Fonterra Co-operative Group Limited Submission on:

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FSANZ Consultation Paper – Proposal P1024

Revision of the Regulation of Nutritive Substances and Novel Foods

28 July 2017

Executive Summary

1. Fonterra welcomes the opportunity to comment on the Proposal to amend the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code (the Code).

2. Noting that this consultation document is intended to have a limited scope, we nonetheless consider that there are too many elements of the proposed revised framework missing to fully assess the proposal. Fonterra is therefore not able to indicate support for the proposed framework at this time. We encourage FSANZ to undertake additional consultation, potentially including a further consultation document, before proceeding to draft regulatory language.

3. We are disappointed that FSANZ is now proposing a modified framework that does not include the self-assessment with notification pathway proposed in Consultation Document 30-15. In our view, the proposed revised framework will not be able to deliver a risk-proportionate regulatory regime that balances food safety and innovation, nor will it address the fundamental issues that have prevented significant utilisation of this regime by industry. We submit that FSANZ should continue to develop the self-assessment with notification pathway as part of the Proposal, to identify amendments to the FSANZ Act to allow this option to advance, or potentially identify a way forward without amendments to the Act.

4. Specifically, Fonterra considers significant additional development is required for:

- The self-assessment with notification pathway
- Eligible Food Criteria (EFC)
- Consideration of overseas approvals
- Data requirements for eligible foods
- Amended data requirements for applications; and
- Treatment of microorganisms

5. Fonterra remains concerned the draft EFC proposed in Consultation Document 30-15 do not provide clarity and certainty for dairy ingredients, and do not provide for appropriate targeting of food safety risk. We welcome the recognition from FSANZ that these criteria require more work, and look forward to working with FSANZ on this as part of targeted consultation with the dairy industry.

6. Fonterra supports consideration of amended data requirements in the Application Handbook to develop a tiered approach where data requirements increase as the risk that may be presented by a food or ingredient increases. However, as long all applications are required to undergo two separate public consultations, the benefits in terms of time and cost savings that can be achieved will be marginal. These tiered requirements will not be an effective replacement for a graduated risk management approach that includes a self-assessment with notification pathway.

7. Fonterra notes there is a significant lack of clarity in the consultation document regarding treatment of microorganisms, and that further work is required to clarify and refine these requirements. In particular we:

- are supportive of maintaining the status quo with regards to use of food cultures within foods;
- are also supportive of maintaining the status quo with regards to the use of probiotics in foods;
- do not consider certain Food Categories, or microorganism purpose (e.g. when used as a probiotic), should be exempt from Grandfathering principles; and
- retain our previous concerns with the approach to determine Eligible Food Criteria for microorganisms.

8. Fonterra supports expansion of the scope of P1024 to include all standards in the Code, including Standard 2.9.1.

9. Fonterra proposes that a period of at least 3 years for exclusivity permissions would be appropriate. We note that another company is also able to develop and submit their own application over the exclusivity period and therefore it does not stop another company from launching a new food.

10. Fonterra welcomes the opportunity to work with FSANZ to address the concerns raised in our submission.

Fonterra Co-operative Group Limited

11. Fonterra is a leading global dairy nutrition business, owned by 10,500 New Zealand farmer shareholders. Fonterra is the world's leading exporter of dairy products and a preferred supplier of dairy ingredients to many of the world's leading food companies.

12. Fonterra is New Zealand's (NZ) largest company involved in large-scale milk procurement, processing and management, with a supply chain spanning more than 140 countries. The company has NZ$14.1 billion in total assets and revenues of NZ$16 billion, employing more than 16,000 people worldwide.

13. In Australia, Fonterra operates 7 manufacturing sites across Victoria and Tasmania and employs around 1,500 people. Fonterra Australia collects around 1.6 billion litres of milk annually from almost 1,100 farmer suppliers and their 300,000 dairy cows.

14. Fonterra is a market leader in the consumer dairy segment with a portfolio of milk, cheese, butter and spreads, ice cream and yoghurt brands in Australia and New Zealand. Some of our consumer brands include Anchor, Fresh n' Fruity, Kapiti, Mainland, Perfect Italiano, Primo, Tip Top and Western Star. Fonterra also operates a dedicated sales channel for the foodservice industry which services restaurants, cafes, hotels and QSR operations.

