plum with high vitamin C content.

Therefore, it is considered that development of a list of traditional foods or ingredients that have undergone nutritional and compositional assessments could be positive and facilitate entry of traditional foods to market. It will be important to consider that in addition to nutritional and compositional assessments, these foods and ingredients should also have undergone public health and safety assessments of their proposed use.

It is important to note that whilst this may be a useful investment of time and resources, any action should be taken in conjunction with First Nations peoples as enhanced employment and educational opportunities, e.g. new harvesting, processing, and packaging methods may be required to bring Indigenous foods to market. This in turn may create better health outcomes for Indigenous communities in terms of healthy food handling practices and also access to healthy, affordable food in remote communities.

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:

No comment.

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:

The food supply chain is constantly evolving and innovating and therefore it is imperative that strategic reviews can be conducted in a timely and succinct manner.

Following approval of a proposal or application, the Food Standards Code is redrafted to take account of the approved amendment. However, this may have unintended consequences which may only be uncovered by a strategic review, e.g. for an issue which was regarded as out of scope of the original application or proposal. It is not uncommon for FSANZ to respond to an issue raised by a stakeholder from a Call for Submission paper that it is "out of scope".

The FSANZ Act should be amended to provide the flexibility necessary to enable FSANZ to drive 'forward-looking regulation' if agreed to by all jurisdictions as part of food regulatory system deliberations. Given the significant investment now being provided by jurisdictions in the area of data collection, analysis and analytics, and the key information they likely hold, further consultation is required as part of the modernisation program. It is encouraged that the FSANZ Act will be amended to enable FSANZ to undertake reviews of food standards and 'position FSANZ as the engine of food safety

intelligence’.

However, there should still be a mechanism by which food standards can be changed, other than by strategic review or the current application/proposal system, that enables the regulatory system to respond quickly to an unanticipated problem with a food standard.

Additionally, there are a number of proposals on hold, or that have been ongoing for many years and out-of-date standards is a key problem to address in the current review. Whilst adequate resourcing is an important factor, other factors are equally important to resolve, such as the lack of legislative obligation for FSANZ to conduct regular reviews and barriers created by statutory time frames and cost recovery for applications, which results in their prioritisation over proposals.

These include:

- P1047 – Review of regulatory nutrient reference values, to update the values in the Food Standards Code from the 1991 recommended daily intakes to the 2006 Nutrient Reference Values – 14 years, put on hold until 2018 and nil action since.
- P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods – 12 years, on hold since 2017 due to other priorities.
- P1028 – Infant Formula – 12 years since the first public consultation.
- P1010 – Review of Formulated Supplementary Sports Foods – 23 years. Commenced with proposal 236 in 2001, abandoned in 2013, then added back on the work plan in 2018.

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

Yes

Free text box, no character limit:

Provided there is adequate resourcing and time to enable a thorough, considered review, there could be positive impacts as it would ensure standards reflect best practice and are founded on contemporary evidence.

Other solutions to drive holistic reviews of food standards (in addition to resourcing) could include:

- Designating regular holistic reviews of standards as a primary statutory function, while also reviewing the statutory timeframes for applications.
- Creating sunset provisions for standards, or regular review timeframes that can be planned for with standardised review processes to assess whether a standard remains fit-for-purpose.
- Enabling FSANZ to be flexible in its workplan with Application timeframes to enable it to prioritise proposals or reviews of standards that reflect ministerial priorities, policies, or known regulatory issues.
- Providing FSANZ with the ability to recognise not only international risk assessments, but also work conducted within the Australia New Zealand food regulatory system (such as through the Food Regulation Standing Committee policy development process and associated Regulatory Impact Assessments).

It is important to note that automatic sunset provisions that results in the removal of food standards without a prior careful review could result in the loss of important requirements that help protect public health and safety, prevent misleading practices and that support public health objectives. If implemented, consideration may need to be given to sunset provisions different parts of the Code at different times because sunset provisions the entire Code, which is very large, on one date could create a significant resourcing issue for FSANZ and all stakeholders that could result in less careful consideration of changes and contribute to mistakes.

Regular holistic reviews of food standards could provide a more tailored mechanisms for identifying and addressing inconsistencies within food standards and opportunities for more effective regulation, provided that it does not detract from other higher priority projects. These reviews should be coupled with the sunset provisions arrangements which could be established with consideration of the linkages between standards.

Holistic reviews could be a mechanism to make certain older standards more contemporary, help remove anomalies and improve ambiguous and unclear drafting. It could also help to provide a more strategic approach where there are multiple industry applications for similar issues, such as different steviol glycosides.

Additional resourcing for FSANZ to undertake such reviews may not be necessary if the role of FSANZ is clear and changes are made to FSANZ's application processes, funding model and approach to priority setting.

A possible trigger for review of food standards could include industry and multi-jurisdictional regulatory uncertainty about an issue that is raised with FSANZ. Some reviews could be of a more strategic and proactive nature if initiated early, particularly in response to new innovations that are likely to result in a series of industry applications.

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:

Greater use of guidelines and codes of practice where these provide practical advice for industry e.g. on safety processes by FSANZ is supported in-principle. However, given these are not enforceable, these are not suitable as a replacement for standards as stand-alone instruments, particularly for labelling, or longer-term public health issues, where there can be less motivation for industry to comply.

Because they clarify how to interpret, implement, and achieve the prescribed outcome of a food standard (e.g. microbiological limit), this may reduce the number of industry enquiries and promote jurisdictional consistency when providing interpretative advice (especially beneficial for multi-jurisdictional businesses). However, such instruments need to be considered in the context of the whole regulatory system, including the potential adoption of existing industry codes or guidelines and the development of new documents by industry in consultation with regulators. Ancillary legislation within each jurisdiction may be required to give codes of practice enforceable effect as industry regulating industry does not work.

A risk-based, decision-making tool to determine whether a standard, code of practice or guideline would be required. The types of 'issues' for codes of practice and guidelines would need to be considered in the context of the modernisation work program (including the development of a regulatory delivery model) and the needs of industry, jurisdictions and consumers. Codes of practice and guidelines can provide sector-specific advice about the interpretation, implementation, and acceptable outcome of a food standard.

If industry-developed codes of practice are utilised, regulators must be confident with the monitoring and auditing arrangements and that adequate education for stakeholders is provided. Such codes could reflect industry-led QA/food safety schemes but be backed up by stronger regulatory options for those not 'in the tent' of industry schemes, or where there is reason to believe that industry schemes are not effective or effectively implemented and audited.

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:

The Code of Practice on Nutrient Claims (CoPoNC) is an old example of a Code that had no regulatory backing and was not well implemented by industry (see <https://search.informit.org/doi/abs/10.3316/ielapa.200711981>)

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:

This is not supported.

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:

Industry regulating industry does not work and has been shown not to work in a range of areas. A significant contributing factor in the success of the food regulatory system in the protection of public health and safety has been FSANZ's independence. Deferring the development of regulatory instruments such as Codes of Practice, or guidelines, to industry will create concerns about real or perceived industry capture.

Another concern is that there may be a sense of ownership of guidance developed by an industry stakeholder that raises a number of questions over governance, content approval and whether the guidance might end up being restricted to those that pay.

Component 2.2

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

Prefer not to respond / I don't know

Free text box, no character limit:

No comment.

Component 2.3

Component 2.3.1

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

No

Free text box, no character limit:

It is noted the recommendations are outstanding from a 2014 Review. It may be beneficial to provide stakeholders with access to this 2014 review paper to help inform the applicability of these recommendations now in 2024. It is noted the Australian Government commenced a Review of the Public Sector Board Appointment Processes in 2023 as part of the Australian Government's Public Service Reform Agenda. Any changes to the FSANZ Board should take into consideration recommendations that will result from this Review.

Amending the compositional requirements of the FSANZ Board should take into consideration additional factors such as First Nations, gender, culturally

and linguistically diverse, geographic and professional background and expertise, age and other inclusion matters.

It is important the core skills required for membership on the FSANZ Board continues to reflect the objectives of FSANZ. The additional skills listed on page 59 of the consultation paper could be considered complementary but not as a replacement to the core skills currently in section 116 of the FSANZ Act. A sufficient spread of expertise on the FSANZ Board should be maintained and consideration could be given to creating and maintaining a board skills matrix.

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:

The FSANZ Board should contain core competencies that are held by members, with core expertise that reflects FSANZ's primary objective – that is, public health and safety, and risk assessment (including microbiology, nutrition and dietary patterns, public health and toxicology).

It is noted the recommendations are outstanding from a 2014 Review. It may be beneficial to provide stakeholders with access to this 2014 review paper to help inform the applicability of these recommendations now in 2024. It is noted the Australian Government commenced a Review of the Public Sector Board Appointment Processes in 2023 as part of the Australian Government's Public Service Reform Agenda. Any changes to the FSANZ Board should take into consideration recommendations that will result from this Review.

The Food Ministers' Meeting (FMM) should be provided adequate time to consider nominees to the FSANZ Board. Consideration should be given to including requirements in the FSANZ Act to ensure there a transparent and equitable selection process for the chair and board members, which is shared in the consultation with the FMM, to ensure the chair and board members have the appropriate skills and knowledge and well suited for the functions required.

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:

The food regulatory system's resources are currently focused on individual business applications to change the Code (usually requested by larger businesses), rather than supporting system-wide improvements that have broader business benefits, particularly small to medium enterprises, and consumers. Therefore, the impact of removing expedited applications may be negative for individual businesses but positive overall for industry and the community by reducing a barrier that requires FSANZ to prioritise applications over proposals.

However, it is important that adequate cost recovery should be available to FSANZ (and other government agencies involved in the food regulation system), particularly for matters such as applications that relate more to commercial interests than public benefit functions.

Other cost-recovery options, such as charging a fee to assess self-substantiated health claims, could be explored.

