Infant Nutrition Council

Industry supporting both
Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

28 July 2017

Food Standards Australia New Zealand
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Dear Sir/Madam

The Infant Nutrition Council (INC) appreciates the opportunity to make a submission on Consultation Paper – Proposal P1024 Revision of the Regulation of Nutritive Substances & Novel Foods.

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

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Associate Members:

- Abbott Nutrition Pty Ltd
- Australian Dairy Park Pty Ltd
- Bayer Ltd
- Bodco Dairy Ltd
- BUBS Australia 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
- New Image Group Pty Ltd
- New Zealand New Milk Ltd
- Nuchev Food Pty Ltd
- Snow Brand Australia Pty Ltd
- Tatura Milk Industries Pty Ltd
- Wattle Health Austalia Ltd
- Westland Co-operative Dairy Company Ltd
- Winston Nutritional New Zealand 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.

Yours sincerely

Jan Carey
Chief Executive Officer

INFANT NUTRITION COUNCIL SUBMISSION ON
Consultation Paper – Proposal P1024
Revision of the Regulation of Nutritive Substances & Novel Foods
28 July 2017

Introduction and Key Points

1. INC appreciates FSANZ's efforts to consult further on issues of significance to Proposal P1024 in the 16 June 2017 *Consultation Paper – Proposal P1024: Revision of the Regulation of Nutritive Substances & Novel Foods* (the Consultation Paper).

2. We are, however, very disappointed that the proposed framework has been modified to remove the industry self-assessment notification pathway. We strongly recommend that pre-market assessment and notification by industry (self-assessment) continue to be developed and put in place. One possibility is to still pursue this as well as consideration of changing the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) to enable a centralised assessment to meet jurisdictional demands. Industry is also open to considering other possibilities for a self-assessment pathway. We strongly suggest that the next consultation paper includes within its scope a self-assessment pathway with a broader range of possibilities that could be reviewed.

3. We strongly support amendment of the framework to accommodate recognition of approvals by specified overseas authorities and the acceptance of food that has a demonstrated history of human consumption overseas through the appropriate pathway.

4. We do not support the modified framework for many reasons including there being no barrier in the FSANZ Act to it proceeding and the loss to innovation and speed to market of an industry self-assessment pathway. Nonetheless, we support continuing the development of some elements of the package raised in the Consultation Paper:
    - Review of exclusive permissions
    - Transition arrangements: grandfathering
    - Transition arrangements: microorganisms
    - Interface with P1028.

5. We are firmly of the view that elements set aside in the current Consultation Paper warrant a further discussion paper before the regulatory measure is drafted for consultation. We raise a number of points for these set aside elements which might be expanded on in a subsequent discussion paper.

6. It will then be important for INC and other stakeholders to consider the package as a whole, with each of the elements fully described, to ensure that the individual elements still contribute to a coherent overall regime. This may involve revisiting elements that were thought to be 'locked down' to refine them once more if necessary.

7. Finally, we would particularly note the concerns around microorganisms including the proposal to restrict grandfathering microorganisms to food culture microorganisms only, and not microorganisms used for other purposes. We strongly oppose the prospect of a positive list in regulation as being unworkable, not feasible and more restrictive than any other regulatory regime worldwide in relation to such substances.

Detailed Comments

Pre-market assessment by industry

8. INC is disappointed that pre-market assessment and notification by industry (self-assessment) no longer feature as an option in the modified regulatory framework. We strongly recommend that pre-market assessment and notification by industry (self-assessment) continue to be developed since we believe it is not the option that cannot be accommodated by the FSANZ Act, but rather the administration of the option, to meet jurisdictional demands. In our view, the option should continue to be developed noting that one possibility is to still pursue the consideration of changing the FSANZ Act to enable a centralised assessment to meet jurisdictional demands but also noting that industry is open to considering other possibilities for a self-assessment pathway.

9. We strongly suggest that a further consultation paper includes within its scope a self-assessment pathway with a broader range of possibilities that could be reviewed.

10. We strongly support amendment of the framework to accommodate recognition of approvals by specified overseas authorities and the acceptance of food that has a demonstrated history of human consumption overseas through the appropriate pathway.

11. Consideration should also be given to continuing investigation of any proposals from submitters that would allow industry self-assessment of low risk foods and ingredients to proceed.

12. We note that the current proposal is supportive of industry conducting the identification of eligible foods, within parameters, which does not require regulatory and scientific oversight to be centralised. The same rationale could be applied to industry self-assessment notification. Similar protections could be implemented as for the identification of eligible foods, such as industry needing to hold appropriate records to substantiate decisions.

