

Introduction

Have you read the Impact Analysis?

Yes

Demographics

What is your full name?

Full name:
Victoria Taylor

Are you answering on behalf of an organisation?

Yes

What is the name of your organisation?

Organisation name::
Cellular Agriculture Australia

Which sector do you represent?

Food Industry

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:

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

Free text box, no character limit:

Section 3 - The problems to solve (Ratings)

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

Not Answered

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:

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?

No

Additional comments (optional):

FSANZ already considers short and long-term risks to health when developing food standards. Hazard and Risk Assessments include toxicology and dietary exposure assessments. Re-defining public health and safety may create expectations that FSANZ will move into the nutrition and preventative health space. This is not FSANZ's role. FSANZ must avoid any scope-creep that could dilute their focus and distort alignment with international standards, thereby adversely impacting trade.

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):

FSANZ' role is to manage a risk & evidence-based system designed to strike a balance between social (safety) and economic (trade) imperatives. Any change that requires assessments to consider public health (beyond existing requirements) will create a material impact. FSANZ needs to demonstrate how this fits within their remit. FSANZ will need to demonstrate how they propose to align this with existing government approaches to public health without duplicating existing activities further eroding efficient food safety regulation.

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

Negative

Additional comments (optional):

It depends on the definition used. Public health can cover dietary guidelines and healthy eating advice through to epidemiology and disease control. FSANZ must seek to promote a competitive and innovative food industry through rigorous food safety assessments, CAA is concerned that any definition beyond the current food safety requirements will create even greater uncertainty for applicants.

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?

Not Answered

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

Free text box, no character limit:

Component 2.1.3

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

Not Answered

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

Component 2.1

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

Not Answered

Free text box, no character limit:

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:

CAA strongly agrees that several FSANZ processes appear to be rules-based, rather than outcomes-based, so sees merit in introducing a risk-based framework. However, the proposed risk framework included in the consultation paper is quite limited. We would welcome the opportunity to contribute further in creating a framework that encompasses a wider scope. The focus on assessing risk in relation to a potential public health impact or health outcome, and then aligning regulatory actions to the risk level, is supported. This will ensure applicants are providing evidence and data central to food safety assessments, rather than additional data required under rules that may lack strong alignment to human health needs.

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

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

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:

The regulation of foods made using cellular agriculture technologies (precision fermentation and cell cultivation) is currently being determined by safety assessments in a number of jurisdictions, including Australia-New Zealand, Canada, the United States, Singapore and Israel.

It is our understanding from discussions with relevant FSANZ representatives that a commitment exists to share information between jurisdictions, but there is merit in formalising such an arrangement. We note the consultation paper highlights that approximately half of all proposals and applications made to FSANZ each year relate to minor processing aid amendments, including substances approved in other international jurisdictions. This appears to be a highly inefficient use of FSANZ resources, and any opportunity to reduce duplication to enable FSANZ resources to be allocated to more compelling and complex issues would be supported.

CAA acknowledges the consultation paper's reference to the Therapeutic Goods Administration's (TGA) Comparable Overseas Regulator (COR) regime, which we believe provides a useful model. This could allow FSANZ to use assessments from CORs where possible, in assessing food safety applications, reducing the amount of time and cost for applicants. We agree that a COR must be sufficiently similar to FSANZ, with consistent standards to support collaborative work, and where formal MOUs have been signed to underpin work-sharing in clear, open and secure communications. CAA also supports the introduction of a minimal check pathway that would expedite approvals for products that have been approved by a COR.

As technology and regulatory science is moving quickly, CAA sees value in FSANZ undertaking an annual harmonisation process to consider adopting new standards into the Food Standards Code. CAA, therefore, supports the recommendation that the Act be amended to enable FSANZ to formally recognise and adopt the assessment and determinations of "overseas bodies." However, CAA does not recommend that FSANZ be compelled to accept assessments automatically and that Australia-New Zealand's particular interests must be served. This is particularly relevant to the cultivated meat sector, where some European Union members implemented bans on the production of these foods.

FSANZ must also be ready to respond publicly as to why a certain assessment approved by a COR was not, or will not be, accepted.

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?

Not Answered

Free text box, no character limit:

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

Yes

Free text box, no character limit:

Such schemes (eg GRAS in the US) are in place globally and function without incident.

We understand FSANZ' current approach to colours and flavours is an example of such a minimal check pathway already operating. Therefore, CAA would support further minimal check pathways being introduced – including extending this to processing aids. We are not aware of any other regulator requiring full, pre-market assessment for processing aids.

Another efficient method for handling applications could be to create an annual omnibus proposal pathway and group like-substances into such in the same way that the annual MRL omnibus approach has functioned for some time.

CAA would also like to see greater risk-based scrutiny applied to the definition of “novel food.” As applications are assessed and the Code amended, how long should a product remain novel, requiring a specific individual application per product?

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:

CAA believes FSANZ should consider additional pathways to amend food Standards. Currently, scale-up cellular agriculture companies must submit an application in lieu of the Standards providing a clear pathway to approval. FSANZ makes recommendations for amendments to the Code at the same time as the assessment is undertaken. Small food companies are being asked to bear an enormous cost and risk in applying for an assessment where there is no certainty about their eligibility under existing Standards (a major procedure assessment for a novel food costs approximately \$200,000). When CAA has sought advice on seeking changes to the Code to support novel food companies in developing their application dossiers, the advice has been that changes will only be made on the basis of an application. While we appreciate the resource requirements for FSANZ to amend food Standards in anticipation of future applications are potentially high, all risk and cost is currently being borne by small food companies.

