Submission regarding the Scoping Paper on the Review of the Food Standards Australia New Zealand Act, November 2020

1a Is there still a compelling case for regulating food?

We strongly agree with the statement that "there is a clear, ongoing need for regulation of food." However, we strongly disagree with the statement in the Scoping Paper that "food producers and manufacturers have a vested interest in assuring food is safe to eat." This is clearly not the case – unless "safe" is defined extremely narrowly. The industry has a vested interest in making money, ensuring that unsafe foods are not pulled from shelves and that regulation doesn't occur.

Over the years the food industry has consistently ignored the long term health impacts associated with unhealthy food and have failed to assess or monitor the combined effects of the cocktail of additives, chemicals and preservatives used in food. As history has shown, producing dangerous products, insisting they are safe, resisting analysis or regulation and delaying any regulatory action is a common business model seen in the food industry.

We also strongly disagree with the statement that "the food regulatory system can be improved, but it is not broken." Our food regulator - Food Standards Australia New Zealand (FSANZ) – is failing us. Whether it is additives that cause hyperactivity in children; endocrine disrupting food packaging; dangerous pesticide residues in food - or the use of novel ingredients such as nanomaterials and genetically modified (GM) ingredients in food – FSANZ has brought a pro-industry bias to its decisions that puts corporate interests before public safety.

FSANZ has become a permitting agency for a suite of destructive and unhealthy food production and consumption practices that an agency with public health and the public's interest in mind would not approve. This role is made even more pernicious by the agency's apparent determination to avoid labelling which would enable us to make informed choices about the food we eat.

Lawrence Lessig, the Harvard academic, describes this kind of conduct as institutional corruption. An agency, sometimes unconsciously, begins to redirect its functions towards 'agents of influence'. It conflates private interests with the public interest and so becomes fundamentally and structurally corrupted. Evidence of institutional corruption is to be found by tracking ordinary rather than anomalous outcomes.[1]

The ordinary outcomes from FSANZ processes, assessments and decisions provide overwhelming evidence that FSANZ serves corporate interests first. When faced with a choice between public and private interest, FSANZ supports the private interest. When faced with choice between commerce and precaution, commerce is preferred. There is no smoking gun in institutional corruption but a shape or direction that is defined by the pattern of daily activities of the organisation.

It is tempting to say that the current regulatory approach to food is severely out-dated, but that fails to recognise that in its current form, FSANZ serves business interests extremely well. We have voluminous and complex legislative structures, rife with loopholes, ambiguities, lack of standards, lack of enforcement and a firewall around public participation in implementing and enforcing these laws. FSANZ will always claim it works to a safety first standard, but behind the curtain of this mantra, business as usual operates without the level of accountability that is expected and urgently needed.

Putting our safety and right to know what's in our food first and foremost is not a radical position. These are the legitimate expectations of anyone in any democratic society. It is time for these priorities to become the new normal in our food regulation system.

1b What market failure(s) should governments seek to address through regulation of food?

Certain ingredients in food are demonstrably harmful and should be banned – these include trans fats. However, whilst other countries around the world are banning or restricting the use of manufactured trans fatty acids (TFAs) in food because of the health concerns[2], FSANZ continues to rely on out-dated World Health Organisation (WHO) advice and cherry-picked data to justify its failure to even require mandatory labelling. This means that foods high in trans fats are being dumped on some of our most vulnerable communities.[3]

Market theory relies on the idea that that consumers have sufficient information to make informed decisions about the foods they chose to buy. In fact, one of FSANZ's key objectives is to provide sufficient information for consumers to make informed choices. FSANZ is demonstrably failing to meet this key objective.

Polling shows that most consumers don't want to eat either genetically modified food or palm oil – but due to labelling loopholes, many are unwittingly doing so.

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2. Are there other significant focus areas that should be considered as part of the Review?

Friends of the Earth is deeply concerned about the opaqueness of this review. It states in the Scoping Paper that key stakeholders – including industry and government stakeholders - have been consulted since July 2020 and that this is what has informed the report recommendations. It is not revealed exactly who these stakeholders are and how they were selected. However, industry influence is clearly evident in the Scoping Paper and in many of its reform ideas. Friends of the Earth and other NGOs specifically registered as stakeholders but were not contacted for input. This is extremely undemocratic and not in the public interest.

We believe that if conducted well, this review could precipitate the overhaul of FSANZ that is so badly needed. However, these shaky beginnings do not inspire confidence.

It is clear that FSANZ needs an overhaul. This reform needs to happen thoughtfully and with certain principles at its heart.

These recommendations are not comprehensive but are the most fundamental of the changes that need to occur.

Recommendation 1: Amend the Objects of the Food Standards Australia New Zealand Act

- Ensuring food safety and our right to know what is in our food must become the primary objectives of the Act. These need to be clearly defined and enforceable standards and criteria established.
- Food safety must be defined specifically to consider long term and chronic diet related public health diseases, such as heart disease, diabetes and obesity.
- The right to know must recognise that citizens want and are entitled to a broad variety of information about the ways in which food is produced. Environmental, social, technological and ethical issues are all important – not just health issues. This needs to be acknowledged and recognised in law.
- All food regulations must be underpinned by the precautionary principle. We recommend the adoption of a definition similar to that of the US Food and Drug Administration, which requires a "reasonable certainty that the…substance is not harmful under the intended conditions of use." This must be an enforceable standard and 'harmful' must be broadly defined. This means that FSANZ must also ensure that it has sufficient data to make informed decisions and that in the absence of evidence of safety, food products or ingredients should not be approved.
- Current provisions in the Act that are based on encouraging business or trade are not appropriate for a food regulator. These provisions should be removed.

Recommendation 2: Significantly strengthen pre-market safety assessments

- Safety assessments must be based on public data subject to independent and unconflicted peer review.
- Industry data should never form the exclusive or primary basis for a finding of safety.
- Safety assessments must be based on sufficient data to make an informed decision;
- Data gaps must be identified and filled before approvals are granted.
- Safety assessments must be public, including the raw data that supports any finding.