13. We consider that without the development of a streamlined pathway, such as the self-assessment notification pathway, the revision of the framework will not be able to deliver on the need to introduce a risk-proportionate regulatory regime that addresses both innovation and food safety. For innovation, speed to market after significant research and development investment is key to generating the return on that investment. The modified framework may address uncertainty associated with the definitions of novel food and nutritive substances and possibly the immediate problem for enforcement, but it will not address the fundamental issues that have prevented significant utilisation of the system by industry nor will it address innovation.

Framework

14. The description in the Consultation Paper confirms our view that pre-market assessment and notification by industry (self-assessment) is possible under the current FSANZ Act but that:

    > "Government stakeholders advised that they would only support a self-assessment notification pathway if the framework incorporated centralised regulatory and scientific oversight … [and the] … (FSANZ Act) does not permit FSANZ to undertake such a role. Nor is FSANZ resourced for such a role." (p3 Consultation Paper)

15. There are other ways to meet jurisdictional demands in addition to and/or instead of amendment of the FSANZ Act. INC considers that the original three pathway framework should continue to be developed while recognising that:

a) commencement of the self-assessment notification pathway may need to be delayed while alternate ways to meet the jurisdictional demands are developed such as amendment of the FSANZ Act
b) eligible food criteria might be expanded to better capture low risk foods.

16. INC therefore does not support the modified approach but does at present still support continuing work on all the elements that are necessary for a three-pathway framework (the eligible food criteria pathway, the self-assessment notification pathway and the FSANZ assessment pathway) and the alternate options identified above.

Other Issues

17. INC welcomes the opportunity to comment on the three issues identified for stakeholder input, namely '*Exclusive permission and the protection of investment in new product development'*, '*How foods which are being sold before gazettal of the revised standards should be addressed*' and, importantly for INC, '*The consideration of novel foods and nutritive substances applicable to Standards 2.9.1 and 2.9.2*.' We cover these following our discussion of issues for subsequent consultation.

Issues for subsequent consultation

18. INC notes that several issues have been set aside to be dealt with in a further call for submissions:
    A. the criteria to determine which foods may be self-assessed (eligible food criteria)
    B. data requirements for eligible foods
    C. designation of responsibilities for holding dossiers for assessment against the eligible food criteria
    D. consideration of overseas approvals in the context of a new framework
    E. regulatory impact analysis.

19. We consider that, except for the regulatory impact statement, these issues are fundamental to the proposed framework to the extent that they warrant a further consultation paper from FSANZ before a draft regulatory measure is developed as part of a further call for submissions.

20. A further consultation paper could explore some of the matters raised by the last Call for Submissions paper and consideration of the comments from stakeholders on these, thereby progressing each of these before settling on the regulatory measure.

21. The fundamentals of the approach to the framework are each integral to its overall integrity and need to be viewed as a whole. INC's position on the issues raised for consultation now may evolve and change when all the fundamentals are fully described within a single package,

A. Eligible food criteria

22. INC has highlighted concerns with the eligible food criteria previously. The draft eligible food criteria from March 2016 did not provide clarity and certainty for all infant formula product ingredients, particularly dairy products. As well, the criteria did not provide for appropriate targeting of food safety risk. We are therefore pleased that there is a recognition that these criteria require more work. In light of the critical nature of eligible food criteria to the regulatory framework (both the three-pathway and the modified framework), further consultation on the criteria would be important before the regulatory framework proceeds.

23. The principles INC has previously outlined for the eligible food criteria are:
    - The eligible food criteria should recognise the long history of safe use of many infant formula ingredients especially dairy products. Many foods and ingredients with a

long history of safe consumption are produced through fractionating and concentrating various components. Fractionation and concentration processes are not inherently unsafe. In dairy this covers cheese, milk powders and milk protein concentrates. The question is about impact on the total diet intake and this requires proportionality of approach.

- The focus for eligible food criteria should be on whether the finished product will significantly alter total dietary intake of nutrients, not individual components.
- The eligible food criteria should support a risk-proportionate approach that addresses both innovation and food safety. The regulatory framework should not be more restrictive than is currently the case and should not require pre-market assessment by FSANZ for all concentrated ingredients. The basis for comparison should be what can be delivered to a final product through ingredients.
- Eligible food criteria need to account for different addition rates of ingredients (with comparison in the final product) instead of forcing a focus solely on comparison between ingredients.
- Eligible food criteria need to allow for the use of appropriate food products and ingredients for comparison of concentration. For example, there should not be a requirement to use fluid milk as the basis for all comparisons but rather comparison in a safety assessment should focus on what can be delivered to a final product through typical ingredients (including Milk Protein Concentrate (MPC), Whey Protein Concentrate (WPC), cream powders, sweet whey powder, etc). For infant formula, the appropriate point of comparison for concentration for ingredients is not necessarily always the source commodity but could be breast milk. Points of comparison for concentration could also include other ingredients used in infant formula products.