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

Positive

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

Component 2.2.3

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

Yes

Free text box, no character limit:

CAA supports the delegation of low-risk proposals from the Board to the CEO to create efficiencies. This should be subject to periodic stakeholder input and Ministerial oversight to ensure it functions as intended. We suggest that good governance would include a mechanism for the CEO to refer low-risk items to the Board in the event of an unexpected stakeholder or technical issue.

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

Free text box, no character limit:

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

Positive

Free text box, no character limit:

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

Free text box, no character limit:

Component 2.2.4

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

Not Answered

Free text box, no character limit:

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?

Not Answered

Free text box, no character limit:

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:

CAA strongly agrees that regular standards reviews should be core business for FSANZ. It is assumed that FSANZ already has the capability to undertake the suggested monitoring, environmental scanning, consultation and data analysis to understand where revisions are required. It is a logical extension that this sectoral awareness is converted into action, providing a fit-for-purpose regulatory system.

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

Not Answered

Free text box, no character limit:

Component 2.2.6

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

Yes

Free text box, no character limit:

CAA supports the use of Codes of Practice and guidelines to reduce the regulatory cost and overall burden on doing business. These should be developed with industry stakeholders and involve the enforcement agencies. Without the latter, they would lack effect and potentially exacerbate inconsistent implementation of the Code.

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

Free text box, no character limit:

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

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

Component 2.2

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

Not Answered

Free text box, no character limit:

Component 2.3

Component 2.3.1

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

Yes

Free text box, no character limit:

CAA does not have a strong opinion on the composition of the FSANZ board but notes representative boards in a government context are inconsistent with contemporary governance principles. Independent directors recruited via external and transparent processes is likely more appropriate, and consistent with many other government boards.

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

Not Answered

Free text box, no character limit:

Component 2.3.2

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

Negative

Free text box, no character limit:

This would have a major effect on food innovation. There is a relationship between the more efficient use of FSANZ resources and removing the option for expedited assessments. If the Act allows a more efficient approval process, for example, with the option to accept overseas assessments (particularly for minor processing aid amendments), then a corresponding decrease in assessment times should be the logical outcome. That said, the ability of a company to make a commercial decision to apply for an expedited assessment is an acceptable option in a user-pays environment.

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:

CAA does not support an industry-wide levy, as it will increase the burden on companies and stifle innovation, particularly for emerging technologies being pursued by pre-revenue start-up companies.

A more appropriate way to improve FSANZ resourcing is to increase government funding.

We note that comparable international bodies invest significantly more resources to support standard-setting. The Impact Analysis outlines the funding shortfall of Australia - New Zealand relative to other countries (noting some overseas regulators have a wider scope).

We submit that there must be a balance between funding FSANZ to ensure the integrity and rigour of our food safety system is maintained, and providing a cost-efficient regulatory system that encourages innovation and new applications.

Feedback to CAA from cellular agriculture companies (domestic and international) highlights the high cost of engaging with FSANZ, compared with the US and Singapore (who do not charge fees). Considering the relative size of the consumer markets in those three jurisdictions, current costs make Australia-NZ the least attractive market for new applicants.

On 4 April 2024, the Singapore Food Authority approved an application from Australian-based company Vow to sell their cultured quail in Singapore. In announcing the approval, Vow stated "We knew we wanted to launch our products into the Singaporean market first, not only because of the globally renowned culinary scene, but also because of the clear regulatory pathways and the ease of doing business."

Vow's paid application for FSANZ approval was submitted at the start of 2023, and has yet to progress to the second call for submissions, suggesting a two-year approval process. This is clearly inconsistent with a high-performing regulatory regime.

In this context, proposing a larger cost-shift on to industry would be unacceptable.

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:

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

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

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?

Not Answered

Free text box, no character limit:

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

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

How would this need to be implemented to be successful?

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

How would this need to be implemented to be successful?

Free text box, no character limit:

Component 2.3

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

Not Answered

Free text box, no character limit:

Component 2.4

Component 2.4.1

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

Not Answered

How would this need to be implemented to be successful?

Free text box, no character limit:

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

Free text box, no character limit:

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

Free text box, no character limit:

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?

Not Answered

Free text box, no character limit:

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

Free text box, no character limit:

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?

Not Answered

Free text box, no character limit:

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

Free text box, no character limit:

Component 2.4.4

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

Not Answered

Free text box, no character limit:

What should be the focus of such information sharing arrangements?

Free text box, no character limit:

Component 2.4.5

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

Not Answered

Free text box, no character limit:

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

Free text box, no character limit:

Component 2.4.6

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

Yes

Free text box, no character limit:

Industry guidelines would be beneficial, particularly for the cellular agriculture sector, where businesses are in pre-revenue, start-up and scale-up phase and are unlikely to have a dedicated regulatory expert on staff. Providing information that allows company founders to understand the regulatory requirements may drive innovation while decreasing the amount of contact with FSANZ for basic, industry-specific information.

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?

Not Answered

Free text box, no character limit:

Component 2.4.7

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

Not Answered

Free text box, no character limit:

Component 2.4

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

Not Answered

Free text box, no character limit:

Section 6 - Net Benefit

Section 6 - Net Benefit (Option 1)

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

Not Answered

Free text box, no character limit:

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

Free text box, no character limit:

What are the current delay costs to industry?

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

Section 6 - Net Benefit (Option 2)

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

Not Answered

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

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?

Not Answered

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

Section 8 - Best option and implementation (Delivery risks)

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

Not Answered

Free text box, no character limit:

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

Not Answered

Free text box, no character limit:

Section 9 - Evaluation of the preferred option

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

Not Answered

Free text box, no character limit:

Other comments

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

Not Answered

Free text box, no character limit:

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: