

Review of the Food Standards Act 1991: Scoping paper for public consultation, 2 October 2020

EXECUTIVE SUMMARY

1. The Infant Nutrition Council (INC) welcomes the opportunity to submit to the *Review of the Food Standards Australia New Zealand Act 1991: Scoping paper for public consultation* (the Scoping Paper). The food regulatory system as it currently stands has not changed in any significant way since it was established in 2000. The last substantive review of the FSANZ Act was undertaken in 2007 but its focus at that time was quite specific. By contrast, the food environment has changed enormously in the past 20 years, locally, nationally, regionally and globally. If Australasia is to maintain a pre-eminent place in the global food supply environment and deliver to our consumer needs, then FSANZ and its underpinning legislation must be world-class. The current review is therefore critical to the food and related industries ongoing success, economically and socially.
2. The Forum on Food Regulation (the Forum) has set as a priority area of work “maintaining a strong, robust and agile Food Regulatory System” and it is to this end that INC targets its comments. The scope of the INC remit is limited to infant formula products and toddler milks and this means that there are some areas of enquiry that are not relevant to the INC scope.
3. Of the five broad areas of focus in the Scoping Paper, INC’s broadest interests are in “Objectives” and “Legislative processes and decision-making”. In these two areas, we support in some shape (in principle, in part, to some extent or strongly) all but one of the Reform ideas presented.
4. One of our top priorities is our strong belief that ‘public health’ as an objective in the FSANZ Act is far too broad and we point to the many public health activities that are inappropriate for FSANZ. “Public health” needs to be more narrowly defined to ‘consumer health’ or ‘consumer dietary health’. Another top priority is our strong support for trade being a core goal reflective of the significance of the health and wellbeing of our communities on trade – domestic and international.
5. Another top priority, reflected in our strength of support, is Reform ideas 8 – Reframe legislation to support more agile, risk-based processes; 9 – Redefine the decision-making arrangements to support timelier and more efficient sign-off of regulatory measures; and 10 – Provide for FSANZ to adopt or accept risk assessments from overseas jurisdictions. These three areas have huge potential to increase the efficiency and effectiveness of the regulatory system.
6. Finally in the top list of priorities is our strong support for review requests by the Forum to meet specified criteria in recognition that when the best scientific evidence is applied to an assessment by FSANZ, a review request must be based very strongly on new evidential data and not ideology.
7. We do not support an expansion of functions and certainly not without additional, commensurate and appropriately funded resources. Nor do we support joint

agenda setting between FSANZ and the Forum. While it would be advantageous for the political and scientific agendas to be broadly complementary or broadly aligned, we do not believe that an independent statutory authority should be tied to political agendas.

8. In a broad-ranging review of this significance, we consider it inappropriate to focus on one standard such as health claims. Nonetheless, we appreciate this is an issue of consistency that will likely attract comment from other stakeholders.
9. In conclusion, we have no issues with the current operation of the FSANZ board and generally do not support any of the Reform ideas in this area nor do we support expanding cost recovery. The bulk of FSANZ's work is 'public good' and this demands public funding which has been severely decreased in the past decade due to the sinking lid applied by successive Australian Governments on the FSANZ funding base. FSANZ is a part of the Australian public sector and the approaches to budgetary constraints applied across the board to Australian Government agencies apply equally to FSANZ irrespective of the bi-national role it has.
10. A summary table of the INC's position on each of the Reform ideas is at [Attachment A](#).

DETAILED COMMENTS

The following comments follow the approach taken in the Scoping Paper.

1. Background and context to the Review

Question 1a. Is there still a case for regulating food?

11. INC believes there is still a case for regulating food to ensure it is safe for people, especially vulnerable population groups such as infants. There is also a case for regulating food to provide consistent consumer information of certain aspects such as ingredients and provide a 'level playing field' for food manufacturers.

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

12. The key market failures requiring regulation are food related issues that are injurious to health: lapses in food safety and hygiene and inadequate information for consumers (e.g. regarding allergens, unsuitability for certain segments of the population). In this regard it is important to ensure a level playing field – food safety and hygiene practices throughout the entire supply chain (including food packaging operators). It is not acceptable to have 'free riders' where safety is concerned.
13. Although not a market failure, a limitation on access to science can be addressed by food regulation where the best available science is identified only once by the regulator to set standards instead of by every operator in the market. This ensures consistent parameters are set in the food environment.
14. Actions to address potential market failures should be subject to rigorous cost-benefit analysis to ensure that what might be considered a market failure can be cost-effectively addressed by a proposed course of action.

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

INC is the association for the infant formula industry in Australia and New Zealand and represents manufacturers, marketers and brand owners who between them are responsible for more than 95% of the volume of infant formula manufactured, sold and exported in Australia and New Zealand.

INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula industry in Australia and New Zealand.

The INC is a responsible body that voluntarily restricts its marketing practices to support government policies for the protection and promotion of breastfeeding. The companies represented by INC are:

Members:

- Aspen Nutritionals Australia Pty Ltd
- Fonterra Co-operative Group Ltd
- H. J. Heinz Company Australia Ltd & H. J. Heinz Company NZ Ltd
- Nestlé Australia Ltd & Nestlé New Zealand Ltd
- Danone Nutricia Pty Ltd
- The a2 Milk Company Pty Ltd
- Synlait Milk Ltd

Associate Members:

- Abbott Nutrition Pty Ltd
- Australian Dairy Park Pty Ltd
- Bayer Ltd
- Bodco Dairy Ltd
- Burra Foods Pty Ltd
- Cambricare New Zealand Ltd
- Cargill Australia Pty Ltd
- Dairy Goat Co-operative Ltd
- DSM Ltd
- Fresco Nutrition Ltd
- GMP Dairy Ltd
- GrainCorp Ltd
- Jamestrong Packaging Pty Ltd
- Murray Goulburn Co-operative Co Ltd
- Peerless Foods Pty Ltd
- Nature One Dairy Pty Ltd
- New Image Group Pty Ltd
- New Zealand New Milk Ltd
- Nuchev Food Pty Ltd
- Sonoco Pty Ltd
- Snow Brand Australia Pty Ltd
- Tatura Milk Industries Pty Ltd
- The Infant Food Co. Ltd
- Westland Co-operative Dairy Company Ltd
- Yashili Dairy New Zealand Pty Ltd

The INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants that are unable to have the benefit of breast milk.

2. Objectives

Question 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?

15. INC considers the objectives should be amended. One key change sought relates to the term 'public health'. The term 'public health' focuses on the entire spectrum of health and wellbeing, including the eradication of particular diseases and, in doing so, encapsulates an extraordinarily broad scope. This includes (according variously to the American Public Health Association and the Australia New Zealand Public Health Association):

- Scientists and researchers
- Vaccinators and sanitarians

- Nutritionists
- Epidemiologists
- Toxicologists
- Food operator and food service inspectors
- Health educators
- Social workers
- Community planners
- Public health physicians
- Public health nurses
- Occupational health and safety professionals
- Public policymakers.

16. As all stakeholders are aware, public health works to track disease outbreaks, prevent injuries and illnesses and shed light on why some individuals or population groups are more likely to suffer from poor health than others.
17. The definition of public health by national and international agencies is necessarily broad, promoting the welfare of the entire population but the food system is not about tracking and managing the spread of infectious disease or environmental hazards (outside the food supply chain), and its role is not to help ensure access to safe and quality care to benefit the population. Rather its role is to protect consumer health or consumer dietary health, not public health, and to manage food-related safety, consumer understanding and consumer wellbeing.
18. The Objectives would be sharper, and closer to the goals set down for achievement by FSANZ, if they referred to 'consumer health protection' or 'consumer dietary health protection'. FSANZ is not undertaking the Ministry or Department of Health or WHO roles and its objects should reflect a carve out for its narrower role.
19. Currently, there is inadequate focus on supporting innovation and the competitiveness of the food industry within Australia and New Zealand. FSANZ must only have regard to, "the desirability of an efficient and internationally competitive food industry." Having an internationally competitive food industry should be included as a core objective. Section 3(b) could be amended to: "an effective, transparent and accountable regulatory framework which allows the food industry to work efficiently and be competitive internationally."
20. The types of problems experienced by industry are increased time, and therefore cost, to launch new domestic and export products, loss of market share in export markets and/or inability to capitalise on new export product opportunities. The national economic impacts of these problems can be significant.
21. Another issue is the existing and increasing level of prescription (eg the 90+ sections dealing with the processes for applications and proposals). It should also be noted that FSANZ should have regard to minimising the level of prescription and burdens on industry/stakeholders.
22. INC strongly supports the elevation of Section 18(2)(a) relating to risk analysis and the best available evidence to Section 18(1). As we stated at the outset, risk analysis is a fundamental tenet of all highly respected national, regional and international agencies including EFSA, JECFA and WHO.

Question 4a. Reform idea 1 – What would be the impact of implementing "Reform idea 1 – Define 'public health' and 'safety' in legislation to affirm the inclusion of long-term health and nutrition as a core objective.

23. INC supports with qualification Reform idea 1 – Define 'public health' and 'safety' in legislation to affirm the inclusion of long-term health and nutrition as a core objective. As

described in the response to Ques 3, the priority for INC is around replacing the term 'public health'. We do not consider that 'safety' requires definition. The impacts are noted above.

Question 4b. Reform idea 2 – Recognise trade as a core goal and reframe consumer choice as a factor to which FSANZ 'must have regard'.

24. INC is strongly supportive of part of Reform idea 2– Recognise trade as a core goal and reframe consumer choice as a factor to which FSANZ 'must have regard'.
25. The first aspect regarding recognising trade as a core objective is fully supported. Refer to our response to Ques 3 above. Further, trade needs to be included in section 18(1).
26. The second aspect regarding reframing consumer choice to "must have regard to" needs careful consideration. An alternative could be to amend the wording of section 18(1)(b), for example to, "the provision of adequate compositional and nutritional information relating to food to enable consumers to make informed choices." Similarly, section 3(c) could have a similar insertion to narrow the information covered by the Food Standards Code (versus the scope of wider Consumer Laws).
27. We propose these variations to satisfy a broad range of stakeholders: elevate trade but retain consumer choice through the provision of adequate compositional and nutritional information so that they are given 'equal' consideration. On this basis we would rank the idea 'otherwise'. Safety should always remain the primary concern and any expansion of the role should be resourced.
28. Australia and New Zealand's international trade delivers wealth and wellbeing to both countries and is essential to many thousands of employees throughout the supply chains in the region. Trade is therefore vital to consumers as much as is consumer choice.

Question 4c. Reform idea 3 – Establish criteria in the Act that the Forum must meet to request a review of a draft regulatory measure", and how could the outcome best be achieved?

29. INC strongly supports Reform idea 3 – Establish criteria in the Act that the Forum must meet to request a review of a draft regulatory measure. In establishing criteria, these would need to be framed around the requirements already placed on FSANZ, that it must use the best available scientific evidence etc. While we have reservations about the development of criteria, this could be addressed by the criteria being in regulations and subject to separate consultation. At a minimum, criteria should, for example, require evidence to be provided to support review requests but all criteria should be consulted for appropriateness.

Question 5. Are there other potential issues or solutions relating to legislated objectives?

30. INC strongly supports the elevation of Section 18(2)(a) relating to risk analysis and the best available evidence to Section 18(1). Risk analysis is the principle that underpins highly regarded international standard setting and research agencies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and European Food Safety Authority (EFSA) and is a fundamental tenet of Codex Standards' setting. It would demonstrate a maturing of the system and the agency and confirm FSANZ's place very clearly on the international stage in the field of food safety and consumer health.

31. It would provide the means to better prioritise and to undertake approaches that aligned with international approaches. We cannot identify any negative impacts of this approach.

3. Functions

Question 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?

32. INC does not support an expansion of FSANZ's functions that would dilute its focus on its current core functions. INC considers FSANZ's functions to be generally appropriate for a trans-Tasman agency and for which responsibilities such as enforcement rest constitutionally or sovereignly with other jurisdictions. The functions compare favourably with the European Food Safety Authority which has a similar role in the EU region and similarly involves sovereign countries. INC is therefore cautious about expansion of FSANZ functions and emphasises that FSANZ resourcing would need to be increased to take on any additional functions.

33. In any event, if significantly changed functions were proposed, INC's New Zealand members would not support New Zealand's participation. New Zealand's focus on the food regulatory environment is considerably more global than the Australian jurisdictions due to the heavier reliance of the nation on exporting the majority of the food it produces. Nonetheless, there may be a case for FSANZ to undertake dietary surveys for both countries not just Australia, since New Zealand's dietary information is severely out of date.

Question 7a. What would be the impact of implementing "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" and how could the outcome best be achieved?

34. INC supports in principle 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. This last point is more targeted to the Australian context than to New Zealand's. In any event, INC has reservations about singling out a particular set of functions such as long-term health and nutrition. While long-term health is an admirable aspirational goal, this could divert the focus from immediate health effects to the detriment of the system.

35. Nonetheless, INC considers it appropriate for FSANZ's functions to reflect its current activities but does not support any broadening of functions without a commensurate increase in funding. We consider FSANZ's funding situation to be so critical that it cannot effectively undertake current activities within its current funding base. This is evidenced by not being able to reach even the first 'Call for Submissions' in a programme of work that has been conducted for almost a decade for a review of Standard 2.9.1 *Infant formula products*. This Standard addresses products for the most vulnerable sector of the population and yet it has had to be set aside on numerous occasions, most recently for the Review of Application A1155, simply because reviews are statutory processes and the expertise in this area in FSANZ are limited and must be diverted to meet statutory functions.

36. In terms of current functions, there is a strong Australian focus appropriate to the inclusion of standards for food hygiene and production for Australia and INC is neutral on matters that are not of a more trans-Tasman nature.

37. INC strongly supports FSANZ continuing its international facing roles. In many cases this is undertaken on behalf of the Australian Government in parallel with New Zealand Government activities in these areas. We recognise the strong contribution this makes as an input to the development and amendment of standards for the Australia New Zealand Food Standards Code (the Food Standards Code) and the maintenance and enhancement of the international level expertise within FSANZ as well as the contribution to international standards setting that is vital for international trade.
38. INC supports a role for FSANZ to provide assistance to industry intending to make applications to create or vary for regulatory investigations. The impact of this is to both government (FSANZ) and industry, by ensuring time is not wasted on aspects of an application that could otherwise be clarified before it is submitted for assessment. It also ensures applications are not rejected on grounds that could have been addressed through early engagement and that supportive commentary can be provided in identifying gaps and potential problems for the applicant to address before submission. A successful comparator is the investment by the New Zealand Government in the health and nutrition claims area of the Ministry for Primary Industries. With a small, expert team in Government, New Zealand companies have access to expert advice and support for the preparation of assessment dossiers to substantiate proposed health claims.
39. INC does not support FSANZ's involvement in critical food safety investigations. INC's New Zealand members do not see a need for this and if it proceeded, it would need to be designated as Australia-only. INC would not support diverting resources from jointly funded core activities to such activities for Australia-only. It is also the case that to participate in food safety investigations, FSANZ would have to undertake interpretations of the Code, a point worth noting in the comment below.
40. INC does not believe FSANZ should be involved in general 'public health' promotion campaigns but would support a FSANZ role in targeted consumer health campaigns for which the food supply was a factor. This should only occur with additional resourcing.

Question 7b. What would be the impact of implementing "Reform idea 5 – Amend s13 of the Act to reflect a broader range of functions that FSANZ could deliver now and in the future" and how could the outcome best be achieved?

41. Apart from the clarity proposed in Reform Idea 4 above with respect to activities currently undertaken, INC does not support any broadening of FSANZ's functions and does not support Reform idea 5 – Amend s13 of the Act to reflect a broader range of functions that FSANZ could deliver now and in the future.
42. Should Australian jurisdictions and stakeholders support such a move, then INC would not oppose Australia-only functions. INC notes there could be logic in Australia supporting a single centralised 'voice of food safety' that States and Territories could complement.

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

43. INC has no further comments to make on FSANZ's functions.

4. Legislative processes and decision-making arrangements

Question 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?

44. INC acknowledges that a strategic approach to reviewing standards could be positive but we would not support this without separate funding and resources.
45. The development of the Food Standards Code began with the intention that as individual Standards were completed they would be progressively commenced. This only occurred for one Standard (Standard 1.3.1 *Food Additives*). This proved unworkable because of the interdependence of the Standards within the Food Standards Code and the need to make consequential changes to non-target standards as new Standards were developed. The same process applies to proposals and in part to applications, that amendments necessary to achieve one outcome can require consequential amendments to others.
46. It is also the case that proposals have the potential to achieve strategic reviewing but this has been severely limited in the past decade due to the shrinking of the FSANZ funding base. FSANZ is a part of the Australian public sector and the approaches to budgetary constraints applied across the board to Australian Government agencies apply equally to FSANZ irrespective of the bi-national role it has. This compares to EFSA which was set up by the EU under the General Food Law - Regulation 178/2002 and funded from the combined EU resources, not aligned to any particular jurisdiction.
47. The impact of the current approach is a piecemeal approach to review driven by topical developments, such as plain English Allergen Labelling, rather than a strategic approach. Reviews that are undertaken all have issues with timeliness. Industry faces uncertainty as a result. As well, older standards could be inhibiting trade and innovation.

Question 10a. What would be the impact of implementing "Reform idea 6 – Remove exemption of food standards from sunseting arrangements" and how could the outcome best be achieved?

48. INC strongly opposes a sunseting arrangement for food standards. With the current resourcing and statutory approach to applications and reviews and constant requests from the Ministerial Forum for FSANZ to undertake additional work, there would be a very high risk of gaps being created, statutory timelines missed and Ministerial priorities being delayed. No stakeholder group would benefit from this situation.
49. As well, this would not necessarily be the most strategic use of resources and could significantly divert resources. The risks and related costs of sunseting standards would far outweigh the benefits.
50. An alternative could be for an independent (funded and led) review of strategically prioritising standards for review that could identify the top three priority standards for review in each of a three to five-year period.
51. Such an approach could form the blueprint for an achievable, separately funded work programme that could still operate within the overall parameters of the FSANZ Act and the FSANZ work program.

Question 10b. What would be the impact of implementing "Reform idea 7 – Resource FSANZ to undertake regular, more holistic reviews of food standards" and how could the outcome best be achieved?

52. INC supports in principle Reform idea 7 – Resource FSANZ to undertake regular, more holistic reviews of food standards.
53. As noted above, a review to prioritise standards for review could form a blueprint for a separately funded work programme. Not all standards need review to the same extent and some probably not at all. FSANZ should not undertake its own ‘holistic review of food standards’ in the current funding environment but rather should be separately resourced to deliver a review programme that reflects the needs of stakeholders: Government, industry and consumers.

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

54. There is limited opportunity to secure a regularised programme of Standards Review without explicit and separate funding. INC would not support the diversion of existing funds for such a purpose when current reviews, such as for *Standard 2.9.1 Infant Formula Products* (Proposal P1028) and that pending for *Standard 2.9.4 Formulated supplementary sports foods* (Proposal P1010), are struggling to progress.
55. That aside, INC considers that the publication of revised or new standards by Codex could act as a trigger for review and concurrently promote appropriate harmonisation.

Question 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?

56. The FSANZ Act contains a single rigid process for applications and proposals that takes no account of risk or proportionality. As the Scoping Paper states, around half of all applications made to FSANZ each year relate to low risk processing aids. As well, all applications for processing aids have been approved for use in other jurisdictions such as Europe, the USA or Canada. Nonetheless processing aids must be assessed and decisions on them taken in exactly the same way as a new food ingredient or a new Standard.
57. The waste of scarce resources is the result of pre-determined processes and decision-making.

Question 13a. What would be the impact of implementing "Reform idea 8 – Reframe legislation to support more agile, risk-based processes" and how could the outcome best be achieved?

58. INC strongly supports Reform idea 8 – Reframe legislation to support more agile, risk-based processes, as delivering the same outcome and at the same time freeing up resources to be dedicated to higher risk areas of work. As described, this would see much of the detail from the FSANZ Act move to regulations.
59. In order to determine the best approach to any particular amendment need, a risk ranking framework might be established but this should be developed by FSANZ because it has the expertise for this purpose. Risk management, risk assessment and risk analysis are a composite scientific discipline across food, building, transport/aviation etc and should be designed and conducted by experts not by lawyers. It should not be legislated and while Table 8, Indicative risk framework is a starting point, further refinement might be applied to remove potential bases for challenge in its application in future.

Question 13b. What would be the impact of implementing "Reform idea 9 – Redefine the decision-making arrangements to support timelier and more efficient sign-off of regulatory measures" and how could the outcome best be achieved?

60. INC strongly supports Reform idea 9 to redefine decision-making to support timelier and more efficient sign-off of regulatory measures. We are supportive of the Forum, the FSANZ Board and the CE of FSANZ having decision-making powers about food standards determined on the basis of risk. By this, we would support the FSANZ Board or the FSANZ CE having decision-making powers in relation to, for example, Standards in the group of 1.3 (food additives, vitamins and minerals, processing aids, contaminants and prohibited and restricted plants and fungi). We suggest that where a substance has been approved as safe and only the production method changes, this should not need consultation and such variations could be signed by the FSANZ CE.
61. We restate our very strong opposition to the delegation of powers to the Food Regulation Standing Committee (FRSC). The reasons for this go to the heart of good regulatory practice since there is no transparency (as with the Forum, no Official Information or Freedom of Information requests can be sustained unless all jurisdictions agree and there is no publication of submissions made to FRSC consultations although the opportunity to do so has existed for over 15 years), there is no single point of accountability that is publicly available, and there is a history of dominance by public health practitioners over all.

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

62. INC considers that the Policy Guidelines as issued by the Forum on Food Regulation should be developed and reviewed by a panel comprising government, industry and consumers and not exclusively by Government. Consideration should also be given to making them legislative instruments or identifying a viable alternative to redress a significant imbalance of power.
63. Our concerns are that the current process is totally opaque and decisions on content not apparent. The following Table, using the *Policy Guidelines on Food Labelling to Support Consumers to Make Informed Healthy Choices* as an example, highlights these concerns.

Table 1: *Policy Guidelines on Food Labelling to Support Consumers to Make Informed Healthy Choices* (the Policy Guideline on Food Labelling) Process

Expectation	In Practice
Genesis of development	No consultation. FRSC recommended the Policy Guideline on Food Labelling with no input on that recommendation from industry or consumers. The first that other stakeholders/public knew of this was in a Forum Communiqué from August 2019.
Supporting material provided to explain the rationale for the inclusion of provisions in Policy Guidelines	None. This is contrary to Good Regulatory Practice. The Policy Guideline on Food Labelling emerged for public consultation in December 2019 with no accompanying explanatory material. This was explained to INC upon enquiry made to the Australian Department of Health as "it is not usual practice to release an explanatory document that provides the rationale behind clauses in a policy guideline." It should be very usual practice.

Consultation	Consultation is ad hoc. There is no update beforehand other than an (untimed) entry in the FRSC workplan so that stakeholders can plan response resourcing. Another example is that there was no consultation at all on the last amendment of the <i>Policy Guideline on Health, Nutrition and Related Claims</i> which had significant impacts for industry.
Rationale for final provisions	In the past there has been no visibility of the decision making that has accepted or rejected comments made by stakeholders during any consultation. We acknowledge that there is a summary document on this for the Policy Guideline on Food Labelling.
Updates on interregnum work	There was no visibility of interregnum work on the Policy Guideline on Food Labelling following consultation in Dec 2019/Jan 2020 and no updates were provided on progress until this Guideline was published 10 months later in early November 2020.

64. If a Policy Guideline developed exclusively by Government can be interpreted only by Government with no recourse for other stakeholders, the imbalance of power in the decision-making process is absolute even though the impact on industry, trade or consumers may be profound. This is a market failure. If a policy guideline was a legal instrument, recourse could be through the courts. The alternative, more palatable alternative is to include stakeholders in the genesis and development or amendment of Policy Guidelines to redress the imbalance.

Question 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?

65. The current approach of using only applications or proposals to develop or vary food standards is not inherently an issue. It is the constraints of the process and the application of parameters of the process that create the issues of risk prioritisation, resourcing, lack of agility and a general clogging up of the system. It is akin to having a legal system with no provision for lower courts or mediation or arbitration as more cost-effective options to pursue.

Question 16a. What would be the impact of implementing "Reform idea 10 – Provide for FSANZ to adopt or accept risk assessments from overseas jurisdictions" and how could the outcome best be achieved?

66. INC strongly supports Reform idea 10 – Provide for FSANZ to adopt or accept risk assessments from overseas jurisdictions which would result in explicitly accommodating risk assessments from internationally recognised overseas agencies in the assessment of Australian and New Zealand applications and in the conduct of proposals. We do not see a need for these to be limited to specific international agencies but to include internationally recognised overseas agencies.
67. It would be important for FSANZ to incorporate dietary modelling into such assessments in order to tailor responses to the Australian and New Zealand dietary patterns. We note this can only be done effectively where current dietary information exists. We note that New Zealand dietary information is seriously out-dated particularly for children and young people (the data is based on dietary consumption collected before the turn of the 21st century and which is over 20 years old).

68. If implemented, this Reform idea would result in FSANZ's scarce resources being applied in areas where no assessment has been conducted overseas. We would also note that an application for a substance that has been rejected overseas should not bias an assessment by FSANZ since the factors resulting in rejection could be dietary specific to a particular country or other country-specific factors could be at play.

Question 16b. What would be the impact of implementing "Reform idea 11 – Enable FSANZ to adopt international standards" and how could the outcome best be achieved?

69. INC supports in part the proposal for FSANZ to adopt or adapt international standards but this should be limited to particular areas of technical exactitude. These might include relevant standards generated by Codex and other agencies in the area of methods of analysis and sampling, irradiation and microbiology. Public consultation should still be retained since international standards might be agreed that had not taken account of Australian or New Zealand views on them.

70. In any case, INC would want the coherence of the Food Standards Code to remain and this may require the 'adaptation' of international standards to conform to the general form of standards in the Food Standards Code. That is, the standards should be consistent. We do not consider mutual recognition to be appropriate since we envisage this being a one way street of Australia and New Zealand leveraging the work of international agencies.

71. Monitoring international developments would be necessary if such monitoring was not already in place.

Question 16c. What would be the impact of implementing "Reform idea 12 – Create industry-led pathways to expedite applications and bring new products to market" and how could the outcome best be achieved?

72. INC supports in part Reform idea 12 – Create industry-led pathways to expedite applications and bring new products to market. This support varies for the suggested pathways as follows:

- A greater role for industry self-certification – The concept of a greater role for industry self-certification is supported in principle but NOT the model outlined in the scoping paper based on the TGA model. The TGA model requires all products to be included on the Australian Register of Therapeutic Goods (ARTG). The food model is based on categories of foods or food substances not on the products themselves (with a few exceptions such as genetically modified foods). The TGA model also does not handle complex organic substances and struggles with non-therapeutic products. In our view the food model as applied by FSANZ is more efficient than the TGA model.
- A streamlined applications pathway especially incorporating the proposals for low risk substances without Forum sign-off is strongly supported. This would in part align with the TGA's self-assessable approach to low-risk medicines, where no efficacy, quality or safety review is conducted prior to product commercialisation. This could extend to substances previously assessed as safe but for which a new method of production has been developed.
- An initial safety assessment prior to market entry – this would require a fulsome post-market surveillance program and is not something we would necessarily want to see since it could divert resources from core work undertaken by FSANZ.

73. The boost to innovation and to research and development of even a limited improvement would have major benefits for Australia and New Zealand businesses and the economies of both countries.

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

74. INC has no further solutions to propose.

5. Partnerships

Question 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?

75. As set out in the Scoping Paper, political agendas of Governments do not always align with the vision of statutory authorities. Political agendas change over time and are more susceptible to populist interests. In a science-based authority, it is important for the independence of FSANZ to stand apart from political interference. INC supports dialogue on priorities, but the vision and work program should be owned by FSANZ with inputs from stakeholders not just Governments. There are examples in the COVID-19 environment where government and science organisations have aligned comfortably but there are also examples where they have not and political agendas have impacted quite disastrously.

76. An example of Government involvement that is fraught is in the setting of Policy Guidelines. As their development takes place with very little public or industry input, some quite perverse outcomes result and the impact of that is being seen in the way that the *Policy Guideline on Infant Formula Products* is not working in relation to Application A1155. Different stakeholder groups have vastly different views on what is possible or not possible under that Policy Guideline. The expert group convened by FSANZ to consider Application A1155 concluded that the dose response effect "in relation to the competitive inhibition of 2'-FL of binding *C. jejuni* to its epithelial cell receptor ... cannot be extrapolated to a dose response effect on reducing infection in infants or children because these types of studies cannot be done in humans." (p22 FSANZ Review Report on A1155). In other words, the Policy Guideline cannot work in the way it has been written.

Question 19a. What would be the impact of implementing "Reform idea 13 – Facilitate joint agenda setting between FSANZ and the Forum" and how could the outcome best be achieved?

77. INC does not support joint agenda setting between FSANZ and the Forum for the reasons set out above. Ministers on the Forum are largely influenced and biased by Party commitments and politics and compromises to satisfy these could see a perverse collection of incoherent measures as one jurisdiction traded off its agenda with another. INC supports dialogue and discussion between the parties but FSANZ must maintain its integrity and the integrity of the system.

Question 19b. What would be the impact of implementing "Reform idea 14 – Amend statutory timeframes to support more strategic prioritisation of work" and how could the outcome best be achieved?

78. INC does not support Reform idea 14 – Amend statutory timeframes to support more strategic prioritisation of work" and how could the outcome best be achieved. The Scoping Paper proposes that timeframes might be established for the completion of proposals on a

case-by-case basis, that is, the application of a maximum timeframe. This is basically how Codex operates both in terms of general reviews of standards and task forces set up to consider particular issues such as the current Taskforce on Antimicrobial Resistance and the past Taskforces on Animal Feeding and Biotechnology.

79. INC does not support such an approach because of concern that a statutory maximum timeframe could divert resources from other areas that emerge during the conduct of the proposal.
80. The Scoping Paper also suggests creating more flexibility around statutory timeframes for applications. INC strongly opposes such an approach. It can take a longer period under current arrangements with time taken to accept an application and 'stop the clock' provisions. To add the ability for applications to be put on hold is proposing a solution without fixing the problem – resourcing. Instead INC favours a tiered approach with set timeframes and processes specified for categories of applications e.g. low risk; medium risk; high risk or high complexity.

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

81. INC considers that collaboration, if not already in place, should be a feature of agreeing system priorities. As well, having tiered approaches relevant to risk would result in efficiencies such as treating processing aids in one way and more complex aspects of the food system in another.

Question 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?

82. Both government and industry are impacted by inconsistent interpretation of food standards. The issue for governments is that decisions in one jurisdiction could bring the system into disrepute if another jurisdiction takes a different position. This creates confusion and subsequently a loss of confidence by consumers in the system. Guidance on the intent of provisions could capture some of the context and rationale for the provisions in a standard reflecting a certain course (see below).

Question 22a. What would be the impact of implementing "Reform idea 15 – Enhance FSANZ's role in providing guidance about food standards within its current statutory remit" and how could the outcome best be achieved?

83. INC supports in principle Reform idea 15 – Enhance FSANZ's role in providing guidance about food standards within its current statutory remit. Our concerns relate to what guidance is being discussed, where the guidance might appear (we do not favour inclusion in the Food Standards Code) and its form (we favour non-binding). Guidance currently available does play a role although perhaps not so much for the matters within the scope of the INC. As noted above, guidance could help explain why a course has been selected and could assist with overcoming jurisdictional differences of interpretation.
84. Nonetheless, the standards FSANZ develops need to continue to ensure the prevention of behaviours, practices or events that put the industry at risk relative to food safety or reputational issues through measures such as regulation of packaging and formula suppliers/producers so that significant risks are appropriately managed and the consumer is protected. The absence in Australia of clear guidelines along the lines of the New Zealand "Manufacture of Dairy Based Infant Formula Products and Formulated

Supplementary Foods for Young Children (2017)" is an omission that could be addressed through guidance around the following:

- Design and operations of manufacturing environments and materials for nutrition packaging, processing and filling/ packing
- Storage and transport of the packaging, ingredients and filled product
- Requirements for compliance of imported products (i.e., packaging, ingredients and filled products) to these same expectations.

Question 22b. What would be the impact of implementing "Reform idea 16 – Provide for FSANZ to give binding interpretive advice on food standards" and how could the outcome best be achieved?

85. INC supports with caution Reform idea 16, the provision for FSANZ to give binding interpretive advice on food standards., Any binding advice should be undertaken very judiciously since it suggests that the legislative provision or standard is confusing and therefore could be improved with better drafting. However, we are aware of binding determinations made in tax and customs law and there may be a limited place for it in the food environment. Proposals in this regard need to be more specific and subject to broad discussion and consultation. This comment also applies to the provision of non-binding interpretations by FSANZ.

Question 22c. What would be the impact of implementing "Reform idea 17 – Enhance FSANZ's regulatory role by providing limited enforcement powers" and how could the outcome best be achieved?

86. INC strongly opposes Reform idea 17 – Enhance FSANZ's regulatory role by providing limited enforcement powers. INC's New Zealand members note in particular that New Zealand is well served by the enforcement approach of the Ministry for Primary Industries.

87. INC recognises that there are complexities faced by Australia due to the many food related enforcement agencies operating across the country and that some of this complexity may well be removed by specific enforcement functions being allocated to FSANZ.

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

88. INC has no further comments to make on interpretations.

Question 24a. To what degree is the food-medicine interface an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

89. This is not relevant to the scope of INC's mandate.

Question 24b. To what degree is the oversight of health claims an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

90. See response to Reform idea 19 below.

Question 25a. What would be the impact of implementing "Reform idea 18 – Focus efforts on improving the food-medicine interface through regulatory practice" and how could the outcome best be achieved?

91. This is not relevant to the scope of INC's mandate.

Question 25b. What would be the impact of "Reform idea 19 Broaden the role of FSANZ to assess general level health claims".

92. INC does not support Reform idea 19 – Broaden the role of FSANZ to assess general level health claims and that the conduct of assessment should be based on risk. Reform idea 19 assumes that FSANZ must assess all general level health claims and that this would require application when, for low risk claims, industry self-substantiation could be undertaken and present as a more efficient option. This could also be safeguarded through a system of 'accreditation' for companies wanting to undertake self substantiation based on criteria such as expertise and experience.

93. However, at some stage where resourcing permitted, there should be a program of examining the health claims approved by highly regarded agencies such as EFSA since Standard 1.2.7 commenced, and for there to be an efficient mechanism to add such claims to the Food Standards Code.

Question 25c. What would be the impact of implementing "Reform idea 20 – Align definitions and powers in legislation between therapeutic goods and foods" and how could the outcome best be achieved?

94. This is not relevant to the scope of INC's mandate.

Question 26. Are there other potential solutions relating to improving the food-medicine interface?

95. INC has no further comment on the food-medicine interface.

6. Operations

Question 27. To what degree are FSANZ's governance arrangements an issue for the system? What are the types of problems that different stakeholder groups face as a consequence?

96. INC does not consider FSANZ's governance arrangements to be an issue for the system.

Question 28a. What would be the impact of implementing "Reform idea 21 – Streamline Board appointments and nominations" and how could the outcome best be achieved?

97. INC does not consider the Board appointment and nomination process to be an impediment for the system except where it might result in an unfilled vacancy on the Board. We would defer to FSANZ for its view on what streamlining might achieve. We note that larger boards increase diversity and skills. We therefore see no value in and do not support Reform idea 21 – Streamline Board appointments and nominations.

Question 28b. What would be the impact of implementing "Reform idea 22 – Establish minimum term length for Board members" and how could the outcome best be achieved?

98. The relevant departments involved in appointment processes can already propose periods of appointment to address continuity. There is no need for setting minimum terms. INC therefor does not support Reform idea 22 – Establish minimum term length for Board members.

Question 28c. What would be the impact of implementing "Reform idea 23 – Reduce Board size" and how could the outcome best be achieved?

99. INC continues to oppose a reduction in Board size and does not support Reform idea 23 – Reduce Board size. We note the impost on resourcing of a large board but cutting board size should not be the solution if it results in sub-optimal skills availability or decision-making. We note that while some might consider the ideal board size to be 8-9 members, larger boards do exist for particular reasons. The Australian Institute of Company Directors states that "there is no perfect size for any board and optimal board size is influenced by many factors including: • Size and complexity of the organisation and its business/ operations • The diversity of the business lines of the organisation (geographic and functional) • Cultural norms within the industry in which the organisation operates (for example, university boards tend to be larger)". In the case of FSANZ, reflecting the bi-national scope of FSANZ for composition and labelling and its involvement across the entire food chain in Australia, then 12 members is appropriate.