B. Data requirements for eligible foods

24. Data requirements for eligible foods can only effectively be commented on once the requirements for eligible food criteria have been further developed. Ideally this would be undertaken in a further consultation paper

C. Designation of responsibilities for holding dossiers for assessment against the eligible food criteria

25. INC considers that there needs to be a distinction between ‘dossiers’ held in relation to self-assessment against eligible food criteria versus those for pre-market assessment.

26. We suggest that the documentation held for assessment against eligible food criteria be called ‘data files’. This is because the requirements for assessment against eligible food criteria will be different in terms of scope, extent and detail to dossiers held for industry self-assessment and for pre-market assessment by FSANZ. We suggest the supplier, as defined in the Australia New Zealand Food Standards Code (the Food Standards Code) will hold the ‘data files’ for assessment against eligible food criteria. This would not preclude an ingredients supplier, for example, holding ‘data files’ for their ingredients for the express purpose of providing these to manufacturers wishing to use those ingredients.

27. Flexibility should be provided for who holds eligible food criteria ‘data files’ providing the repository can readily be identified on a case-by-case basis. We also suggest that some ingredients would be eligible foods without the need for assessment or data files.

D. Consideration of overseas approvals

28. INC supports recognition of overseas approvals for the pre-market assessment pathways. The extent of regulatory oversight for such approvals requires further discussion. For example, the homogeneity of infant population groups especially aged

0-6 months, should remove the need for further dietary modelling for Australia and New Zealand. There should also be provisions such that overseas approvals accepted for infants aged 0-6 months should be deemed safe for use for older infants aged 6-12 months since the 0-6 months group is the more vulnerable group.

29. We also consider that some foods with overseas approvals would meet the eligible food criteria pathway. This needs to be recognised when considering how overseas approvals are handled within the new regulatory framework. Overseas approvals need to be handled in the regulatory framework so as to capture the benefits of the earliest possible access to them.

FSANZ Summary of findings

30. INC continues to support the development of a new framework but recognises this is still evolving. We note that while there was 'overall stakeholder support for developing a new framework' this support was based on the proposed three-pathway framework albeit conditional on centralised regulatory and scientific oversight. The current modified approach does not support innovation nor speed to market and while some adjustments at the edges might improve the current system, they do not go far enough.

31. We note that government stakeholders were concerned that individual jurisdictions would be responsible for assessing the content of dossiers and about whether dossiers complied with relevant Code requirements. We also note that such assessment might lead to inconsistent outcomes across Australia and New Zealand. Government stakeholders do not want to be involved in assessment and suggested that only if another authoritative agency (such as FSANZ) undertook this role would they support the option of a self-assessment pathway. Of the submitter options for self-assessment, the following is a summary:

    Option 1 – Streamlined application process: Public consultation must occur. FSANZ to investigate streamlining assessment

    Options 2, 3, 5, 6 and 7 – FSANZ committee to over-see self-assessment dossier or undertake initial screening on need for an application or use independent expert reviewers or give power to determine whether FSANZ assessment required or list safe novel foods on website: Any opinion/list from such a committee/body/group has no legal or regulatory status and no regulatory certainty. Enforcement agencies cannot rely on opinions to take enforcement action. The opinions are not binding.

    Option 4 – Accept overseas approvals: Set aside

    Option 8 – No application process: FSANZ Act requires Code amendments to be by way of application or proposal.

32. Other than option 4, these options are not about the framework but implementation of the proposed framework. We believe, for example, that Option 3, independent expert reviewers, could be an adjunct to a streamlined application process as an interim measure for industry self-assessment notification and FSANZ pre-market assessment. Option 8 is a true statement, but a self-assessment notification pathway was not envisaged as resulting in an amendment to the Code.

33. In developing the streamlined application processes and reviewing matters concerning data provision, we have noted use of data from similar population groups. In this context, we encourage FSANZ to consider the similarity of infant populations 0-6 months worldwide who would all be consuming breast milk in the perfect world. For older infants, any ingredients and processes accepted for infants 0-6 months should be deemed safe for older infants and young children since the more vulnerable group is that of infants 0-6 months.

Proposed Approach

34. INC supports developing some elements of the eligible food criteria concept to provide greater clarity and certainty about the regulation of new foods and substances. This would have been required under the three-pathway regulatory framework as well. The other elements identified would also have required consideration in the three-pathway regulatory framework and we support progressing them:
    - the concept of a novel food in the new framework
    - existing permissions for novel foods
    - consideration of nutritive and related substances
    - amended data requirements for applications.

Proposed Approach: the concept of a novel food in the new framework

35. INC supports removal of the current definition from the Food Standards Code and the criterion of a cut-off date of commencement of the provisions or to another Food Standards Code pre-market assessment requirement. The third criterion, of being subject to the eligible food criteria and data requirements, needs to be further developed in order for an understanding of the impact to be assessed. We note that the proposal is that "[S]uppliers would need to hold records to substantiate that the data requirements have been met" (p7 Consultation Paper).

36. The term 'supplier' is somewhat problematic because of its varied use in the Food Standards Code. We note the definition "includes packer, manufacturer, vendor or importer of the food" but we also note that it is often qualified when used in the Food Standards Code and ask that care be taken in any regulatory measure in this regard.

37. INC supports flexibility in relation to this element so that due diligence can be conducted by the user of the novel food to confirm data requirements in the same way that a supplier of food/ingredients relating to genetic modification can develop records of declarations as to the food's status.

38. The proposal is that "Those foods that do not meet the eligible food criteria will require assessment and approval by FSANZ before being marketed. That is, an application or proposal would be required." (p8 Consultation Paper). We believe that the self-assessment notification pathway needs to be developed as an option for foods that do not meet the eligible food criteria but that are low risk. We recognise that the provisions for this pathway may not be able to be commenced until implementation issues are addressed.

Proposed Approach: existing permissions for novel foods

39. INC notes that conditional use is already a feature of FSANZ assessment of applications of certain foods and that extensions of such conditions requires an application to FSANZ. We also note that where no conditions are specified, novel ingredients may be used in any food for retail sale and that there is no mechanism to remove novel food permissions from the Code after a certain period of time.

Will the removal of permissions from Schedule 25 create problems relating to requirements for specifications for these foods?

40. INC supports the removal of novel food permissions that have no associated conditions placed on them after safety assessment. Those familiar with the processes applied by FSANZ would be aware of the application/proposal process and would know where to look for assessments and those not familiar would quickly find out through due diligence searches. In relation to identity and purity, not all novel foods listed in Schedule 25 of

the Food Standards Code have entries for identity and purity and not all entries for identity and purity are novel foods. In other words, there should be no problems removing permissions from Schedule 25 for the requirements for specifications for these foods. In terms of the Food Standards Code continuing to list the identity and purity of novel foods, this decision should be made on a case-by-case basis.

Which of the novel foods listed in Schedule 25 are used only in foods regulated by specific Part 2.9 standards?

41. DHA is likely to be the food of interest to the infant formula industry from those listed in Schedule 25. There is also a question around timing of removal of novel foods from Schedule 25 in advance of conclusion of P1028. We would suggest there be coordination of changes to the Food Standards Code.

Are there other issues associated with removing permissions from Schedule 25? Please elaborate.

42. Infant formula manufacturers find the list of novel foods a useful reference tool but recognise that this does not necessarily justify retaining them in a regulatory measure. INC suggests that a guidance document listing the approvals over time would be equally as useful.

Consideration of nutritive and related substances

43. INC notes the considerable uncertainty created by a term that may or may not apply to foods and ingredients and is so broad as to include "any substance that has been concentrated, refined or synthesised to achieve a nutritional purpose when added to food".

44. We continue to support removal of the definition 'used as a nutritive substance'. We note that vitamins, minerals, electrolytes and L-amino acids require pre-market approval for inclusion in the Food Standards Code irrespective of function and that this should not be impacted by such a change. Any standards that include nutritive substance permissions should be revised to reflect removal of this concept. However, as outlined above, industry considers a guidance document listing historic approvals or 'not-novel' opinions etc, a useful reference tool.

45. In relation to Standard 2.9.1, the use of nutritive substances is covered in four sections:
    - 2.9.1—5 (covering use and labelling
    - 2.9.1—12 (referring to form of vitamins etc)
    - 2.9.1—21 (statement of nutrition information) and
    - 2.9.1—24 (concerning prohibited representation of nutritive substances).

46. All these could be recast to remove reference to 'nutritive substance' and alternative arrangements made for requirements.

Do you consider other nutritive type substances (in addition to vitamins, minerals, electrolytes and L-amino acids) should always be subject to pre-market approval by FSANZ? Please provide reasons for your view.