Recommendation 3: Strengthen post-approval processes

- A surveillance, monitoring and reporting system is needed to allow the detection of long term, chronic or cumulative health effects not anticipated during the assessment process. Pre-market assessments should define the unresolved risks and uncertainties to inform monitoring and surveillance programmes.
- Clear guidelines are needed to trigger the review of existing approvals based on new information - particularly peer-reviewed materials and regulatory interventions overseas. Criteria for the review of new information must be put in place to ensure consistent, rigorous and reviewable assessments.

Recommendation 4: Strengthen labelling requirements

- The 'gaming' of labelling should be prevented by ensuring that only specifically permitted terms are used in labelling and that all ingredients used in food are listed.

Recommendation 5: Strengthen parliamentary oversight of and public participation in FSANZ's work and decisions

- The Act should be amended to allow the review of decisions taken by FSANZ that have substantive impacts on food, food safety and the public interest. Review provisions should include open standing and merits based review.
- The Food Code should be made a legislative or disallowable instrument subject to Parliamentary oversight and amendment.

Recommendation 6: Actively address industry bias and conflicts of interest

- An independent audit of the committees and consultants used by FSANZ should be undertaken to determine the extent to which potential or actual conflicts of interest exist.
- Clear enforceable regulations should be introduced to ensure that members of scientific advisory committees have no conflicts of interest.

Recommendation 7: Strengthen and clarify enforcement provisions

- Amend the Food Standards Australia New Zealand Act so that it is clearer that FSANZ is responsible for instigating, ensuring and coordinating the enforcement by other agencies of national food related issues such as food recalls.
- Enforcement must not be discretionary for any matters potentially relating to food safety or our right to know what's in our food.

OBJECTIVES

3. To what degree are the current legislated objectives an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

The object of FSANZ's Act is to ensure "a high standard of public health protection throughout Australia and New Zealand" and "a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand."[4]

The Objects clause of the Act also requires a labelling regime that provides "adequate information" so that the public can make informed choices.

Apart from the provision that calls for a 'high degree of consumer confidence in the safety of food' – which is about convincing the public that their regulator is doing its job – the priorities of the Act are essentially correct. Food safety and the right to know what's in our food should be the primary objects of the Act. So why then are we in the midst of a public health epidemic directly related to our diet? Why are new technologies being used in our food without being assessed for safety? And why is it so difficult to find out if our food contains a whole range of ingredients – including GM ingredients, palm oil, additives and nanomaterials?

The root of these problems lies in FSANZ's institutional corruption and policy based on an ideology that the market knows best.

Both the Objects clause and the broader regulations are not clearly drafted, interpreted, implemented or enforced and FSANZ itself is not subject to adequate levels of accountability or review.

The combined effect of these multiple failings is a regulatory regime in urgent need of a serious overhaul.

As Lawrence (2009) notes, "despite the protection of public health and safety being the primary objective in the setting of food standards, there is no clear definition of what this objective means in policy practice."[5]

However, FSANZ has taken an extremely narrow view of 'public health', limiting it to "acute safety concerns."[6] According to Lawrence, this position can be traced back to 1994 when the then Australian Food Standards Council declared a policy that in the absence of evidence of harm, trade and innovation should not be restricted.[7] This effectively shifts the onus of proof to civil society - forcing us to demonstrate harm, and abandons the implicit precaution in the Objects clause. Since 1994, FSANZ has fully internalised both the shifting of accountability and the pre-eminent place of trade and commerce in food safety decisions.

Similarly, FSANZ claims that it doesn't know how broadly to interpret its obligation to provide adequate information to the public, although it has consistently taken the narrowest and most pro-industry stance relating to any labelling requirement and resisted labelling, often on spurious grounds.

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4. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each idea best be achieved?

• Reform idea 1 –Define 'public health' and 'safety' in legislation to affirm the inclusion of long-term health and nutrition as a core objective

This Reform idea is strongly supported. Food safety must be defined specifically to consider long term and chronic diet related public health diseases, such as heart disease, diabetes and obesity. To date, FSANZ has taken an extremely narrow view of 'public health', limiting it to "acute safety concerns."[8] Even one of FSANZ's own committees has stated that:

"the absence of a definition of public health within the FSANZ Act has resulted in perceptions in the public health community that considerations around industry regulatory burden are given more weight than the economic and social burden due to poor diet and resulting ill health, and ambiguity regarding the public health role of the regulator when developing and reviewing food standards."[9]

Industry has been the obvious beneficiary of this culture of interpreting food laws in a minimalist fashion.

To implement this reform idea:

- All food regulations must be underpinned by the precautionary principle. We recommend the adoption of a definition similar to that of the US Food and Drug

Administration, which requires a "reasonable certainty that the…substance is not harmful under the intended conditions of use." This must be an enforceable standard and 'harmful' must be broadly defined.

- Safety assessments must be based on public data subject to independent and unconflicted peer review.
- Industry data should never form the exclusive or primary basis for a finding of safety.
- Safety assessments must be based on sufficient data to make an informed decision;
- Data gaps must be identified and filled before approvals are granted.
- Safety assessments must be public, including the raw data that supports any finding.
- A surveillance, monitoring and reporting system is needed to allow the detection of long term, chronic or cumulative health effects not anticipated during the assessment process. Pre-market assessments should define the unresolved risks and uncertainties to inform monitoring and surveillance programmes.
- Clear guidelines are needed to trigger the review of existing approvals based on new information - particularly peer-reviewed materials and regulatory interventions overseas. Criteria for the review of new information must be put in place to ensure consistent, rigorous and reviewable assessments.

• Reform idea 2 - Recognise trade as a core goal and reframe consumer choice as a factor to which FSANZ 'must have regard'

We strongly oppose this reform idea. Current provisions in the Act that are based on encouraging business or trade are completely inconsistent with the regulator's key objective of protecting public health. These provisions should be removed.

A key goal identified for FSANZ under its Act is "the provision of adequate information relating to food to enable consumers to make informed choices" and should continue to remain so.[10] Clearly our right to know what's in our food extends well beyond health issues.[11] Yet FSANZ consistently prioritises industry interests over that right.

A 2011, government commissioned, independent review of food labelling received hundreds of submissions. According to the review report, the "issues most frequently raised, in no particular order, included the welfare of animals, religious beliefs, environmental issues, human rights, methods of production and the country-of-origin of food products."[12] As the report noted, the food label is a convenient method to provide consumers with values information at the point of purchase.[13]

FSANZ consistently supports industry in minimising or rejecting labelling and in doing so fails to satisfy our right to know what is in our food. FSANZ may refuse labelling altogether (e.g. food colourings and chemicals used in food production), may utilise sham labelling rules that leave the vast majority of relevant foods unlabelled (e.g. GM labelling), may allow the renaming of additives as a way of avoiding labelling; or may claim that its powers are limited and that it cannot require labelling (e.g. palm oil labelling).

As the regulatory authority responsible for food labelling, FSANZ is responsible for ensuring that voluntary labelling systems meet the requirements of the Food Code or are exempted from its provisions.

One of the few labelling initiatives intended to deal with the public health epidemics of obesity and heart disease, is the voluntary health star rating system. This is so bad that confectionery can receive a higher rating than yoghurt.[14]

Marion Nestle, a prominent American academic in food politics notes that the Australian Government's star system is a lot like the industry star system in the US "but is even more favourable to manufacturers of processed foods."[15]

Most foods aren't labelled under this scheme and companies that do label certain products do it predominantly for marketing reasons - not as a mechanism to improve public health.[16]

FSANZ reviewed the proposed health star rating system[17] and decided to exempt it from the provisions of the Food Code that govern health claims made on food packages.[18] So, when Milo, which is 46 per cent sugar got 4.5 stars of out 5,[19] FSANZ effectively gave this misleading label the tick.

FSANZ has questioned the breadth of the Food Acts Objects clause:

> *"While the FSANZ's objectives include 'the provision of adequate information to enable informed consumer choice', it is not clear how broadly this objective should be interpreted particularly where matters of personal choice are concerned that are not directly related to food safety and nutrition."*[20]

The characterisation of a host of environmental, community and ethical issues – such as climate and food issues or animal welfare issues – as matters of personal choice is a deceptive attempt to dismiss the issues themselves as though they are nothing more than individual whimsy. Additionally, FSANZ has questioned whether concerns of a portion of the community should be addressed when regulation will impact the entire community – a logic that would mean virtually no labelling of anything, ever.

The lack of an interpretation of 'adequate information' is in itself an extraordinary admission by FSANZ – after all, the agency has presumably been implementing this objective of the Food Act for 25 years. Finally, the interpretation of adequate information as restricted to 'safety and nutrition' issues is not supported anywhere in the Food Act itself.

FSANZ has blamed its failure to provide adequate information on the requirement in the Handbook of Best Practice Regulation to prepare a cost benefit analysis for some regulatory changes, maintaining that because only a portion of the community will benefit, the cost to the broader community will be too high.[21]

FSANZ even tries to argue that labelling isn't very effective at changing behaviour without complementary measures,[22] apparently forgetting that it has the authority and power to implement a number of 'complementary' measures to food labelling, such as education.[23]

The labelling of the cocktail of chemicals used in food production is not required at all despite the large number of agricultural chemicals that are known to be dangerous to human health. For example, an ABC report in March 2015 revealed that pesticides banned worldwide are used to grow 70 per cent of Australia's strawberries.[24] Surely, we have a right to know this?

FSANZ argues that other regulatory bodies may be better suited for non-health related labelling,[25] although other regulatory agencies have no legal obligation to provide adequate information regarding food to the public.

There is a clear push from industry to limit labelling that may suggest that their foods are risky. For example, industry has successfully pushed on regulators to discourage manufacturers from labels such as 'non-nano' or 'GM free' because such a label suggests that there is something wrong with nanomaterials or GMOs.[26]

In order to make informed choices about what we eat, we need a labelling system that is accurate, responsive and gives us the kind of information we need.

Currently, FSANZ falls far short of that standard. The proposal to require FSANZ to have 'regard' to matters other than health, is far too weak a standard to support and is highly unlikely to result in any change to the current decision-making which is heavily biased towards industry interests.

Reform idea 3 – Establish criteria in the Act that the Forum must meet to request a review of a draft regulatory measure

We strongly oppose this reform idea. The Forum provides one of the few checks and balances that exist when it comes to FSANZ's decisions. However, the Forum is also an unaccountable body and its decisions can not be subject to judicial review which is problematic.

The example of two new genetically modified ingredients in baby formula referred to in Table 4 of the discussion paper provides a good example of why current provisions in the Act that are based on encouraging business or trade are so problematic and why the oversight role of the Forum is so important. Contrary to the discussion paper's assertion, states did not object to the proposal solely on the basis of a lack of proven health benefit. In their submission regarding the proposal, the Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions stated that "FSANZ has not sufficiently demonstrated the protection of public health and safety at the proposed levels" and that "the departments are concerned more broadly about the level of evidence deemed acceptable by FSANZ".[27]

Generally, 'decisions' of regulatory agencies are subject to review - firstly by Parliament - and then the courts. Under the Westminster system of laws, this kind of review is considered essential to the proper oversight of government decisions. However, most of FSANZ's 'decisions' on whether and how to regulate particular foods are not accountable to Parliament.

Standards or variations of standards under the Food Code are not disallowable instruments meaning Parliament does not have the opportunity to review a large number of FSANZ decisions.[28] These

standards include decisions regarding food labelling, any required warning statements, nutritional information and the approval of GM foods, food additives, nanomaterials, processing aids and chemical residues.[29] Many decisions resulting from these unaccountable regulations cannot be challenged by members of the public either.