Component 2.3.3

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

Negative

Free text box, no character limit:

We have concerns with the practical implementation of an industry-wide levy and that this may have consequential effects for downstream users (for example, passing the costs onto consumers). Within the current environment of the cost-of-living crisis, there is concern that the proposed levy may exacerbate these pressures and any changes should take into consideration the ACCC Supermarkets inquiry 2024-25. It is also noted in Table 15, that the Impact Analysis expects industry to pass the levy onto consumers at an amount of \$AUD 10 million per annum. Therefore, the levy will benefit FSANZ and industry at a cost to consumers.

While an industry-wide levy would assist with the cost of the food regulatory system to FSANZ, it would need to be proportionate to the varying sizes of food businesses.

It would be beneficial to provide further information on the type of food business that would be captured by the proposed levy, noting that the proposal suggests "the largest 5,000 food businesses". For example, would the levy include only businesses that have a food business license or could it be any business that is involved in the sale of food including importers, supermarkets and petrol stations?

It is noted that the proposed levy would only apply to Australian food businesses however the revenue generated would also benefit New Zealand food businesses, yet these are not captured in the proposal or to be considered in a review of the FRA/Treaty. There is a risk that Australian food businesses captured by the levy may move their operations and/or head office to New Zealand to avoid the levy whilst still accessing the benefits of the Australian New Zealand food system.

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:

The levy should be proportional to the business' operations with large and multinational corporations charged significantly more than smaller corporations. However noting that the cost regardless is expected by the Impact Analysis to be passed onto consumers.

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:

No comment.

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

Positive

Free text box, no character limit:

Depending on the fee amount charged, large sized and multinational corporations would be able to afford to make applications however smaller companies may not have the ability to pay and may be at a disadvantage.

Further information on this proposal would be beneficial to determine the expected impact including:

1. The number of paid applications on average per year
2. The number of unpaid applications on average per year
3. The proposed application fee amount
4. If the fee amount will be indexed each year
5. If FSANZ will be committing to timeframes for all applications (not just expediated applications) now that a fee is being charged.

Charging a fee to assess an application could be a reasonable cost-recovery option provided the fees are transparent and scalable based on the resources required. If a fee is to be charged for each application, then consideration should be given to removing the ability to expediate applications by paying an additional fee.

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

Prefer not to respond / I don't know

Free text box, no character limit:

In undertaking entrepreneurial activities and seeking funds from industry, it will be important to ensure that there is no real or perceived industry capture and that FSANZ retains its independence. This needs to be carefully considered and mitigated if proceeding.

Cost-recovery through entrepreneurial activities by FSANZ may result in reduced industry innovation, inhibition of the creation of a culture of government transparency and accessibility, and a perception of reduction of services to the public. There may also be a potential negative impact on food safety, if there is cost-associated reluctance by businesses to access FSANZ for information which educates or otherwise leads to improved food safety practices.

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?

No

Free text box, no character limit:

The proposed avenue of cost-recovery from jurisdictions is of concern. It is not thought that jurisdictions should be required to pay for using and participating in the system that underpins the bi-national food system. We also note the extensive resources that jurisdictions currently commit to the system via application and proposal consideration, support of working groups as well as significant cost-shared funding of projects and functions.

Cost recovery from jurisdictions will not contribute to a more sustainable funding base as jurisdictions experience many of the same resourcing pressures as FSANZ and may instead result in a reduction of engagement by jurisdictions with FSANZ to save on costs.

FSANZ's role in food recalls is limited to coordination at the national level only and jurisdictions are responsible for communication, investigation, monitoring and enforcement of food recalls in each of their jurisdictions. This requires a significant number of resources which are already funded by each jurisdiction. If a cost was charged for FSANZ to coordinate a food recall then jurisdictions may instead take on this role to reduce their costs.

Consideration may also need to be given to clarifying whether FSANZ's role in coordinating food recalls should be enshrined in legislation.

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:

No comment.

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?

No

Free text box, no character limit:

It is not clear how charging jurisdictions fees for proposal work and industry for application work would assist in prioritizing proposals. If administration of the Food Standards Code, which included holistic reviews, was a core function of FSANZ, this would greatly reduce the number of proposals and project work requested by jurisdictions. Ultimately, amending the statutory time frames of applications would also be required for FSANZ to rebalance its priorities of applications versus proposals. In addition, the workplan is often conducted in partnership with jurisdictions with jurisdictional resources relied on to enact this work. If a charge was placed on adding to the workplan, would FSANZ use these resources to take up these activities instead of jurisdictions?

There is concern with the proposed avenue of cost-recovery from jurisdictions. It is not thought that jurisdictions should be required to pay for using the system that underpins the bi-national food system. It is also noted that the extensive resources that jurisdictions currently commit to the system via application and proposal consideration, support of working groups as well as significant cost-shared funding of projects and functions.

Cost recovery from jurisdictions will not contribute to a more sustainable funding base as jurisdictions experience many of the same resourcing pressures as FSANZ and may instead result in a reduction of engagement by jurisdictions with FSANZ to save on costs.

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

Negative

Free text box, no character limit:

This could serve to undermine the success of the food regulatory system as a nationally coordinated system. Such a levy could create disincentive to partake in the national system (particularly for smaller jurisdictions).

How would this need to be implemented to be successful?

Free text box, no character limit:

No comment.

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

Other

Free text box, no character limit:

No comment.

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:

The likely impact of this action would be to reduce proposals and project work requested by jurisdictions through the FMM. Much of this work relates to updating out-of-date standards, addressing regulatory issues or acting on Ministerial policies to improve public health and safety, which should ordinarily be part of FSANZ's core functions. This will likely result in even fewer proposals being progressed and a greater focus on individual industry applications.

A successful independent food standards body, such as FSANZ, requires adequate funding. FSANZ's funding has significantly decreased over the years and is well below that of comparable overseas countries (per capita). In recognition of the impact of ensuring a safe and healthy food supply on the population and on the economic value of Australian foods, we are of the view that adequate base funding of FSANZ rather than piecemeal funding is needed.

Jurisdictions work in partnership with FSANZ as part of the food regulatory system and undertake project work, leading and participating in working groups and subcommittees. The resources required for jurisdictions is funded by the jurisdiction, for example in Queensland, the resources for Queensland Health are paid by the Queensland Government and not by service charges or cost recovery from industry or FSANZ.

How would this need to be implemented to be successful?

Free text box, no character limit:

It would be necessary to adequately fund FSANZ to administer the Food Standards Code by regularly reviewing standards, addressing regulatory issues and acting on Ministerial policies to improve public health and safety. It might then be possible to charge jurisdictions for additional project work that falls

outside of this remit.

Component 2.3

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

Yes

Free text box, no character limit:

Savings on research costs within the food regulatory system may be possible without changing the existing system and legislations. Greater collaboration with universities and other research agencies may reduce costs associated with surveillance and other research activities by attracting university students (e.g. on PhD scholarship) to undertake research on FSANZ-initiated projects. Higher education research and/or research agencies may apply for Commonwealth and/or private sector grants and/or matching funding, e.g. ARC-linkage. This has the benefit of engaging specialised research expertise.

However, careful, informed, and technically skilled national coordination and ongoing management of such projects is required to consistently deliver intended outcomes. This would require additional long-term, consistent funding of such positions, potentially within FSANZ.

Other cost savings may also be possible without changing the existing system and legislation. For example, digital compliance monitoring and streamlined analysis reporting could result in cost savings for jurisdictions and FSANZ.

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?

Yes

How would this need to be implemented to be successful?

Free text box, no character limit:

It is important that FSANZ, as a scientific and technical body that prepares food standards, needs to be well aligned with food regulation policy priority setting framework of state, territories, the Commonwealth and New Zealand governments. FSANZ priorities for dealing with applications and proposal are already discussed at Food Ministers' Meetings, however, this could be elevated to a broader discussion about a shared vision of system priorities that extends further than prioritising work on applications and proposals.

It needs to be kept in mind in establishing any mechanism for developing shared system priorities, that Minister's may have little technical, or policy related knowledge of food policy and standards issues and that they may rely heavily on briefings by their departments and the deliberations and decisions of FRSC. Furthermore, in the past it has sometimes been difficult to get ministers on the Food Ministers' Meeting engaged on food regulation issues and Food Ministers' meetings may be attended by proxies rather than relevant ministers. As such, the role of the FRSC would need to be considered in the establishment of any FSANZ and FMM joint priority setting mechanism.

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

Free text box, no character limit:

In addition to the factors listed on page 63 of the report under Component 2.4.1 (that is, public health and safety, strategic plan, bi-national issues, other plans, emerging trends and evidence base), consideration would need to be given to (1) resources and (2) any urgency to deal with an emergent issue or threat (ideally in a proactive manner). Emergent issues may include the introduction of a new technology. Past examples of novel technologies have included irradiation, genetically modified food, and presently the development of cell-cultured foods. Past threats have included new diseases like bovine spongiform encephalopathy.

Whatever the mechanisms for agreeing system priorities, they will need to take account of how these priorities might vary, for good reasons, among different jurisdictions.

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

Free text box, no character limit:

No comment.

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:

It is agreed that it would be helpful for a formal mechanism to be established for FSANZ and FRSC to engage with each other on the development of food standards, which currently need to go via the Food Ministers' Meeting. However, it is acknowledging that FSANZ has recently proactively engaged with FRSC on some standards related matters, like targeted consultation on Proposal P1062 Defining added sugars for claims.

A formal mechanism for FSANZ to engage with FRSC to create a shared understanding of objectives and limitations with regard to food standards development would be helpful for clarifying the scope of proposals.

A formal mechanism for FSANZ to engage with FRSC would also be helpful for matters identified outside the scope of FSANZ that may need to be progressed by FRSC or referred to other forums to manage. While FSANZ does not have a role in setting food regulatory policy, FSANZ may identify issues during assessing applications and proposals that require policy consideration (e.g. as a result of innovation) but fail to raise these with the FRSC. This may result in policy effectively being set by the progression of industry applications setting a precedence rather than through policy processes considering a broader range of issues. Failure to progress policy work 'outside the scope of FSANZ' has previously resulted in some matters being unnecessarily being stalled. For example, when FSANZ was considering an application to permit low-THC hemp seed foods, it dismissed certain issues as being out-of-scope (e.g. policing, drug minimisation, medical cannabis regulation concerns) and did not raise these as policy related matters that needed to be resolved. As a consequence, a review was requested by the FMM and permission for low-THC hemp seed food products could not be implemented until a number of policy issues were addressed including amendment of state and territory legislation.