47. INC does not propose any other substances should always be subject to pre-market approval. We support an approach whereby other products that may have previously been considered nutritive substances or "used for a nutritive purpose" (e.g. the addition of an ingredient to increase the protein content of a product) will, under the future regulatory framework, be assessed against the eligible food criteria to determine eligibility or whether pre-market assessment (industry or FSANZ) is required. The opportunity for self-assessment notification should be developed for such products as well as pre-market assessment by FSANZ. Such an approach has the potential to provide consistency across the treatment of nutritive substances and novel foods. However, the effectiveness of the approach cannot be assessed without an understanding of the content of the eligible food criteria and how they will be applied.

Amended data requirements for applications

48. INC notes that the Application Handbook sets out mandatory requirements for applications for novel foods and nutritive substances and that there are different data requirements for different types of novel foods. FSANZ makes clear that there is no explicit tiered approach to data requirements in relation to varying levels of risk that consumption of different foods or substances may present. A tiered approach where data requirements increase with complexity or risk that may be presented by a food should be developed for two reasons: to identify the data requirements for low risk foods for self-assessment notification and to assist in streamlining applications for FSANZ assessment with medium risk and complexity.

49. We therefore support amendment of the data requirements in the Application Handbook to reflect the varying levels of risk from foods. This might include the requirements for low risk foods as an interim arrangement for self-assessment notification pending amendment of the FSANZ Act or it might endure beyond amendment of that Act. The principle of 'safety first' should apply, not benefit. We would be pleased to consider further consultation on:
    - the factors that should be considered when assessing the "complexity" or risk of a food in order to develop a tiered application process
    - the form and description of simplified data collection options, including leveraging of data from similar population groups e.g. between EU and Australia and New Zealand
    - general safety requirements with additional requirements considered on a case by case basis for example, not mandating clinical trials across the board to demonstrate safety when a substantial body of evidence already exists as to safety.

50. INC welcomes the exploration by FSANZ of other administrative, business and risk assessment processes that may provide opportunities for streamlining the application and FSANZ assessment process. Reducing the need or extent of consultation depending on complexity and risk should be key factors driving progress in this area.

Exclusive permissions

51. The Consultation Paper focuses heavily on the public interest in the information included in applications. INC acknowledges this is an important interest but it is equally important for this to be balanced against the commercial imperative to protect commercially sensitive information. The current arrangements provide for the protection of certain sensitive commercial information (such as manufacturing parameters) and INC stresses the importance of this arrangement continuing in the future.

Does there remain a requirement to provide exclusive permission as a condition of use in the Code?

52. Yes, INC considers the facility should be available. We understand there has not been wide use of the facility to date but this should not be the reason for removing the facility.

What costs to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible.

53. INC does not hold data relating to costs associated with the grant and use of exclusive permissions. However, there would be industry costs associated with preparing the justification for the granting of an exclusive permission in any application seeking such a permission. INC members may be able to provide data relevant to this question. If manufacturers are granted exclusivity for a longer set time for their innovations, they could be more willing to engage in initiatives to achieve enhanced processes and greater transparency which would likely be seen as beneficial to the Government and the wider community.

What direct and indirect benefits to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible.

54. INC does not hold data relating to benefits associated with the grant and use of exclusive permissions. However, the most significant industry benefit would relate to the capturable benefit that exclusivity delivers as an offset for the research and development required for the novel element.

Why should Australian and New Zealand food laws make Australian and New Zealand food regulators bear the onus and cost of protecting industry's intellectual property in products being sold commercially?

55. INC does not believe that the provision of exclusive permissions in Australian and New Zealand food laws makes Australian and New Zealand food regulators bear the onus and cost of protecting industry's intellectual property. By supporting the provision, Australian and New Zealand food regulators are supporting innovation in the food supply and often, the research and development conducted in the two countries that underpins such developments. There are well-reported statements from both Governments concerning support for innovation and related export growth and it is these aspects that exclusive permissions are delivering on.

Why are other existing measures (such as intellectual property laws allowing a patent or innovation patent) not adequate to protect industry's investment in developing commercial food products?

56. Often, measures operate in tandem or as alternates in specific circumstances. It is not a case of the adequacy of other existing measures but a question of what more can be done specifically through food law to foster research and development investment by the food industry.

57. Unlike in industries such as the pharmaceutical industry, where patents can be granted for specific chemical entities, it is difficult (or impossible) to patent a food or even a substance found in food. This is also difficult when trying to patent manufacturing processes for foods. Therefore, a regulatory solution for granting protections for food

companies remains the best opportunity. This is reflected by the EU's incorporation of this protection into its new regulation (as referenced in the Consultation Paper).

What other alternatives exist to protect industry's investment in developing commercial food products (i.e. other than reliance on the Code and Australian and New Zealand food laws)?

58. As the Consultation Paper and the foregoing questions reflect, alternatives include intellectual property laws and/or patent arrangements. There may also be other data protection provisions that can be relied on.