15. Food safety and quality, and innovation are priorities for every part of the Fonterra business. We have innovation capability on either side of the Tasman, including state-of-the-art research facilities in Palmerston North, New Zealand and a global network of research and development facilities. Fonterra products are synonymous with innovation in bone health, maternal health, child and infant nutrition and dairy goodness. Fonterra products and ingredients are found in many types of manufactured food products, pharmaceuticals, food service outlets including bakeries, restaurants and hotels, and homes across Australia, New Zealand and around the world.

General Comments

16. Fonterra welcomes the opportunity to comment on the Proposal to amend the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code (the Code), as set out in Consultation Document 15-17.

17. As noted in our submission on the previous consultation document (30-15: Call for submissions – Proposal P1024 Revision of the Regulation of Nutritive Substances & Novel Foods), Fonterra agrees with FSANZ's view that the current regulatory regime for nutritive substances creates uncertainty for both enforcement agencies and industry. We welcome consideration of a revised regime that removes this ambiguity while also addressing the full range of objectives as set out in Consultation Document 30-15[1]. As these objectives demonstrate, improving the framework for regulating nutritive substances and novel foods requires achieving a balance between protecting the integrity of the food supply and supporting industry innovation.

[1] p11: "FSANZ's primary objective in standards development is the protection of public health and safety and this is the primary consideration FSANZ has taken into account in developing and assessing options. FSANZ has taken other secondary considerations into account, noting that options should be proportionate to the varying levels of risk of new foods entering the market; should be objective, clearly understood and enforceable; and should provide industry with the opportunity to access the market quickly and without undue regulatory burden. Compatibility with international approaches to the regulation of novel foods is also a consideration in formulating an amended approach."

18. With this in mind, Fonterra supported several elements of the proposed framework from Consultation Document 30-15:

- Recognition that there are varying levels of risk arising from **new** products, and that a graduated risk management approach is appropriate to manage those risks;
- Recognition that it is appropriate to use existing products and ingredients with a history of safe use as a point of comparison for safety assessments;
- Intent to align with international approaches; and
- Introduction of a pathway for pre-market self-assessment as an alternative to FSANZ pre-market assessment.

Regulatory Framework (Section 2)

19. In light of our support for the introduction of a graduated risk management approach, we are disappointed that FSANZ is now proposing a modified framework that does not include the self-assessment with notification pathway. Without the inclusion of a streamlined pathway, such as the self-assessment with notification pathway, the updated regulatory framework will not be able to deliver on the objective to introduce a risk-proportionate regulatory regime that balances food safety and innovation. Further, the value of the amendments now proposed is limited only to addressing the uncertainty associated with the current definitions for enforcement. It will not address the fundamental issues that have prevented significant utilisation of this regime by industry.

20. We also note that the move away from introducing a risk-proportionate framework by removing the option for a streamlined assessment pathway amplifies the need to ensure the Eligible Food Criteria (EFC) are appropriately targeted. EFC that exclude too many low risk foods and ingredients will increase the number of substances that require a FSANZ pre-market assessment, increasing both time and cost to market for no safety benefit. Without a self-assessment with notification pathway, it will be critical that the EFC pathway is broad enough to include a wide range of low risk foods/ ingredients that might otherwise have gone down the self-assessment with notification pathway. We have previously expressed a range of concerns with the EFC as outlined in Consultation Document 30-15, and continue to encourage FSANZ to undertake additional targeted consultation with the dairy industry to address these weaknesses.

21. We acknowledge the indication from FSANZ that they will consider the possibility of amending data requirements for FSANZ pre-market approvals, as well other administrative, business and risk assessment processes, as an attempt to streamline the application and FSANZ assessment process for different types of foods and ingredients. We look forward to providing comments on these proposals in a separate consultation, however we note that this is not an effective replacement for introducing a streamlined, industry self assessment with notification pathway in a graduated risk management approach.

Summary of findings/development of self-assessment with notification pathway

22. Fonterra notes the discussion of options proposed by submitters that would amend the proposed framework from Consultation Document 30-15 (Table 1: Submitter suggested options for self-assessment pathways) and the accompanying commentary that “most exceed FSANZ’s remit

under the FSANZ Act" when "FSANZ must operate within the requirements of the FSANZ Act when developing or varying food regulatory measures."

23. Fonterra considers that it is important to get the nutritive substances and novel foods regime right to support continued growth and innovation in the Australia and NZ agricultural and food sectors. This regime is consequential enough that time should be taken to implement the optimal regime, rather than pushing through a limited process that only addresses a portion of the limitations of the regime. We note that the investigation of changes to the regime has been underway since 2012, and do not see any pressing issues that require these changes to now be pushed through in a short time frame.

24. We understand that it is not within the remit of FSANZ to seek to change the FSANZ Act, but observe that limitations and gaps in the Act are most often identified during FSANZ's operations. As such, FSANZ does have a responsibility to articulate the limitations of the Act and the options that have been identified for how these limitations should be addressed. The self-assessment with notification pathway with centralised assessment received substantial support from both industry and government submitters, and is also consistent with the support for industry self-assessment that was indicated by the Ministerial Council in directing FSANZ to include such a pathway in the health claims regime. We submit that FSANZ should continue to develop this pathway as part of the framework. This could identify specific amendments to the FSANZ Act to allow this option to advance, or could even result in a way forward that would allow this pathway to be implemented without amendments to the Act. If changes to the FSANZ Act are then required to implement the most effective regulatory framework, then those changes can be pursued subsequently to the development of the regime.

25. Further, we note that it is not the self assessment with notification pathway that cannot be accommodated by the Act but rather the administration of the option to meet jurisdictional demands. We understand it could be possible to continue to develop the self assessment with notification pathway so it could be put in place but not commenced until such time as the Act is amended to provide for centralised assessment. This is an approach that we would support.

Issues for subsequent consultation (section 1.3)

26. We note that Consultation Paper 15-17 does not address all issues of relevance to this Proposal, and specifically excludes a range of issues that are crucially important for the proposed framework. Between the exclusion of some of the most significant issues identified in the previous round of consultation, and the elements of the revised framework that are insufficiently described in the current consultation paper, we consider that there are too many elements of the proposed revised framework missing to fully assess the proposal. Fonterra is therefore not able to indicate support for the proposed framework at this time.

27. We note FSANZ's statement that "If a draft food regulatory measure if prepared, there will be a further call for submissions on the proposed draft measure". We understand this to mean that the next stage of consultation will include draft regulatory language. We consider that there are too many elements of the framework that require considerable further development before being ready to be translated into a draft regulatory measure. We therefore encourage FSANZ to undertake additional consultation, potentially including a further consultation document, before proceeding to draft regulatory language.

28. Specifically, Fonterra considers significant additional development is required for:

- The self-assessment with notification pathway (or an alternate, streamlined pathway for low risk foods e.g. ensuring all such foods are captured within the EFC pathway)
- Eligible Food Criteria (EFC)
- Consideration of overseas approvals
- Data requirements for eligible foods
- Amended data requirements for applications (section 2.2.4 of Consultation Paper 15-17); and
- Treatment of microorganisms

Eligible Food Criteria (EFC)

29. We have previously highlighted significant concerns with the EFC as outlined in Consultation Document 30-15. The draft EFC do not provide clarity and certainty for dairy ingredients, and do not provide for appropriate targeting of food safety risk. We welcome the recognition from FSANZ that these criteria require more work, and look forward to working with FSANZ on this as part of targeted consultation with the dairy industry.

30. We have outlined our principles for these EFC in the past, and reiterate them here.

- The EFC should recognise the long history of safe use of dairy ingredients:
    - many dairy foods and ingredients with a long history of safe consumption are produced through fractionating and concentrating various milk components, including cheese, milk powders and milk protein concentrates.
    - the focus should be on whether the finished product will significantly alter total dietary intake of nutrients.

- The EFC should support a risk-proportionate approach to balancing innovation and food safety:
    - the regime should not require FSANZ pre-market assessment for all concentrated dairy ingredients.
    - The regime should also recognise the contributions of the broader food regulatory system in supporting the safety of the food supply, e.g. appropriate labelling to identify allergens.