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

Free text box, no character limit:

Consideration could be given to FSANZ formally engaging with FRSC in relation to the scope of important and major proposals to ensure there is agreement and a shared understanding. This may potentially reduce the risk of proposals ultimately being rejected.

Consideration should also be given to a formal mechanism for FSANZ to advise of out-of-scope issues identified during proposals that may require further policy work or be referred to other forums or agencies to progress because some issues are broader than food policy and regulation. For example, out-of-scope issues may relate to Australian Consumer Law, drug policy and policing. Furthermore, implementation of some food standards may require amendment of state and territory laws, for example, previously the sale of low-THC hemp seed foods and in the future the production of cell-cultured foods. Ideally, and more efficiently, out-of-scope issues may need to be considered by FRSC and if necessary, then referred to FMM if they require formal referral to another ministerial forum or agency.

Possibly FSANZ could engage discussion with FRSC by lodging agenda papers for discussion at FRSC. For more strategic discussions such as priorities could be held in longer workshops, possibly in conjunction with other strategic workshops held by FRSC on an annual basis.

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:

It is appropriate for FSANZ to assume a role as database custodian for Australia on key food composition, nutrition and food safety data directly relevant to the role of FSANZ and food standards. It needs to be acknowledged that FSANZ has held this role in relation to the Australian Total Diet Study and other datasets, and that this role should be maintained and enhanced to improve intelligence-led decision making in relation to food standards.

It needs to be acknowledged that database custodianship requires long-term funded staffing and infrastructure (i.e. IT systems) to support the databases. Suitable protocols and processes must be established to ensure privacy, the security of the databases and the ability of jurisdictions to access data for their own approved purposes. FSANZ's independence must also be retained.

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

Free text box, no character limit:

FSANZ should be the guardian of key composition and nutrition data bases which underpin food standards including labelling (NIP, health claims). Furthermore, support is given to FSANZ maintaining the data it already holds on monitoring the safety of the food supply and continuing these functions in relation to the Australian Total Diet Study, Implementation-Subcommittee food surveys, surveys undertake by or for FSANZ on various contaminants, and food safety standards baseline studies. All these studies were undertaken with a view assessing food safety and nutritional risks and informing the development of better food standards.

Although some food safety data is held by FSANZ, such as food recalls due to notifiable pathogens, other food safety data is more properly held by other agencies. For example, OzFoodNet holds epidemiological data about incidence of food-borne pathogens (at whole genome level), outbreak investigation findings relating to food pathogens and consumer consumption patterns and can provide early warning of a potential outbreak. There does not appear to be value in FSANZ taking guardianship of this database, though it is acknowledged the information may be valuable to FSANZ when microbial risk assessment for standard setting and preparing imported food risk assessments.

The role of FSANZ has a database custodian needs to be clarified in relation to the newly established Australian Centre for Disease Control to ensure there is not duplication. Furthermore, opportunities could be explored for the two agencies to work collaboratively in relation to food safety data (particularly for microbial foodborne illness pathogens) and help build national capability under the One Health model.

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:

Cautious support is given to building of better strategic relationships with comparable international agencies to share assessment or standards to make these together for mutual benefit as part of the harmonisation process and participating in relevant food standards forums and committees to enhance Australia and New Zealand's influence. However, extending the international role into other areas such as policy and trade should be the role of other government agencies and not the remit of FSANZ.

Potential benefits for jurisdictions include reduced costs associated with regulatory assessment work and access to contemporary data about food safety risks, population health, food consumption and consumer expectations to inform priorities and policy. Greater international harmonisation may also assist with trade opportunities.

The international role of FSANZ could be enhanced through a more collaborative role and through greater participation and sharing of information with jurisdictions and other stakeholders.

Intelligence FSANZ obtains from some international forums could be shared with jurisdictions, particularly where it may help inform monitoring and enforcement decisions, food regulatory risk assessment, and state/ territory food legislation.

What should be the focus of such information sharing arrangements?

Free text box, no character limit:

Sharing of safety and risk assessments with comparable international jurisdictions to assist in reducing duplication appears appropriate where confidentiality can be maintained and data interpreted within the context of Australia.

It should be noted that FSANZ already has a role in sharing food incident and food recall information for internationally traded foods via the International Food Safety Authorities Network (INFOSAN) and other networks such as the European Commission Rapid Alert System for Food and Feed (RASFF). These arrangements need to be maintained. Consideration may need to be given to whether any changes are required to the FSANZ Act to facilitate the sharing of information on investigations and recalls with other countries. Many foods are sourced in whole or part from overseas or exported. It is important that Australia be able to effectively communicate and collaborate with other countries in relation to unsafe foods.

Component 2.4.5

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

Yes

Free text box, no character limit:

Inclusion of statements of intent may help ensure that the policy position and intent of the standard is clear. However, they may only assist with interpretation of the Food Standards Code only if drafted well and do not restate the obvious. Furthermore, statements of intent may be less effective for requirements (e.g. for specific products) that are spread across multiple parts of the Code.

Versions of statements of intent (purpose statements) were previously included in food standards but were removed when the Food Standards Code's drafting was reviewed in 2016. The need for purpose statements was somewhat reduced with the inclusion of the Basic Requirements provisions (Standard 1.1.1 Division 4) in the Code that link food standards back to the requirements for sale of food and offences in State and Territory Food Acts.

FSANZ now publish an 'explanatory statement' in the approval report for each application and proposal that is similar to the proposed statements of intent. These are published on the FSANZ website under the name of each application and proposal but appear to not be published on the Federal Register of Legislation. However, due to the horizontal structure of the Code, it may be difficult to cross reference them on the Federal Register of Legislation site. It should be noted that the approval reports for older applications and proposal do not include an explanatory statement. Potentially the explanatory statements in the approval reports could fulfil the purpose of the statements of intent if they are more accessible, that is publicly available in a consistent manner and able to be easily searched.

It would also assist if greater emphasis were given to clearer drafting of standards (including definitions) to ensure they are easier to interpret. The structure of the Food Standards Code makes it difficult to interpret some requirements due to the requirements being scattered across multiple parts of the Code (i.e. horizontal structure) and the need for extensive cross referencing. As such, the statements of intent may not in their own right solve the

regulatory problem but assist with the other options, particularly guidelines that can include 'vertical' guidance on the horizontal structure of the Code.

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:

The underlying policy and intent of the standard written in plain English. They could include the purpose of the requirement and a plain English explanation of the requirement.

It should be noted that FSANZ currently publish the purpose and a short explanation of each requirement in the approval reports for each application and proposal provided to the FSANZ Board and Food Ministers' Meeting.

General statements of intent for each standard in the Code may provide some guidance but be of lesser value for interpreting requirements that are spread across multiple standards. If statements of intent are published solely within approval reports (akin to Bills), it could become complicated and confusing when there have been multiple amendments of a requirement.

One of the current difficulties for interpretation of requirements for specific food products is related to horizontal structure of the Code which means requirements may be spread across multiple standards. For example, requirements for kava may be found in multiple standards within Chapter 1, Standard 2.6.3 and multiple schedules. In the case of kava, a general statement of intent stating the intent was to ensure kava beverage is prepared and consumed in line with historically safe practices may have been useful in clarifying whether colourings and flavourings were permitted, but to improve understanding may need to be also supported by guidance material to assist the lay public identify specific requirements relevant to kava.

To ensure statements of intent are useful, consideration will need to be given to the best way to publish them and make them searchable considering historical changes to a requirement. For example, some standards are regularly amended, which could result in multiple statements of intent making it difficult to identify the relevant one.

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

Free text box, no character limit:

FSANZ previously provided guidelines on the Food Standards Code that included useful practical examples for industry. Whereas statements of intent could assist consistent interpretation of the standards, guidelines could focus on their practical application.

FSANZ is best placed to develop the guidance information on the Food Standards Code due to their scientific and technical knowledge and understanding of the intent of the drafting of food standards. FSANZ can also more efficiently develop these during or shortly after standards development and place on their website for jurisdictions to link to from their own websites rather than each jurisdiction recreating similar guidelines.

Guidance on the Food Standards Code will assist jurisdictional consistency, be beneficial for multi-jurisdictional businesses, make it easier for businesses to understand requirements and hence comply, and improve the agility of the food regulatory system. Clarification may reduce the number of industry enquiries to regulators (local and state government).

There is a spectrum of different types of guidance, which span from general guidance material on food standards through to advice provided on a specific issue to businesses considering their unique circumstances. When developing this option, it would be useful to rank the types of advice on such a spectrum to help decide which are most appropriate, benefit the widest number of stakeholders and help solve the policy problems.

Interpretation in a general context, provided it is correct, should not be considered an enforcement function. Consideration should be given to minimising conflicts with enforcement, equity in providing advice to small to medium businesses that may not otherwise be able to afford suitable advice, and food enforcement agencies being also able to access interpretive advice from FSANZ.

The challenge of inconsistencies goes hand-in-hand with inconsistencies of the Food Standards Code. Instead, the Food Standards Code should be able to be amended in a timely manner to consider areas where inconsistencies arise and ability to keep up to date with emerging trends and new food safety issues. While some types of advice can help interpret drafting of food standards, this should be considered a short-term strategy, and mechanisms implemented to correct unclear food standards or clarify its intent.

For interpretive advice, the approach could be that these matters are reviewed through a mechanism where more people/agencies have input such as through a committee that includes jurisdictions. Consideration should be given to mechanisms where interpretation is carried out by a diverse range of stakeholders which may ultimately arrive at a better outcome.