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

100. INC has no further comments to make on FSANZ's governance arrangements.

Question 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?

101. INC does not consider FSANZ's approach to setting its own workplan presents an issue for the system. INC considers that FSANZ's approach to resourcing its work within the continuing budgetary constraints of the Australian Government presents a major and significant issue for the system. It impacts its ability to undertake its current work programme in a timely manner, it hampers initiatives to be proactive and address prospective issues and it consigns it to being a reactive responder to issues.

102. Increasing the FSANZ budget is the most efficient and effective solution.

Question 31a. What would be the impact of implementing "Reform idea 24 – Expand scope of applications for which FSANZ can recover costs" and how could the outcome best be achieved?

103. INC does not support Reform idea 24 – Expand scope of applications for which FSANZ can recover costs. This is mere tinkering at the edges while the ship sinks.

104. As the Scoping Report notes, cost recovery only contributes around 3% to the overall budget now and even a doubling of that (which could not result from Reform idea 24) would not address the fundamental issue of the sinking lid and current dire budgetary position.

Question 31b. What would be the impact of implementing "Reform idea 25 – Provide for limited expansion of scope of activities for which FSANZ can recover costs" and how could the outcome best be achieved?

105. INC does not support Reform idea 25 – Provide for limited expansion of scope of activities for which FSANZ can recover costs. We consider this to be in the same category as Reform idea 24 and merely tinkering at the edges while the ship sinks. This does,

however, have other negative impacts such as diverting scarce resources away from the food standards setting role to raise funds.

106. The application process is so expensive now as to be the preserve of the largest national companies or multinationals. Charging for pre-application advice merely aggravates an already skewed system that is out of reach for most if not all small to medium businesses. An analysis of the companies making applications now substantiates this view.

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

107. INC has no further comments to make on FSANZ's operations.

7. Key reflections

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

108. Objectives, Legislative processes, Decision-making and Resourcing.

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

109. INC has not identified other key issues or challenges related to FSANZ and the Act that are not represented in this scoping paper.

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

110. INC has made suggestions on reform ideas in the response to preceding questions.

Summary of INC Position on Reform Ideas in FSANZ Act Review

Note: Positions use the following terms:

Strongly supports – a top priority

Supports – without qualification

Supports with qualification – changes are needed to some aspects

Supports in part – some parts are not supported

Supports in principle – the idea has merit but more information/description is needed

Supports with caution – concerns about the extent of application of the idea

Not support – opposed

Not support strongly opposed – fundamental concerns with the idea

Not relevant – not within the INC mandate

Objectives			Functions	
1. Define 'public health' and 'safety' in legislation to affirm the inclusion of long-term health and nutrition as a core objective. SUPPORTS WITH QUALIFICATION	2. Recognise trade as a core goal and reframe consumer choice as a factor to which FSANZ 'must have regard'. SUPPORTS IN PART	3. Establish criteria in the Act that the Forum must meet to request a review of a draft regulatory measure STRONGLY SUPPORT	4. Amend the Act to better reflect the functions FSANZ currently delivers, particularly as they relate to supporting long-term health and nutrition SUPPORTS IN PRINCIPLE	5. Amend s13 of the Act to reflect a broader range of functions that FSANZ could deliver now and in the future NOT SUPPORT
Legislative processes and decision-making arrangements				
6. Remove exemption of food standards from sunseting arrangements NOT SUPPORT STRONGLY	7. Resource FSANZ to undertake regular, more holistic reviews of food standards SUPPORTS IN PRINCIPLE	8. Reframe legislation to support more agile, risk-based processes STRONGLY SUPPORTS	9. Redefine the decision-making arrangements to support timelier and more efficient sign-off of regulatory measures STRONGLY SUPPORTS	10. Provide for FSANZ to adopt or accept risk assessments from overseas jurisdictions STRONGLY SUPPORTS
Partnerships				
11. Enable FSANZ to adopt international standards SUPPORTS IN PART	12. Create industry-led pathways to expedite applications and bring new products to market SUPPORTS IN PART	13. Facilitate joint agenda setting between FSANZ and the Forum NOT SUPPORT	14. Amend statutory timeframes to support more strategic prioritisation of work NOT SUPPORT	15. Enhance FSANZ's role in providing guidance about food standards within its current statutory remit SUPPORTS IN PRINCIPLE
16. Provide for FSANZ to give binding interpretive advice on food standards SUPPORTS WITH CAUTION	17. Enhance FSANZ's regulatory role by providing limited enforcement powers NOT SUPPORT STRONGLY	18. Focus efforts on improving the food-medicine interface through regulatory practice NOT RELEVANT	19. Broaden the role of FSANZ to assess general level health claims NOT SUPPORT	20. Align definitions and powers in legislation between therapeutic goods and foods NOT RELEVANT
Operations				
21. Streamline Board appointments and nominations NOT SUPPORT	22. Establish minimum term length for Board members NOT SUPPORT	23. Reduce Board size NOT SUPPORT	24. Expand scope of applications for which FSANZ can recover costs NOT SUPPORT	25. Provide for limited expansion of scope of activities for which FSANZ can recover costs NOT SUPPORT