- The basis for comparison should be what can be delivered to a final product through ingredients
    - The criteria should account for different addition rates of ingredients (with comparison in final product) instead of forcing a focus solely on comparison between ingredients.

- The criteria should provide the ability to use appropriate food products and ingredients for comparison of concentration
    - For dairy products, the criteria should not require fluid milk to be used as the basis for all comparisons.
    - A more appropriate basis for comparison in a safety assessment is what can be delivered to a final product through typical dairy ingredients, or those historically consumed, including Milk Protein Concentrate (MPC), Whey Protein Concentrate (WPC), cream powders and sweet whey powder.

- For infant formula, the appropriate point of comparison for concentration for infant formula is not necessarily always the source commodity but could be breast milk. Points of comparison for concentration can also include other ingredients used in infant formula products.

Consideration of overseas approvals

31. As noted in our previous submission, Fonterra supports amending the framework to accommodate recognition of approvals specified overseas authorities, and the acceptance of food that has a demonstrated history of human consumption overseas. We encourage FSANZ to reflect these approvals in such a way that there is genuine benefit to be gained from the overseas approval, in order to minimise both administration burden and unnecessary data re-substantiation for products whose safety has already been established.

Amended data requirements for applications in Application Handbook (section 2.2.4)

32. As noted above (para 21), Fonterra supports consideration of amended data requirements in the Application Handbook to develop a tiered approach where data requirements increased with complexity or risk that may be presented by a food or ingredient. We look forward to providing comments on these proposals in a separate consultation. At this stage, we offer a few comments for consideration:

- The data required should focus on what is required to establish the safety of the substance, not benefit or efficacy. These elements are covered off in other regulatory regimes, such as the health claims approval process.

- The data requirements should recognise the validity of data from similar populations (e.g. the EU).

- The requirements should be outcome focussed and recognise the availability of alternative means of establishing the safety of the food ingredient (e.g. not mandating clinical trials if a substantial body of evidence already exists to demonstrate safety).

- The consultation documents notes “the Handbook could more explicitly set out different levels of data required for different types of foods; with data requirements increasing with complexity or risk that may be presented by a food”. We look forward to working with FSANZ to identify the factors to be considered when assessing the “complexity” or risk of a food, noting that “complexity” may be a challenging concept to describe when applied to food products and ingredients (as the difficulty in developing adequate EFC has demonstrated).

- We also note that, while we are supportive of the concept of differentiating the data requirements for applications, as long all applications are required to undergo two separate public consultations, the benefits in terms of time and cost savings that can be achieved will be marginal. These tiered requirements will not be an effective replacement for a graduated risk management approach that includes a self-assessment with notification pathway.

Microorganisms (Section 3.2.2)

33. Fonterra notes there is a significant lack of clarity in the current FSANZ proposal for regulation of microorganisms. We have provided additional detail on our concerns in the Appendix (Responses to selected questions for submitters) but outline our key concerns below.

34. Fonterra are supportive of the status quo with regards to use of food cultures within foods. Our understanding is FSANZ are trying to encapsulate status quo through grandfathering food categories. This would therefore continue to enable foods produced with food cultures to not be subject to FSANZ pre-market assessment when a food culture is added. Fonterra are supportive of this approach, provided our understanding of scope is correct as detailed below.

35. Fonterra is also supportive of maintaining the status quo with regards to the use of probiotics in foods. We do not consider an alternative approach for probiotic use is justified. If changes are to be proposed to the regulation of microorganism used as probiotics, then Fonterra consider grandfathering provisions should also capture current use of probiotics.

36. We also wish to reiterate the concerns from our submission on Consultation Document 30-15 regarding Eligible Food Criteria as drafted for application to microorganisms, which we understand FSANZ now intend to apply to 'novel' microorganisms or those not used for food culture purpose. The proposed approach of grandfathering in certain foods is not sufficient to address the substantive concerns with the EFC.