Is the current 15-month period applied to exclusive permissions sufficient? If 15 months is not considered sufficient, please explain why this is the case and what period of time would be sufficient and why. Please provide data if possible.

59. No, the current fifteen months exclusion period is insufficient. It does not provide sufficient time for the applicant to gain a tangible benefit from this provision due to the time it takes to commercialise a product post regulatory approval. This is probably the reason that the current provisions are underutilised.

60. We note that the EU recognises the need to protect innovation and has a 5 year data protection mechanism for its novel food regime:

> *"(30) Under specific circumstances, in order to stimulate research and development within the agri-food industry, and thus innovation, it is appropriate to protect the investment made by the applicants in gathering the information and data provided in support of an application for a novel food made in accordance with this Regulation. The newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Union list should be protected. Those data and information should, for a limited period of time, not be used to the benefit of a subsequent applicant, without the agreement of the initial applicant. The protection of scientific data provided by an applicant should not prevent other applicants from seeking the inclusion of a novel food in the Union list on the basis of their own scientific data or by referring to the protected data with the agreement of the initial applicant. However, the overall five-year period of data protection which has been granted to the initial applicant should not be extended due to the granting of data protection to subsequent applicants."*
>
> Source: (REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001)

61. We believe at present, it is reasonable that the period of exclusivity is extended to be no less than 3 years. However, data protection aspects would benefit from re-evaluation and this may lead to a higher period of exclusivity.

62. Setting exclusivity at no less than 3 years takes account of variable regulatory assessment approaches used internationally and associated timelines. By way of example, in the US, under the new regulation established in 2016, the review of novel ingredients by the Food and Drug Administration (FDA) will take between 6 and 9 months. As described in Hanlon et al., 2017 (Food Chem Toxicol, 105: 140-150), since implementation of the novel ingredient (GRAS) notification process in 1997 the average review length in the US has been 6 months. By comparison, in the EU, since implementation of the novel food regulation (EC No 258/97), the average time from submission to authorisation has averaged approximately 36 months.

63. As this range of times suggests, the regulatory timeline has a significant impact on when new products are placed on markets in different countries/regions. Since the data requirements are similar (or the same) between different countries/regions' agencies for

reviewing novel foods, often petitions/applications are submitted to multiple regulatory agencies within a relatively short period of time. Moving forward, in addition to this consideration, consideration of how each country treats proprietary data will be necessary. It may be that the implementation of data protections in the EU (beginning in January 2018) could stimulate more applications being submitted there, in advance of petitions/applications in other countries.

Does the innovation activity your business undertakes typically occur in Australia or New Zealand? Will this change if the period for exclusive permissions are increased and, if so, how and why? Please provide data if possible

64. There is variation across the industry and INC members are better placed to respond on this question. In general, businesses that do not locally manufacture will have longer lead times in the supply chain to bring a product to market.

Does your business typically place new products on the market at the same time or before placing them on the market in larger overseas markets? Please provide examples or data if possible.

65. N/A

Transition arrangements for currently marketed foods

66. As noted in our earlier submission, grandfathering is the only pragmatic approach for transition under this kind of regime. We note that jurisdictions can still enforce the requirement that food offered for sale is safe to consumers under jurisdictional specific Food Acts. These provisions will enable management of products for which there are specific known concerns at the time of transition.

67. The Consultation Paper refers to the cut-off being applied to products "on the market" and "foods supplied" at the date of gazettal. We assume this means if foods/ingredients are available for sale in New Zealand or Australia on the date of gazettal. However, clarification of these terms is sought as it is important that foods produced in New Zealand and Australia for export as well as foods available for sale in Australia and New Zealand are covered.

68. INC does not support the creation of a positive list of products being grandfathered.

Microorganisms

Summary of INC position

69. INC welcomes FSANZ's proposal to maintain status quo for 'food culture microorganisms' which means that these do not require pre-market approval by FSANZ. INC, however, has concerns with FSANZ's proposal to expand the scope of P1024 to cover the regulatory and safety requirements for microorganisms added for a purpose *other than* as a "food culture microorganism".

70. INC considers that the discussion developing on microorganisms goes beyond the primary objective for P1024 which was to overcome ambiguity in the current Food Standards Code on nutritive substances. INC does not support a framework that changes status quo in recognition of inherent safety of microorganisms used across a number of foods and is concerned about the risk of trade barriers from such an approach.