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?

No

Free text box, no character limit:

It is not clear that it is necessary to amend the FSANZ Act to allow FSANZ to do this. FSANZ should consult with stakeholders such as First Nations, Māori peoples, and Culturally and Linguistically Diverse (CALD) communities to ensure guidance material is culturally appropriate and support its uptake.

Component 2.4.7

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

No

Free text box, no character limit:

Jurisdictions currently collaborate extensively with FSANZ as partners in the food regulatory system. FSANZ could take a lead role on the interpretation of food standards and enhance collaboration with jurisdictions on interpretation matters as discussed in previous questions.

As FSANZ is not an enforcement agency and does not have any enforcement powers, FSANZ should not provide advice or collaboration on the enforcement of the Food Standards Code. Enforcement is dependent on several factors and is based on food safety risk, business compliance history, and jurisdictional priorities (often external to the remit of food safety officers). The Food Standards Code is enacted through jurisdictional legislation and, while based on the model food provisions, there are differences in each jurisdictional legislation which would limit a whole-of-government approach to enforcement decisions.

Component 2.4

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

Yes

Free text box, no character limit:

Ambiguity in the Food Standards Code leads to inconsistencies in interpretive advice provided by jurisdictions and potential duplication of effort when additional information to explain a standard/s is required.

For example, Queensland Health Food Standards and Regulation has developed a business regulatory reform initiative to create a digital food safety hub, known as the Food Pantry, to better facilitate information sharing between regulators, small to medium enterprises and their consumers to improve food safety in Queensland. One of the components of the Food Pantry is Label Buster, a step-by-step guide for businesses to identify the information they need to create a food label. A similar solution provided by FSANZ could be beneficial for all jurisdictions and industry.

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:

No comment.

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

Free text box, no character limit:

No comment.

What are the current delay costs to industry?

Free text box, no character limit:

No comment.

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:

A report on the costs of inconsistency was prepared by mpconsulting for the Jurisdictional Consistency Project, a component of the Priority 3 suite of work. The Key Areas of Inconsistency section includes many references to costs relating to the development and implementation of standards. It is acknowledged that this report may have already been considered through the Impact Analysis process.

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

Yes

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It is noted that the Impact Analysis does not include the cost of a highly processed food supply on long-term health and the impact on the increasing costs of treating chronic health conditions on jurisdictional public health systems. These costs should be considered to provide a balanced assessment of the proposed changes.

In quantifying public health benefits for Option 1 (status quo), it is not clear what is meant by 'public health benefit'. The cost-benefit analysis should clarify what this means and describe both short and long-term impacts (including on diet-related chronic illness).

An underlying assumption of the discussion of Option 1 also appears to be that all applications result in a benefit for consumers and public health. Applications are the process through which an individual business achieves market access for a new product or ingredient. The presence of new market access for an ingredient or product does not always result in a safer or healthier food supply; the benefit is mostly commercial. It can often result in products that can contribute to poor long-term health or those that have questionable benefits (such as formulated supplementary sports foods and formulated caffeinated beverages). It is important to consider that the public health and safety benefits (short or long-term) are more certain with the status quo than in the introduction of a new ingredient or product. The cost-benefit analysis should more clearly articulate the public health impacts of applications.

It is also noted that there has been allocated delay costs to industry applications but not allocated delay costs to proposals. Some proposals take up to 20 years or more to progress which results in delayed costs for public health, industry and jurisdictions.

It is also unclear why the 'Review of the regulatory management of food allergens' has been used as the basis to determine the average public health benefits of proposals. A number of more recent proposals have quantified public health benefits, such as those in P1050 Pregnancy Warning Labels and in the proposals for mandatory fortification with iodine and folic acid.

It is also unclear how the costs of developing and communicating food standards was determined. Specifically, the statement that FSANZ bears 86% of the total resourcing costs. Further clarification on how this was determined would be beneficial. Jurisdictions dedicate extensive resources to assisting FSANZ in the development of food standards and are responsible for the communication, interpretation, and enforcement in each of their own jurisdictions.

In addition, we believe the statement "the majority of the food safety regulation costs are borne by industry and FSANZ to achieve public health outcomes" is not correct as food safety regulation is a partnership between FSANZ, Australian States and Territories, the Australian Government and the New Zealand Government. The costs for food safety regulation is therefore also shared across each of these agencies. For example, in Queensland, the regulation of food safety is the responsibility of Queensland Health, Safe Food Production Queensland, the Department of Agriculture and Fisheries and 77 local governments.

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 costs and benefits to jurisdictions, separate from the Australian Government, could be quantified in further detail. For example, the quantifiable cost included for cost recovery of the proposed food recall coordination levy and for adding items to the workplan is a combined cost of \$AUD 7.8million. What is the proposed cost for each of these two separate cost recovery models? What is the proposed cost per jurisdiction? In addition, the costs and benefits to jurisdictions on changes to applications and proposals is not included in Option 2.

The burden of chronic disease caused by consumption of a highly processed food supply should be considered. This issue has been previously raised by reputable public health groups.