Compounding those omissions is the high level of discretion that FSANZ has in its regulatory powers. Decisions, such as whether nanomaterials in food products are novel foods or new GM techniques are actually GM, can be taken by FSANZ without a formal decision and outside any regulatory process. These 'decisions' can result in FSANZ providing unpublished *ad hoc* 'advice' to manufacturers or simply ignoring new food ingredients or foods produced using new processes - thereby allowing them onto the market. The effect is to create a shadow regulatory regime free from oversight, accountability and review. Recent 'decisions' FSANZ has made include ignoring the presence of nanomaterials in food and interpreting the Act so that it doesn't apply to certain new GM techniques. Neither decision is subject to review and both are for the obvious benefit of industry

The public have few review rights.[30] Citizens cannot seek a merits[31] based review if FSANZ changes the Food Code, authorises a new food, fails to act to protect public health or fails to properly label food. Industry, on the other hand, is privileged with merits review for a host of FSANZ decisions.

Rather than weakening the already inadequate oversight of FSANZ's decisions, we need to strengthen parliamentary oversight of and public participation in FSANZ's work and decisions:

- The Act should be amended to allow the review of decisions taken by FSANZ that have substantive impacts on food, food safety and the public interest. Review provisions should include open standing and merits based review.
- The Food Code should be made a legislative or disallowable instrument subject to Parliamentary oversight and amendment.

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5. Are there other potential solutions to problems relating to legislated objectives?

A shortcoming of FSANZ's Act is that it creates a dual role for FSANZ, requiring that it consider the trade and business implications in everything it does. While facilitating business is not intended to be a priority of the agency, FSANZ has assigned this objective increasing importance. FSANZ's pro-business bias is both legislated and embedded in policy such as the deregulatory reform agenda of the Federal Government - one of the Government's top 5 identified priorities.[32]

A pro-business policy orientation is fundamental to the intergovernmental agreement between the governments of Australia and New Zealand that established a joint food standards system. The first objective of this agreement is "to reduce unnecessary barriers to trade."[33] One of the principles underpinning the Agreement is facilitating access to markets and the desirability of a competitive food industry.[34] The Australia and New Zealand Ministerial Forum on Food has developed a strategic guidance document for the food regulatory system. In this document the public health and right to know provisions of the Act are combined with the objective of supporting the food industry and more generally providing economic benefits to Australia and New Zealand.[35]

Similarly, the facilitation of innovation and trade is identified as one of FSANZ's Board's key functions.[36] Collaboration with industry is encouraged and reliance on industry data in making decisions is the norm.[37]

Current provisions in the Act that are based on encouraging business or trade are completely inconsistent with the regulator's key objective of protecting public health. These provisions should be removed.

FUNCTIONS

6. To what degree are FSANZ's functions (as currently stated in the Act) an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

FSANZ regularly misstates its legal obligations and powers, often ignoring or avoiding implementation or trying to pass problems onto state governments. For example, FSANZ has claimed it has no enforcement powers.[38] However, one of FSANZ's functions is, "in consultation with the States and Territories, to coordinate…enforcement.[39] FSANZ claims it is not responsible for overseeing the import of foods despite that explicit role being named in the Act as an agency function.[40] FSANZ also claims it is not responsible for the interpretation of the Food Code, [41] despite the agency providing interpretations of the terms used in part 3.1.1 of the Code.

FSANZ's claims are not only clearly false but are almost inevitably used to justify a lack of action to protect public health. For example, when Friends of the Earth showed that baby formula containing prohibited nanoparticles could be bought by Australians online, FSANZ claimed it is not responsible for restricting the import of foods not permitted in Australia. Administration of that role rests with the Australian Quarantine Inspection Service (AQIS). However, FSANZ is responsible for ensuring that AQIS has the information it needs to enforce the Food Code.[42]

Rather than providing advice to AQIS that these baby formula products should not be permitted in the country, FSANZ abrogated all responsibility by claiming the goods are not available for sale in Australia.[43] This linguistic nicety is legal nonsense. The effect of this pronouncement is clearly concerning since over 50% of Australians buy goods online. If FSANZ takes no role in enforcing food laws when it comes to imported products, then the agency has openly invited the import of potentially unsafe foods.

Under its Act, FSANZ has the power to coordinate food monitoring.[44] However, the agency has failed to monitor the health impacts of new foods and foods produced using new technologies. FSANZ conducts no monitoring of long term, cumulative and sub-lethal impacts of food consumption or the combined, cumulative and long term impacts of exposure to the cocktails of chemicals used in food production.

Even in those instances where regulation theoretically applies, this often amounts to little more than a rubber-stamping exercise. For example, FSANZ has approved every GM food application that has crossed its desk – even when there has been evidence of potential harm.

7. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?

• Reform idea 4 - Amend the Act to better reflect the functions FSANZ currently delivers, particularly as they relate to supporting long-term health and nutrition

We support this reform idea. Although we find the notion that FSANZ 'currently delivers' anything in relation to long term health and nutrition is somewhat bewildering. The Australian obesity statistics certainly suggest otherwise.

• Reform idea 5 – Amend s 13 of the Act to reflect a broader range of functions that FSANZ could deliver now and in the future

We broadly support this reform idea, but reject the suggestion in the discussion paper that there could be greater potential for collaboration between FSANZ and the private sector on food safety research. Industry research is notoriously biased and we are concerned that FSANZ is already too close to industry.

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8. Are there other potential solutions relating to FSANZ's statutory functions?

- Amend the Food Standards Australia New Zealand Act so that it is clearer that FSANZ is responsible for instigating, ensuring and coordinating the enforcement by other agencies of national food related issues such as food recalls.
- Enforcement must not be discretionary for any matters potentially relating to food safety or our right to know what's in our food.

LEGISLATIVE PROCESSES

9. To what degree are the current processes for strategically reviewing standards an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

Friends of the Earth has provided comment on many standards over many years, supported by robust scientific evidence. This has had no discernible impact on any of FSANZ's regulatory decisions – which have invariably favoured industry interests over public health.

FSANZ appears to have no clear mechanisms in place to review standards as new evidence of harm emerges. The agency has regularly failed to act when overseas regulators have banned or restricted food ingredients and additives because of evidence of harm. Such evidence should trigger an automatic review of standards.

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10. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?

• Reform idea 6 – Remove exemption of food standards from sunsetting arrangements

We are concerned that the exemption of food standards from sunsetting arrangements could potentially lead to the abandonment of certain regulations and labelling requirements, given FSANZ's pro-industry bias.