71. INC does not support the proposal for eligible food criterion for microorganisms:
    a. INC supports the status quo of permissions for all microorganisms in the product standards, with the supplier (as defined in the Food Standards Code) being required to hold the evidence for and to substantiate safety.
    b. INC does not support the eligible food criteria as proposed, and clarity is needed from FSANZ as to what is meant by *'microorganisms are eligible if they are listed in the Code and are cultured to maintain genetic stability'.*
        i. INC supports the principle that microorganisms are cultured using processes that maintain their stability. However, clarification is needed before this could be included as a criterion.
        ii. Furthermore, as genetic stability needs to be determined at a type strain level, INC considers that it would be an insurmountable task to apply this requirement as a criterion for the development of a positive list of microorganisms in the Food Standards Code.
    c. INC supports the status quo of permissions for derivatives of microorganisms in the relevant horizontal standards (e.g. processing aids), requiring pre-market assessment for both the derivative and type source strain, as aligned with the EU Qualified Presumption of Safety (QPS). INC supports suppliers needing to be able to demonstrate that a microorganism that they intend to add to food is identifiable.

72. INC does not believe there is any industry support for the development of a 'positive' list defined in regulation for microorganisms, whether for food culture microorganisms or for microorganisms added for a purpose *other than* as a "food culture microorganism". If such a proposal was to proceed, however, INC would strongly recommend this be undertaken in a proposal specific to this topic. We believe that there would be a substantial amount of work and resources necessary for such a proposal and unless separated would likely lead to a longer development and implementation period for the outcomes of P1024.

Rationale for INC position on microorganisms

73. As already highlighted in the consultation paper, there is a '*significant history of using microorganisms in foods and in the production of foods'*. There has been no evidence of market failure based on a purpose of use. INC considers that the main impetus originally, leading into P1024 was a need for regulatory clarity predominantly for novel foods and nutritive substances, rather than a failure or safety concern relating to biologically active substances. INC therefore does not support differentiating treatment of microorganisms on their basis of purpose of use.

74. For infant formula, follow-up formula, and processed cereal based foods, the permission for L+ lactic acid producing bacteria has been permitted at a Codex level for many years. For other general foods, lactic acid producing bacteria is permitted. INC supports harmonisation with Codex to the greatest extent possible, and considers that the creation of a positive list could inadvertently create trade barriers if not all microorganisms were captured. It would also introduce excessive regulatory burden not proportionate to risk and thus create a disincentive for innovation. The current status quo in the Food Standards Code largely reflects harmonisation with Codex, with permissions for microorganisms related to culture purposes. The Food Standards Code also provides for pre-market assessment of their derivatives as processing aids (e.g. enzymes) with source type strains also requiring pre-market assessment.

75. INC considers that combining a proposal for a positive list, and genetic stability, is unlikely to be feasible, as proof of genetic stability needs to be demonstrated at a type strain level, rather than genus, or species level i.e. *Lactobacillus xxx ATCC 12345,* not *Lactobacillus spp. or Lactobacillus xxx*. Developing an eligible food criteria framework

that positively lists at a type strain level and continual updating of such a list would create substantial regulatory burden and significantly impact innovation, which is not proportionate to the risk.

76. Lastly, INC considers that the proposal to establish a positive list of microorganisms to support the eligible food criteria and the ongoing update of such a list, is reflective of a pre-market assessment of sorts, and is not reflecting the intent and purpose of a low risk pathway. INC considers an eligible food criteria pathway, needs to be sufficiently differentiated from an industry self-assessment notification pathway and a FSANZ pre-market assessment pathway, and recognise the proportionate risk of such ingredients in the food supply, which present diminishingly low probabilities of harm.

77. Eligible food criteria would mean that those microorganisms used as probiotics in all foods, including infant formula products and infant foods, could not be positively listed until some level of pre-market assessment by FSANZ occurred in the creation of this list. INC also queries how frequently the positive list would be updated by FSANZ, without restricting speed to market for innovation. There are a vast number of probiotics being used today, and INC would query whether evaluation by FSANZ would occur in parallel to the establishment of the positive list because we would otherwise question the viability of a transitional arrangement, balanced against regulatory burden and available resource for evaluation.

78. As mentioned above already, combining a proposal for a positive list, and genetic stability, is unlikely to be feasible, as proof of "genetic stability" needs to be demonstrated at a type strain level, rather than genus, or species. This could mean a far greater number of strains being evaluated and a resulting positive list at a type strain level is, to the best of our knowledge, the most restrictive approach when compared to key international regulatory precedence. Even the EFSA QPS does not list at a type strain level.