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

Yes

Free text box, no character limit:

A range of data from reputable public health and academic institutions has previously been provided. This data, along with the national and international burden of disease work should be incorporated into any cost-benefit analysis if this has not already been included.

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

Yes

Free text box, no character limit:

The cost of chronic ill-health created by a highly processed food supply should be included in this analysis. Consideration should be given to the overall impact of applications on public health, the delay costs of proposals and the underlying assumptions for public health benefits being based on the regulation of allergens. In addition, greater consideration should be given to quantifying the public health impact of the proposed reduction in regulatory oversight. The underlying assumption in attributing a public health benefit to applications is presumably due to the nature of FSANZ's pre-market safety assessment process but has not adjusted this under Option 2.

The Impact Analysis suggests that one of the benefits of these reforms will be in freeing up FSANZ to process more proposals and in a timelier manner, however Option 2 indicates that the number of proposals will remain the same. In addition, there is no commentary on the proposed timeframes to complete proposals. While proposals can vary in complexity, it is generally recognised that timeframes of 10 to 20 years (as taken with several proposals currently) are excessive.

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?

Yes

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Consideration should be given to comments previously provided under Section 3 above in relation to certain sub-problems and suggested solutions to improve the extent to which the policy problem is solved by these reforms.

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

No

Free text box, no character limit:

The ratings are quite general and rely on a number of unclear criteria and assumptions.

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

Free text box, no character limit:

In relation to the Option 2 risk 'Alignment of definitions could inadvertently widen the scope for FSANZ and its role in managing public health risks', the Impact Analysis report shows that there is quite a high likelihood of there being a moderate risk that clarifying the definition of the protection of public health and safety within the FSANZ Act to be in line with current policy guidance could inadvertently widen the scope of FSANZ's remit in managing public health risks.

We consider that the risk is lower than stated in the Impact Analysis on the basis that the consideration of longer-term risks of non-communicable food-related illness is already routinely included as part of FSANZ's remit. The Impact Analysis indicates this will largely be a new function for FSANZ, despite FSANZ currently being able to consider long-term risk.

In relation to the Option 2 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 Impact Analysis has assigned a very low-risk rating of 5 and does not adequately reflect that the gazetting of food standards will not only bypass review by the independent FSANZ Board, but also be overseen by non-elected officials.

Consideration also needs to be given to the cumulative risks of the combination of the decision-making processes for low-risk amendments with other proposed pathways for low-risk amendments such as acceptance of overseas risk assessments and minimal check pathways. The overall risk for the protection of public health as well as for the protection of Australia's reputation for a high quality and safe food supply could be significant.

It will also be important to understand how delegated government decision-makers would be authorised to request a review if they had concerns about the proposed amendment. Alternatively, consideration could be given to changing the 'low risk' status of a proposed amendment to higher risk should there be any jurisdiction that does not support the amendment.

In relation to Option 2 risk 'Application of a levy on select industry participants could contribute to financial stress in a sector that is already feeling overwhelmed', the Impact Analysis does not include the risk that the levy will be passed onto consumers further increasing the costs of food and groceries, with a flow-on reputational risk to the Australian Government with the current cost-of-living crisis.

In relation to Option 2 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', this risk does not include any reference to the other proposed cost recovery of jurisdictions to add items to the workplan/Proposals. This risk should be further considered.

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

No

Free text box, no character limit:

See comments in the previous section.

Section 9 - Evaluation of the preferred option

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

Yes

Free text box, no character limit:

In Figure 11 Conceptual Approach for the Evaluation of the Preferred Option, consideration should be given to including be an outcome relating to the impact of the reforms on the Section 3 Object and Section 18 primary objective relating to the protection of public health and safety. This could be included in the measuring success against key outcomes.

Other comments

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

Yes

Free text box, no character limit:

While FSANZ currently does not develop food policy, it frequently identifies issues during its consideration of applications and proposals that should be addressed as policy issues and need to be raised for policy consideration. This could occur with new or novel food, substances, or processes and emerging trends.

The failure to identify and advise the Department of Health and/or Food Regulation Standing Committee has resulted in some issues unnecessarily being stalled. For example, when FSANZ was considering an application to permit low-THC hemp seed foods, it dismissed certain issues as being out-of-scope and did not raise these as policy related matters that needed to be resolved, such as policing concerns. A mechanism needs to be identified where policy issues identified by FSANZ during consideration of applications and proposals can be raised for policy consideration, whether this is considered through the application and proposal process or referred to another agency for out-of-scope matters.

It is important that food regulation keep abreast of emerging issues so that food standards can be kept contemporary. FSANZ has invested resources in considering new developments such as novel food production techniques (e.g. CRISPR-Cas9), acrylamide and nano particles. It is important that this continue to be supported, and it is important that FSANZ raise food standards problems they identify with policy makers so that the work of maintaining food standards receives suitable policy consideration.

It is important to ensure FSANZ has the best opportunities to recruit staff with the necessary skills and to assist in stakeholder engagement. This could possibly involve FSANZ establishing offices outside of the ACT.

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:

No comment.