• Reform idea 7 – Resource FSANZ to undertake regular, more holistic reviews of food standards

We would support regular, more holistic reviews of food standards – providing that 'holistic' means a comprehensive examination of relevant scientific data on for example long term health effects – rather than just regulatory consistency with other countries.

Such reviews should be public – rather than just "in consultation with key stakeholders" as is suggested in the Scoping Paper (unless, of course, FSANZ accepts that the food eating public are key stakeholders).

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11. Are there other potential solutions relating to the timing of reviews of food standards?

In an ideal world, there would be an opportunity for consumer concerns to help prioritise reviews of food standards, as one input at least. The collection of adverse reports, as done routinely by the Therapeutic Goods Administration (TGA) but never by FSANZ could help inform priorities.

We believe a legislated periodic review of standards rather than sunsetting would be a more appropriate reform idea. This work would obviously need to be appropriately resourced by the Federal Government.

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12. To what degree are the current statutory application and proposal processes an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

We believe that a robust risk assessment framework is vital for assessing the risks associated with novel foods. According to the Scoping Paper, "half of all proposals and applications made to FSANZ each year relate to minor processing aid amendments" including those approved overseas. Importantly, many of these "minor processing aid amendments" are genetically modified ingredients that have never existed in the food supply before. Government regulatory oversight is vital to protect public health - and is recognised as such by CODEX guidelines on the safety assessment of GMOs.

The argument in the Scoping Paper that such regulation is a "barrier to innovation" priortises industry interests over public health. The European Environment Agency report *Late Lessons from Early Warnings* thoroughly debunks this now widely discredited idea.[45] Deregulation merely transfers the risks associated with the introduction of new technologies to society as a whole – while the economic benefits go to industry

We strongly oppose industry self assessment and voluntary industry initiatives. FSANZ's voluntary industry initatives on trans fats – which have failed to illiminate the presence of an ingredient for which there is no safe level - illustrate how completely ineffective such initiatives are.

We also strongly oppose giving FSANZ more discretionary powers to change food standards without government and public oversight. The sole beneficiaries of this would be industry, at significant potential risk to public health.

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13. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?

- **Reform idea 8 – Reframe legislation to support more agile, risk-based processes**

We strongly oppose the proposal to transfer much of the detail from the Act into the FSANZ Regulations and to provide for FSANZ and the Forum to ratify amendments. This would effectively remove parliamentary oversight. Accountability needs to be strengthened not weakened. Instead, the Food Code should be made a legislative or disallowable instrument subject to Parliamentary oversight and amendment.

Risk tiering approaches assume that the level of risk can be reliably quantified. This is a potentially dangerous assumption – particularly if it is based on industry self-assessment. We believe that all applications to FSANZ should be open to public consultation and that all novel food ingredients need to be assessed for safety by FSANZ.

- **Reform idea 9 – Redefine the decision-making arrangements to support timelier and more efficient sign-off of regulatory measures**

We strongly oppose the proposal that FSANZ not require sign off from the Forum for applications deemed by FSANZ to be low risk. This removes important checks and balances and is highly problematic.

Importantly, many of the "minor processing aid amendments" referred to in the Scoping Paper are genetically modified ingredients that have never existed in the food supply before. Government regulatory oversight is vital to protect public health - and is recognised as such by CODEX guidelines on the safety assessment of GMOs.

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14. Are there other potential solutions relating to streamlining current legislative process to develop or vary regulatory measures?

This is just code for the further weakening of our food regulatory system – which we don't support.

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15. To what degree is the current approach to using only applications and proposals to develop or vary food standards an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

Industry for 'streamlined' regulation and industry self assessment risk undermining the key objective of the Act which is to protect public health and safety. To maintain this key objective, we believe all applications to FSANZ should be open to public consultation and all novel food ingredients need to

be assessed for safety by FSANZ.

16. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?

- **Reform idea 10 – Provide for FSANZ to adopt or accept risk assessments from overseas jurisdictions**

We strongly oppose this reform idea. Harmonisation has been overwhelmingly used by FSANZ to justify lower standards rather than to harmonise with more stringent or restrictive regulations. For example in relation to nanomaterials and a number of new GM techniques, FSANZ has 'harmonised' with the US, which has rules significantly weaker than the EU. Similarly, the more precautionary approach of the EU to chemical approvals is regularly ignored in favour of the US model of minimum regulation.

Accepting US regulatory assessments would mean a weakening of Australian food standards – which is clearly not in the public interest.

- **Reform idea 11 – Enable FSANZ to adopt international standards**

We strongly oppose this reform idea. Harmonisation has been overwhelmingly used by FSANZ to justify lower standards rather than to harmonise with more stringent or restrictive regulations. For example in relation to nanomaterials and a number of new GM techniques, FSANZ has 'harmonised' with the US, which has rules significantly weaker than the EU. Similarly, the more precautionary approach of the EU to chemical approvals is regularly ignored in favour of the US model of minimum regulation.

- **Reform idea 12 – Create industry-led pathways to expedite applications and bring new products to market**

We strongly oppose industry self-assessment approaches. Leaving the decision about which products or ingredients are 'low risk' to industry is highly problematic. We reject the concept of 'Ethical Business Regulation' and the assertion in the Scoping Paper that "food businesses have a vested interest in assuring that the food products they sell are safe for consumers." Over the years the food industry has consistently ignored the long term health impacts associated with unhealthy food and have failed to assess or monitor the combined effects of the cocktail of additives, chemicals and preservatives used in food. As history has shown, producing dangerous products, insisting they are safe, resisting analysis or regulation and delaying any regulatory action is a common business model seen in the food industry.

We strongly oppose the proposal for industry self-certification, including 'listing' low risk products in the Food Standards Code. The comparison with the TGA's risk-based framework for complementary medicine is highly misleading. Most complementary medicines have a long history of safe use. Novel food ingredients quite clearly don't.