Part 2.9 standards – scope and timing (Section 3.3)

37. As noted in our previous submission, Fonterra supports expansion of the scope of P1024 to include all standards in the Code. We support the extension of scope of P1024 as outlined in Consultation Document 15-17, such that it now includes all standards except for 2.9.1. Fonterra does not agree with a rationale for exclusion of Standard 2.9.1 based on the vulnerability of the population group. We submit that the same framework as applied to general foods should be extended to products covered under Standard 2.9.1, with specific differentiation to address the 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.

Specific comments

38. We note that FSANZ is also seeking comments on specific issues regarding the revised framework, including :

- Consideration of novel foods in the proposed framework
- Consideration of nutritive substances
- Review of exclusive permissions
- Transition arrangements: grandfathering
- Transition arrangements: microorganisms

39. We have provided further detail on specific “Questions for Submitters” in the Appendix.

40. If there are any queries relating to this submission, please contact [redacted]

Yours faithfully

[redacted]

Victoria Landells

[redacted]

Appendix: Responses to selected questions for submitters

Refer Section 2.2.1/2.2.2: Consideration of Novel Foods in the proposed framework

- Fonterra only supports removal of the definition of novel food if the other elements of the proposed regime can be developed to the point that the proposed framework becomes workable.

- **Which of the novel foods listed in Schedule 25 are used only in foods regulated by specific Part 2.9 standards?**
- 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.**
- 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. Fonterra suggests that a guidance document listing the approvals over time, as well as not-novel or nutritive substance opinions (which would not have the status of a regulatory measure) would be equally as useful.

Refer Section 2.2.3 Consideration of nutritive and related substances

- We understand that FSANZ is proposing the following approach:
    - vitamins, minerals, electrolytes and L-amino acids will require pre-market assessment before being added to new products.
    - 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 proposed regime, be assessed against the EFC to determine whether a pre-market assessment is required.
- Fonterra is supportive of this approach in principle, as it provides consistency of treatment across all substances considered under this framework (i.e. nutritive substances and novel foods), but note that it is not possible to reach a definitive view in the absence of clarity over the EFC.

- **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.**

- Fonterra does not consider that there are other nutritive type substances that should always be subject to pre-market approval by FSANZ.
- FSANZ's rationale that vitamins, minerals, electrolytes and L-amino acids should continue to require pre-market approval (for inclusion in the standards that currently contain those permissions) is to ensure a consistent and moderate approach to adding these substances to support public health nutrition policies and ensure the safety of permitted chemical forms. This is a unique rationale that applies only to those nutritive-type substances, and there is no justification for extending this requirement to other nutritive-type substances.

Refer Section 3.1 Review of exclusive permissions

- Fonterra acknowledges that it is important for the FSANZ decision-making process to be transparent and accountable, but is also important to continue to ensure that intellectual property is protected to ensure that investment in innovation is encouraged.
- At the moment there are provisions for protecting commercially sensitive information in the FSANZ Act as outlined in the current Application Handbook and we support the retention of this; noting that confidential commercial information includes (a) trade secrets relating to food; or (b) any other information relating to food that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed. Therefore a range of confidential commercial information can be protected including trade secrets, manufacturing processing and unpublished data.
- Intellectual property protection is included in other international food law regimes for new food applications including the European Union and United States. Under these regimes further protection above any intellectual property laws and patents is deemed appropriate to support research and development of the food industry, and not overly onerous by the regulators. Supporting innovation to grow exports and drive economic growth is a focus for both the Australian and New Zealand Government. Providing a food regulatory regime that is risk-proportionate, timely and protects intellectual property is necessary to encourage innovation in the food industry.
- **Does there remain a requirement to provide exclusive permission as a condition of use in the Code?**
- Fonterra submits that there remains a need to provide for exclusion permission in the Code. Applications to change the Code take considerable time, expertise and money. The exclusivity period means that the company that has borne the cost of the application can be confident that, for a short period of time, other companies will not be able to benefit from the investment made by the applicant. This protection may further encourage applications from companies for new foods and ingredients under the regime.
- **What costs to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible.**
- Fonterra believes that there are limited costs to the community, government and industry in granting the use of exclusive permission with the most notable cost being the opportunity cost of limiting competition for a period of time.
- Limiting competition, such as through an exclusivity period, will create a financial cost to consumers if the company selling the product is able to exert market power and raise the product price. We consider that these costs to consumers are limited by competitive pressures within the food market. Although it is possible in theory for a company to charge a higher price for a novel food or ingredient within the exclusivity period, this would also likely have a negative impact on sales. This is particularly true in the case of the early launch period for a product, as it is difficult to initially attract customers to a new product – evidenced by the high rate of failure of new food product launches[2]. There are also usually alternative offerings within the same category that provide competitive pressures (e.g. other spreads competing against spreads with plant sterols), meaning that a new product still needs to be priced competitively to attract customers against other products in the same category.
- Furthermore, we note that another company could also submit an application for a similar product during the exclusivity period, based on their own data. The exclusivity period does

[2] http://www.nielsen.com/nz/en/insights/news/2015/new-product-development-new-zealands-taste-for-new-things.html; http://www.nielsen.com/au/en/insights/news/2015/a-taste-for-new-things-aussies-demand-innovation-that-offers-convenience-and-is-affordable.html;

not completely restrict another company's ability from selling this new food or ingredient, it is simply providing some protection for a company's investment in an application.

- **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.**
- As noted above, the ability to seek an exclusivity period of a suitable length of time supports innovation by allowing companies a period of time where competitors are not able to benefit from their research and intellectual property. This encourages applications for new foods and ingredients that provide benefits to the community through bringing to market new foods that provide more options for consumers, including options that are healthier (e.g. plant sterols), tastier (e.g. Stevia), more environmentally friendly and more convenient.
- Having an active approvals process for bringing new foods and ingredients to market also provides benefit for industry, both for the companies that are able to bring those new products to market, and for other companies that can seek to take advantage of the new eligible food permission after exclusivity laps without bearing the cost of the application.
- Providing exclusive permissions for a fixed period of time is a low direct cost and low transaction cost approach governments can make towards supporting innovation, which is why some form of exclusivity is a common factor among similar overseas regimes. Supporting innovation in the food industry to grow exports and drive economic growth is a stated priority for both the Australian and New Zealand Governments:
    - Under the Australian National Innovation and Science Agenda (NISA) innovation is deemed critical to improving Australia's competitiveness and driving economic growth[3]. This includes a commitment from the Australian Government to innovation being central to all major policies going forward. The Global Innovation Strategy, under the NISA, has identified the food and agribusiness sector as one of six industry sectors of competitive strength and strategic priority.
    - Innovation as one of the six key platforms of the New Zealand Government's Business Growth Agenda[4], the primary policy vehicle for building a more competitive and productive economy for New Zealand.

  Developing a risk-proportionate regulatory regime that protects the safety of the food supply while also supporting innovation (such as through allowing for appropriate protection of confidential information and intellectual property) is therefore of significant benefit to Government.
- **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?**
- Fonterra does not believe that the provision of exclusive permission means the Australian and New Zealand Food regulators are bearing the onus and cost of protecting industry's intellectual property.
- As we outline further below, the exclusivity period is one element of the network of measures that protects intellectual property, providing additional support for companies that invest in innovation and an application to amend the Code through FSANZ pre-market approval. It fills a gap within this network of measures, but in no way replaces the need for patents, trademarks or protection of confidential commercial information – measures that are provided across a range of government entities.
- We also our comments above regarding the significant government initiatives that highlight the role of innovation in the food industry underpinning economic growth in both Australia

[3] https://www.innovation.gov.au/

[4] http://www.mbie.govt.nz/info-services/business/business-growth-agenda

and New Zealand. By providing these exclusivity provisions, Australian and New Zealand food regulators are supporting innovation in the food supply, and making a judgement that the minimal costs are outweighed by the benefits, in the same way that overseas jurisdictions have done.

- **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?**
- Other existing measures such as patents and trademarks are used to protect intellectually property however it is important that additional measures, such as protection of confidential commercial information and exclusivity provisions, are supported through food law for the food industry.
- The current provisions for protection of confidential information in an application are extremely important:
    - Patent applications are extremely slow (with timelines measured in years, not months) and a Food Standards Code Application may be happening in conjunction with the patent application. The protections offered under a patent will not be available for the information included in the application until the patent application is granted, meaning the confidentiality and exclusivity provisions provide important protection over this period.
    - Patents are very difficult to obtain foods and food ingredients. The confidentiality and exclusivity provisions also provide important protection for foods/ingredients for which patents are not granted.
    - A patent only provides protection of intellectual property for up to 20 years, and it is not always easy to determine whether another party has breached a patent particularly in regards to manufacturing processes. Companies may therefore decide to rely on trade secret protections, which can last generations and ensure that sensitive information is not made available to competitors. In this situation, the confidentiality provisions are crucial to enable an application for a FSANZ pre-market application to be made.
- **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)?**
- Fonterra is not aware of anything other than intellectual property laws including patents and trademarks.
- **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.**
- Fonterra submits that a period of at least 3 years for exclusivity permissions would be more appropriate. The investment in a new food including research and payment for an application is expensive and a 15-month exclusivity period is insufficient protection on this investment. It is not in the interests of Australia or New Zealand to constrain innovation through an exclusivity period that is not long enough for companies to establish market positions for new products.
- FSANZ alone charges approximately $93,225 NZD for an application to extend the permission of an existing food, and approximately $137,500 NZD for an assessment of a completely new food. The cost of research, literature reviews and scientific expertise for the application would be at least $100,000 for a simple application and can be millions of dollars for something more complex.

- We note again that another company is also able to develop and submit their own application over the exclusivity period and therefore it does not stop another company from launching a new food. The exclusivity provision simply protects a company's investment in their application.
- **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.**
- Fonterra currently undertakes the majority of our innovation in Australia and New Zealand. Many things are considered when determining the most appropriate location for innovation activities including where the food will be sold. As New Zealand and Australia are relatively small countries they can be a great first market to refine (e.g. marketing, taste etc.) for new innovations before launching globally. Ensuring that the food regime is streamlined so that it provides an efficient, timely and risk appropriate food law regime will encourage companies to invest in innovation within Australia and New Zealand.
- **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.**
- Fonterra will often place new products in markets overseas before placing them on the market in Australia or New Zealand. This is due to a range of factors, including:
    - Other markets having a more streamlined, cost effective and less ambiguous requirements for novel foods and ingredients based on 'safety' and not perceived benefit. For example the US GRAS application process takes 6 months from submission.
    - Other markets may allow more science based statements so that the benefits of any new innovation can be communicated to consumers and therefore value from innovation realised. The products may be able to make content or function claims on the new ingredient on label (e.g. contains GOS or GOS assists with gut health) so the benefits can be communicated to consumers.

Refer Section 3.2 Transition arrangements for currently marketed foods

- **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).**
- As noted in our previous submission, grandfathering is the only pragmatic approach for transition under a regulatory regime of this nature. We note that jurisdictions can still enforce the requirement that food offered for sale is safe to consumer under the own Food Acts, for products where there are specific known concerns at the time of transition.
- The consultation document refers to the cut-off being applied to products "on the market" and "foods supplied" at the date of gazettal. For ingredients and products sold from business to business, we assume that this this means that the product will be considered "on the market" or "supplied" if it is manufactured in and/ or sold in New Zealand or Australia on, or before, the date of gazettal.
- We do not support the creation of a positive list of products being grandfathered. We agree with FSANZ's assessment that this would be a lengthy and expensive process that would be disproportionate to risk.

- **Do you consider there are categories of foods that should not be grandfathered? If so, please provide justification for your view.**
- Fonterra does not consider that there are any categories of foods that should not be grandfathered.
- **Would the proposed approach for microorganisms present problems for your business? If so, please elaborate.**
- Fonterra does not consider there is sufficient rationale to justify change to the current approach of regulation of microorganisms within the Code. Food containing microorganisms must be safe, as outlined by general provisions within the Food Acts of New Zealand and Australian jurisdictions. Companies currently hold data to support the safety of their microorganisms when used in food. In the absence of market failure or safety concern with use of microorganisms, lack of specific regulations in other jurisdictions covering microorganisms (with the exception of processing aids which is also covered separately by FSANZ), and consistency with Codex, Fonterra's strong preference is to retain status quo.
- Fonterra could tentatively support the grandfathering approach suggested for all foods and food ingredients produced with and containing live food cultures manufactured in, or sold in ANZ, as a means to encapsulate status quo, provided our interpretation of scope is correct i.e. that proposal relates to:
    - Those food cultures which have been intentionally added (and could be cultured) in foods, and are viable at the time of food consumption i.e. those microorganisms that are used during processing and terminated before food consumption are out of scope, and continue to be covered by other Standards within the Code where appropriate (e.g. the production of ethanol from yeast where the yeast is removed from the finished product).
    - Foods and ingredients use of food cultures at or before date of gazettal, and will not include a binding positive list of food cultures referenced in the Regulation for specific food categories.
    - Both foods and ingredients manufactured in ANZ and sold domestically or internationally, as well as imported foods and ingredients.
    - It would thus remain the supplier responsibility of the 'grandfathered' foods to ensure that any food cultures used in these foods are safe and suitable/ have a history of use. Industry may choose to refer to the FC, EFFCA, and IDF jointly produced "Inventory of Microorganisms with a documented history of use in food" lists, or QPS lists, or other as support for this.
- Fonterra are also supportive of status quo with regards to the use of probiotics in foods. Furthermore, we do not consider certain Food Categories, or microorganism purpose (eg when used as a probiotic), should be exempt from Grandfathering principles.
    - Fonterra supports the status quo of provisions permitting the use of lactic acid bacteria, for food culture or other purpose (e.g. probiotic), in food categories. This is aligned with Codex. We do not support exemptions to grandfathering. We are unclear as to why FSANZ would consider a grandfathering principle could not be applied to microorganisms used for a purpose other than food culturing (eg probiotic), and/ or to select food categories (Standard 2.9.1 and Standard 2.9.2) that have been safely used in foods.
    - We consider there is a lack of clarity regarding terms FSANZ use within the proposal in turn contributing to potential confusion regarding scope proposal.
        - While we have outlined our interpretation of scope above, we consider it would be helpful if FSANZ refer either to 'food microorganisms' or 'food

cultures', rather than 'food culture microorganisms'. As FCM is currently applied in the proposal it could suggest the culture has to be 'grown up' and excludes addition of culture to food that doesn't grow (*eg acidophilus addition to yoghurt or a generic bifido that doesn't grow*).

- Food cultures can be probiotics and vice versa, and it is unclear what and why FSANZ are trying to exempt from grandfathering certain microorganisms based a) on nutritional purpose and b) exempt from existing current use in 2.9.1 and 2.9.2.

- We highlight the absence of any market failure or safety concerns with industries current use of "microorganisms", regardless of purpose (e.g. culture or probiotic), across all categories. FSANZ could create significant in-market issues in consumer confidence and significant trade barriers by creating any regulatory uncertainty with regards to existing use of microorganisms within food categories. The use of lactic acid bacteria 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.

- We still have substantive concerns with the approach to determine Eligible Food Criteria for microorganisms i.e. Fonterra does not support the EFC proposed for microorganisms. Further work will be required to develop an EFC that can be appropriately applied to "novel" microorganisms.
  - Clarity is needed as to what is meant by microorganisms are "eligible if they are listed in the Code and are cultured to maintain genetic stability". In principle we support that a culture should be stable, however under what conditions should this be measured? The intent of such a criterion needs further consideration.
  - Any positive list created should only be at the genus or species level, not strain level (too difficult technically to maintain a list to this level of detail).
  - Fonterra supports that a food business would need to be able to demonstrate that a microorganism that they intend to add to food is identifiable, and belongs to a taxonomic group.

- Finally, Fonterra are not clear on (and do not agree with) some of FSANZ's comments regarding safety of microorganisms.
  - We agree microorganisms with a safe history of use do not raise safety concerns, however do not necessarily consider a change in "amount" of a microorganism used during production, or consumed within a typical range in food product, as posing a safety concern.
  - We do not consider that the presence of a toxic gene should necessarily preclude a microorganism from being an eligible food (if it's on a genome it doesn't necessarily mean it will be switched on), instead this should mean further testing to support safety would need to be conducted.

3.3 Part 2.9 standards – scope and timing

- Please refer to our comments in paragraph 37.