79. INC reiterates the absence of any market failure or safety concerns with industry's current use of lactic acid bacteria across all food categories. FSANZ could create significant in-market concerns as well as trade barriers by creating any regulatory uncertainty with regards to the current status of such ingredients specifically in Standard 2.9.1, or when used for a purpose other than food culturing. The use of lactic acid cultures in infant formula is not subject to pre-market notification in Codex or the EU, and the current statement permitting the use of lactic acid cultures in Standard 2.9.1 is generally consistent with Codex.

80. INC raises concerns about the need to retrospectively review microorganisms added for a purpose other than a "food culture microorganism" or exempt certain food categories such as Standard 2.9.1 from grandfathering, taking into consideration the above.

81. In line with the policy principles for infant formula products (and general foods), any ingredient added to infant formula (or food generally) must be safe. Industry holds a high level of scientific documentation to support the safety of any microorganism addition, regardless of technological or other purpose.

82. INC also queries where the level of evidence and criteria requirements will eventuate in assessing these microorganisms, and whether the scientific substantiation framework applied would be overly restrictive and override considerations on a history of use. Hypothetically, if a probiotic type strain used on the market for in excess of twenty years was assessed to have potential safety concerns, this would create major disturbances in trade and the marketplace for products already on the market. More significantly, this

would have an impact on consumer confidence. Impacts could be either domestic, or have greater significance if the product was also traded internationally.

Please indicate whether you support the 'grandfathering' of foods which are available for sale in Australia and New Zealand at the time of gazettal (of a new framework in the Code).

83. INC supports the 'grandfathering' of all foods at time of gazettal of a new framework in the Food Standards Code but to ensure a smooth transition this must include foods produced in New Zealand and Australia for export as well as foods available for sale in Australia and New Zealand. This is needed to avoid major disturbances to trade and potential to impact on consumer confidence. A fundamental principle of government to government assurances on food safety is that food produced for export meets domestic standards (other than labelling). The only exception with respect to ingredient use, composition and food safety criteria is where it is not possible to meet both domestic and importing country requirements, in which case the importing country requirements take precedence.

Do you consider there are categories of foods that should not be grandfathered? If so, please provide justification for your view.

84. INC does not consider that there are any categories of foods that should not be grandfathered. We do not support eligible food criteria for microorganisms in an environment where microorganisms have been added to foods available for sale locally and/or for export for many years. If a review of microorganisms progresses and this was to conclude that the safety of probiotic type strains with a long period of apparent safe history of use were potential safety concerns, this would significantly undermine consumer confidence and have very significant trade implications. Support for grandfathering microorganisms would be reconsidered only if microorganisms were considered under eligible food criteria.

85. The Consultation Paper proposes potential exclusions either due to:
    - nutritional purpose of use (microorganisms added for a purpose other than as a 'food culture microorganism' and where a history of safe use cannot be demonstrated)
    - based on Special Purpose Food categories relating to infants (Standard 2.9.1 *Infant formula products* and Standard 2.9.2 *Infant foods*).

86. This would mean that those microorganisms used as probiotics in all foods, including infant formula products and infant foods, could not be positively listed until some level of pre-market assessment by FSANZ occurred in the creation of a list. INC queries how frequently a positive list would be updated by FSANZ, without restricting speed to market for innovation. There are a vast number of probiotics being used today, and we also wonder whether evaluations by FSANZ would occur in parallel to the establishment of a positive list because we suspect this would raise questions about the viability of a transitional arrangement, balanced against regulatory burden and available resource for evaluation.

87. Grandfathering microorganisms at the time of gazettal considers the following:
    - no evidence of market failure
    - industry due diligence in substantiation of safety

- a history of use and safe consumption in the Australian and New Zealand population or in countries importing products from Australia or New Zealand.

Would the proposed approach for microorganisms present problems for your business? If so, please elaborate

88. See above. INC foresees significant difficulties with the approach proposed for microorganisms. As already stated INC does not support the establishment of a positive list of microorganisms for inclusion in the Food Standards Code and for this to form the basis of food eligibility criteria. Our view is that the resources that would be required to implement this approach would be better allocated to activities that will provide greater value to stakeholders with respect to improved food safety and integrity of the food supply.

89. We also reiterate the potential for trade implications and the need to take into account the significant volumes of foods manufactured in Australia and New Zealand for export.

90. Individual INC members will respond regarding their respective businesses.

Part 2.9 standards – scope and timing

91. INC continues to strongly support expansion of the scope of P1024 to include all standards in the Code. INC supports the scope extension made thus far to P1024 such that it now includes all standards except for 2.9.1. INC does not agree with a rationale for exclusion of Standard 2.9.1 based on vulnerability of the population group. Conditions specific to this group can be effected from within a coherent overall framework for novel foods that covers the Food Standards Code in its entirety. A carve out for population groups risks issues related to consistency, timing and approach.