As the Scoping Paper notes, currently FSANZ's regulatory attention is focused on pre-market approval. Post approval processes need to be significantly strengthed, including the implementation of:

- A surveillance, monitoring and reporting system to allow the detection of long term, chronic or cumulative health effects not anticipated during the assessment process. Pre-market assessments should define the unresolved risks and uncertainties to inform monitoring and surveillance programmes.
- Clear guidelines to trigger the review of existing approvals based on new information - particularly peer-reviewed materials and regulatory interventions overseas. Criteria for the review of new information must be put in place to ensure consistent, rigorous and reviewable assessments.

17. Are there other potential solutions relating to additional pathways to develop or vary food regulatory measures?

Parliamentary oversight of and public participation in FSANZ's work and decisions needs to be strengthened, rather than further weakened:

- The Act should be amended to allow the review of decisions taken by FSANZ that have substantive impacts on food, food safety and the public interest. Review provisions should include open standing and merits based review.
- The Food Code should be made a legislative or disallowable instrument subject to Parliamentary oversight and amendment.

PARTNERSHIPS

18. To what degree is the current alignment between policy development and standards setting an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

We acknowledge that FSANZ's priorities appear to be predominantly driven by industry. While additional resourcing may help progress additional work identified by the Forum, we believe a complete overhaul of FSANZ is required to address the institutional corruption of the agency outlined in qu. 1a.

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19. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?

- **Reform idea 13 – Facilitate joint agenda setting between FSANZ and the Forum**

  We support this.

- **Reform idea 14 – Amend statutory timeframes to support more strategic prioritisation of work**

  We support this.

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20. Are there other potential solutions relating to agreeing system priorities between FSANZ and the Forum?

We believe there should also be an opportunity for public input into the agency's priorities.

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21. To what degree does inconsistent interpretation of food standards present an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

FSANZ regularly misstates its legal obligations and powers, often ignoring or avoiding implementation or trying to pass problems onto state governments. For example, FSANZ has claimed it has no enforcement powers.[46] However, one of FSANZ's functions is, "in consultation with the States and Territories, to coordinate…enforcement.[47] FSANZ also claims it is not responsible for the interpretation of the Food Code, [48] despite the agency providing interpretations of the terms used in part 3.1.1 of the Code. FSANZ's claims are not only clearly false but are almost inevitably used to justify a lack of action to protect public health.

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22. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?

- **Reform idea 15 – Enhance FSANZ's role in providing guidance about food standards within its current statutory remit**

  We support this.

- **Reform idea 16 – Provide for FSANZ to give binding interpretive advice on food standards**

  We support this.

- **Reform idea 17 – Enhance FSANZ's regulatory role by providing limited enforcement powers**

  We support this.

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23. Are there other potential issues or solutions relating to interpretation of food standards?

States and territories vary dramatically in the resources available to interpret and enforce food standards. We believe there is a strong need for a coordinated national response to the enforcement of food regulation. However, we are concerned about the ability of FSANZ to deliver this - given its appalling track record.

OPERATIONS

28. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?

- **Reform idea 21 – Streamline Board appointments and nominations**

  We strongly oppose the proposal to remove the statutory requirement for the Minister to seek nominations from prescribed organisations, and/or to reduce the Forum's role in signing off all Board appointments. To do so would remove important checks and balances and allow the Board to be potentially stacked with industry representatives. This is clearly not in the public interest.

- **Reform idea 23 – Reduce Board size.**

Commercial management boards do not generally include the CEO, so this initiative is supported. We are concerned that a reduction in the Board size will reduce the number of points of view around the table. It is vital that the board contains public health and consumer representatives to ensure that FSANZ delivers its core functions of protecting public health and ensuring consumers have sufficient information to make informed choices about the foods they eat.

29. Are there other potential solutions relating to FSANZ's governance arrangements?

Clear enforceable regulations should be introduced to ensure that members of FSANZ's board have no conflicts of interest.

30. To what degree does FSANZ's approach to setting its own workplan and resourcing its work present an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

We acknowledge that FSANZ's priorities appear to be predominantly driven by industry. While additional resourcing may help progress additional work, we believe a complete overhaul of FSANZ is required to address the institutional corruption of the agency outlined in qu. 1a.

31. What would be the impact (positive, negative or otherwise) of implementing each of the reform ideas below? How could the outcome specified for each reform idea best be achieved?

- **Reform idea 24 – Expand scope of applications for which FSANZ can recover costs**

We oppose this idea as it sets up even more of a client relationship between FSANZ and the food industry. Cost recovery is already problematic. For example, the applicants for the current food irradiation proposal have paid to have it expedited. This means less time for the community to respond. A food industry levy is a better idea if the Government deems cost recovery necessary.

• Reform idea 25 – Provide for limited expansion of scope of activities for which FSANZ can recover costs

We oppose this idea as it sets up even more of a client relationship between FSANZ and the food industry. Cost recovery is already problematic. For example, the applicants for the current food irradiation proposal have paid to have it expedited. This means less time for the community to respond.

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32. Are there other potential solutions relating to FSANZ's operations?

While additional resourcing may help progress additional work, we believe a complete overhaul of FSANZ is required to address the institutional corruption of the agency outlined in qu. 1a. A food industry levy is a potential solution if the Government deems cost recovery necessary.

SUMMARY

33. What are the top 2-3 most pressing issues to resolve through change to the Act and associated operations and responsibilities of FSANZ?

- Ensuring food safety and our right to know what is in our food must become the primary objectives of the Act. These need to be clearly defined and enforceable standards.
- Food safety must be defined specifically to consider long term and chronic diet related public health diseases, such as heart disease, diabetes and obesity.
- The right to know must recognise that citizens want and are entitled to a broad variety of information about the ways in which food is produced. Environmental, social, technological and ethical issues are all important – not just health issues. This needs to be acknowledged and recognised in law.

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34. Are there key issues or challenges related to FSANZ and the Act that are not represented in this scoping paper?

Yes – and this is not surprising - since key stakeholders were not involved in the initial consultation that informed the development of the Scoping Paper.

Friends of the Earth is deeply concerned about the opaqueness of this review. It states in the Scoping Paper that key stakeholders – including industry and government stakeholders - have been consulted since July 2020 and that this is what has informed the report recommendations. It is not

revealed exactly who these stakeholders are and how they were selected. However, industry influence is clearly evident in the Scoping Paper and in many of its reform ideas. Friends of the Earth and other NGOs specifically registered as stakeholders but were not contacted for input – despite being vocal critics of FSANZ for years. This is extremely undemocratic and not in the public interest.

FSANZ is categorically failing to meet its key objectives of protecting public health and our right to know what is in our food. FSANZ's failings are chronic, ubiquitous and inevitably favour the industries that the agency is supposed to regulate. It is clear that these problems are so systemic they are not failings as we normally understand them but the predictable behaviour of an agency that is so captured and corrupted by its associations with industry that it is no longer capable of carrying out its purpose or functions. This pro-industry bias manifests itself in a number of different ways including:

Rejecting the precautionary principle

FSANZ rejects precaution in favour of supporting the giant food corporations that increasingly control the food chain.[49] The agency noted in relation to its refusal to label dangerous food colourings that the precautionary principle "is generally going to be at odds with a principle of minimum necessary regulation."[50] There is no question that FSANZ errs in favour of minimum regulation not public safety. And in this era of deregulatory fundamentalism, the problem is becoming worse.[51]

FSANZ further corrupts the precautionary principle based on a phony interpretation of it. In assessing a GM soybean, FSANZ created a straw man argument, positing that the precautionary principle imposes an impossible burden of absolute proof and then dismissed the principle: "because the demands for proof of no harm are scientifically unattainable, this interpretation provides no useful terms of reference."[52]

There is substantial work demonstrating how the precautionary principle can and should function within a regulatory regime.[53] FSANZ's rejection of the precautionary principle is not just academic but has significant food safety implications.

Reports in 2001 and 2013 by the European Environment Agency found that many new technological developments have been allowed onto the market without a proper understanding of their effects. Once on the market, regulators have consistently ignored warning signs and the costs of inaction have been enormous. The reports look at the history of products such as asbestos, PCBs and halocarbons. They find little evidence that precautionary regulation has slowed innovation or destroyed markets. The myth that the precautionary principle is unworkable is inevitably accompanied by a view – contradicted by the history recounted in these reports – that markets will ensure that products are safe.[54]

FSANZ's lack of precaution has clear and profound effects on all of us and the food we eat. At a broad level it has allowed FSANZ to assume the safety of a number of untested new food ingredients and to ignore evidence of harm. It has also shifted the onus of proof that a given product is unsafe onto the public - when they may not even know they are being exposed to particular foods or have the resources to establish that such foods cause harm.

Redefining safety

FSANZ often claims that - in the absence of formal safety testing - food manufacturers are required to ensure food is safe before they put it on the market.[55] However, this supposed standard has no criteria and no testing or reporting requirements - rendering it unenforceable and meaningless. There is no requirement that a finding of safety even has to be in writing much less that the finding of safety must be based on any data[56] and it doesn't appear that FSANZ has ever audited any company's claim that a food is safe.

In a recent report on consumer and competition law, the Australian Consumer and Competition Commission stated that:

> *"Many consumers assume (incorrectly) that Australia's product liability laws impose a clear obligation on suppliers not to supply unsafe products, and that because a product is offered for sale in Australia it has met minimum safety standards."*[57]

Even if the 'safe food' requirement was real, FSANZ's definition of safe food is so weak and vague as to render this requirement meaningless. According to FSANZ:

> "*Food is not unsafe merely because its inherent nutritional or chemical properties cause, or its inherent nature causes, adverse reactions only in persons with allergies or sensitivities that are not common to the majority of persons."*[58]

This definition would appear to permit a food manufacturer to market a food that has adverse impacts on 49% of the population.

Likewise under FSANZ's definition, food is not unsafe if it causes harm other than physical harm.[59] For example, behavioural problems caused by food colourings (which must carry warning labels in the EU) would not be considered unsafe (see section 2.4).

Another way in which FSANZ redefines safety is to claim that the absence of evidence of harm is the same as evidence of safety.[60] This is potentially true when one has a body of evidence, but asserted from a position of relative or total ignorance it is an absurdity.

Furthermore, in the absence of data FSANZ does not require that the data gaps be filled. The precautionary principle approach of 'no data no market' does not apply here.

Some of the obvious precautionary steps FSANZ should take include independent peer review of data, commissioning studies to duplicate results or rejecting studies that are clearly deficient. None of those obvious steps are taken by FSANZ.

The European Environment Agency's 2010 report concluded that "misplaced 'certainty' about the absence of harm played a key role in delaying preventive actions….However, there is clearly nothing scientific about the pretence of knowledge."[61]

Reliance on industry science

FSANZ consistently relies on industry-funded science as the basis for approving chemical residues in food, GM foods, additives and other ingredients where legitimate health concerns exist. FSANZ often relies exclusively on industry-funded studies in its safety assessments, most of which are unpublished and therefore not peer-reviewed or publicly available.

In the natural sciences a single publication is usually insufficient to convince other scientists of the validity of a claim. Yet, as Professor Jack Heinemann notes "unpublished work from developers are used to make regulatory decisions that affect what we put in our bodies."[62]

Rejecting independent science

FSANZ regularly resists or rejects peer-reviewed studies that raise concerns regarding the health impacts of agricultural chemicals, food additives, genetically modified (GM) ingredients and nanomaterials. Yet FSANZ has never criticised data produced by corporations applying for approval.

When confronted with science that directly or indirectly questions FSANZ approvals or processes, FSANZ generally posts a repudiation of the peer reviewed science on its website. These responses are never peer-reviewed. This has occurred for the work of a number of scientists, including Professor Jack Heinemann, Dr Judy Carman and Professor Giles-Eric Seralini[63]

A 2013 peer-reviewed paper by Professor Heinemann *et al.*[64] raised concerns regarding FSANZ's failure to assess the safety of double stranded (ds) RNA molecules in food crops. These may be created, intentionally and unintentionally, by GM and can change the regulation of, or even silence, genes. FSANZ responded[65] by saying ds RNA is ubiquitous throughout food, and the agency's literature review didn't suggest harm to humans. This ignored the fact that these GM ds RNAs may be entirely new.[66]

As the Centre for Integrated Research into Biosafety observes:

> *"FSANZ has the power in its legislation, it has the option under international food safety guidelines, and it has a responsibility to the people of Australia and New Zealand to ask for evidence of no detectable adverse effects from new dsRNAs in specific GMOs.*
>
> *The purpose of risk assessment is to identify risk and then mitigate it before harm arises. FSANZ seems to be suggesting that they cannot ask for these risks to be investigated because they are awaiting scientific evidence that someone has already been harmed. We say: get the evidence of safety; don't wait for harm."*

FSANZ also criticised a paper[67] by Dr Carman *et al.* showing severe stomach inflammation and uterine changes in pigs fed GM food. FSANZ made false claims about how the pigs were killed, the mycotoxins in pig feed and the photos of GM fed pigs. The agency also misrepresented the number of pigs in a group. Carman and Vliger's response to FSANZ's critique states that FSANZ "extrapolated from these and other errors to make further incorrect statements and conclusions."[68]

FSANZ's criticisms reflect the hypocrisy of an organisation that holds public interest science to one standard and industry science to a much lower one.

Ignoring data gaps

Good science notes both gaps in information or further studies that should be carried out in order to develop scientific understanding. Often, there is not enough information to make informed regulatory decisions. The fact that FSANZ allows products to be commercialised in these circumstances is neither good science nor good policy.

Good science assesses the full range of potential impacts of an ingredient, including cumulative, long term and synergistic impacts. FSANZ however consistently narrows the range of potential risks looked at.

For example, in determining acceptable exposure levels to agricultural chemicals, FSANZ assesses each chemical individually. The agency doesn't assess the cumulative effect of chemicals that are known to operate in the same way on the human body - nor the combined effects of the chemical cocktails used on many food crops. Chemicals are often poorly studied and understood. It is estimated that there are approximately 38,000 chemicals in use in Australia that have never been assessed for safety.[69] Developing a 'safe' maximum residue level for chemicals in food, given this profound uncertainty, becomes little more than guesswork.

Good science questions its conclusions and challenges them over time. However, FSANZ resists reviewing its decisions in light of peer-reviewed evidence and doesn't put in place the mechanisms that would allow it to determine if its assertions of safety are correct. In many instances, because of inadequate regulation, labelling and surveillance it is virtually impossible to track any potential adverse impacts associated with food ingredients.

In recent years major advances have been made in our understanding of how our bodies work and interact with chemicals and foods. Despite the discovery of the epigenome and the microbiome; the harm caused by endocrine disruptors at minute levels; and the realisation that the central dogma of genetic modification - that one gene creates one protein - is false FSANZ has not reassessed any of its approvals.

FSANZ's reliance on bad science in assessing the safety of our food is putting us all at risk.

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35. What other reform ideas should be considered to address the issues identified in the paper, assuming no resource constraints?

It is clear that FSANZ needs an overhaul. This reform needs to happen thoughtfully and with certain principles at its heart.

These recommendations are not comprehensive but are the most fundamental of the changes that need to occur.

Recommendation 1: Amend the Objects of the Food Standards Australia New Zealand Act

- Ensuring food safety and our right to know what is in our food must become the primary objectives of the Act. These need to be clearly defined and enforceable standards.
- Food safety must be defined specifically to consider long term and chronic diet related public health diseases, such as heart disease, diabetes and obesity.
- The right to know must recognise that citizens want and are entitled to a broad variety of information about the ways in which food is produced. Environmental, social, technological and ethical issues are all important – not just health issues. This needs to be acknowledged and recognised in law.

- All food regulations must be underpinned by the precautionary principle. We recommend the adoption of a definition similar to that of the US Food and Drug Administration, which requires a "reasonable certainty that the…substance is not harmful under the intended conditions of use." This must be an enforceable standard and 'harmful' must be broadly defined.
- Current provisions in the Act that are based on encouraging business or trade are not appropriate for a food regulator. These provisions should be removed.

Recommendation 2: Significantly strengthen pre-market safety assessments

- Safety assessments must be based on public data subject to independent and unconflicted peer review.
- Industry data should never form the exclusive or primary basis for a finding of safety.
- Safety assessments must be based on sufficient data to make an informed decision;
- Data gaps must be identified and filled before approvals are granted.
- Safety assessments must be public, including the raw data that supports any finding.

Recommendation 3: Strengthen post-approval processes

- A surveillance, monitoring and reporting system is needed to allow the detection of long term, chronic or cumulative health effects not anticipated during the assessment process. Pre-market assessments should define the unresolved risks and uncertainties to inform monitoring and surveillance programmes.
- Clear guidelines are needed to trigger the review of existing approvals based on new information - particularly peer-reviewed materials and regulatory interventions overseas. Criteria for the review of new information must be put in place to ensure consistent, rigorous and reviewable assessments.

Recommendation 4: Strengthen labelling requirements

- The 'gaming' of labelling should be prevented by ensuring that only specifically permitted terms are used in labelling and that all ingredients used in food are listed.

Recommendation 5: Strengthen parliamentary oversight of and public participation in FSANZ's work and decisions

- FSANZ's decisions must be made reviewable, even if they were not made under an enactment. Review provisions should include open standing and merits based review.
- The Food Code should be made a legislative or disallowable instrument subject to Parliamentary oversight and amendment.

Recommendation 6: Actively address industry bias and conflicts of interest

- An independent audit of the committees and consultants used by FSANZ should be undertaken to determine the extent to which potential or actual conflicts of interest exist.
- Clear enforceable regulations should be introduced to ensure that members of scientific advisory committees have no conflicts of interest.

Recommendation 7: Strengthen and clarify enforcement provisions

- Amend the Food Standards Australia New Zealand Act so that it is clearer that FSANZ is responsible for instigating, ensuring and coordinating the enforcement by other agencies of national food related issues such as food recalls.
  Enforcement must not be discretionary for any matters potentially relating to food safety or our right to know what's in our food.

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