Fonterra Co-operative Group Limited Submission on:

Fonterra Co-operative Group Limited
PO Box 417, Wellington 6140
Level 12, Vodafone on the Quay,
157 Lambton Quay, Wellington
New Zealand
t +64 4 913 9341
www.fonterra.com

FSANZ Call for Submissions – Proposal P1024

Revision of the Regulation of Nutritive Substances and Novel Foods

24 March 2016

Executive Summary

1. Fonterra welcomes the opportunity to comment on the Proposal to investigate the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code. We agree that there is ambiguity under the current regulatory regime for nutritive substances, and support a review that would remove this ambiguity.

2. Fonterra supports several aspects of the proposal including adopting a risk-based approach, the intention to align with international approaches and introduction of a pathway for pre-market self-assessment.

3. There are, however, areas of the regime where we see significant challenges in applying the proposed regime to dairy ingredients.

4. FSANZ has focused on concentration of components as a key indicator of safety risk, and has designed a framework that identifies concentrated foods and ingredients as requiring additional safety assessment. The dairy industry, however, has a long history of fractionating and concentrating milk to produce foods and ingredients with safe use (e.g. cheese, milk powders and milk protein concentrates). This history of safe should be recognised by the regime to support efficient allocation of regulatory resources and avoid unnecessary regulatory burden.

5. Addition of dairy components to a food at a concentration higher than that achievable from whole milk does not automatically create a health risk. A more appropriate basis for comparison in a safety assessment is what can be delivered to a final product through typical dairy ingredients (including Milk Protein Concentrate (MPC), Whey Protein Concentrate (WPC), cream powders, sweet whey powder, etc). This then enables a meaningful comparison for addition rate of concentrated dairy ingredients and components delivered to a final product to other dairy ingredients that could alternately be used.

6. Further to the concerns noted above, evaluation of the proposed Eligible Food Criteria against examples of common dairy ingredients demonstrates that the Criteria do not provide clarity or allow an objective assessment of the “eligibility” of dairy ingredients. Under Eligible Food Criterion 2 (EFC2) it is not possible to objectively evaluate whether a product is “simply processed”,

or should be considered as an extract or a substance. It is also not possible to determine which ingredients or products can be used as the basis for comparison for Eligible Food Criterion 3 or 4.

7. Fonterra has also identified a range of more specific concerns with the Eligible Food Criteria, including:

a. The proposed exclusion of enzymatic processing from the list of eligible food processes under EFC2;
b. The need for an expanded approach to identifying eligible microorganisms; and
c. Recognition that the proposed regime is fundamentally a series of positive lists (for eligible microorganisms, commodities and food classes, processes and potentially enzymes) and thus a pragmatic approach for amending these lists is required.

8. Fonterra requests FSANZ re-consider the Eligible Food Criteria in light of these concerns. Fonterra requests additional targeted consultation with the dairy industry before drafting commences on a revised proposal to address these weaknesses.

9. As noted above, Fonterra is supportive of introducing a pathway for pre-market self assessment by industry, although the ability to protect intellectual property (IP) will be critical for this pathway to have utility for industry. We propose an alternative approach, similar to the self-determined US GRAS system:

a. Company X develops the dossier to use as the basis for determination;
b. The dossier is subject to an independent expert review;
c. Company X holds the dossier and independent expert review in house; and
d. The dossier can be requested by food authorities if required.

10. We also consider ingredients destined for infant formula should included in the scope of this review, and that the proposed regime, with some modifications outlined subsequently in our submission, should be applied to these products.

11. Fonterra notes that consistency in implementation and enforcement across jurisdictions will be critical for this regime. The introduction of the Eligible Food Criteria and pre-market self-assessment with notification pathways, in particular, will require consistency of implementation across jurisdictions to avoid creating significant business risk for companies.

12. Finally, Fonterra encourages FSANZ to consider whether the proposed changes have any implications for New Zealand and Australian exports of dairy products, in particular clarification of the relationship between the proposed regime and existing New Zealand and Australian approaches for addressing conflicts between domestic and export market regulatory regimes.

13. Fonterra welcomes the opportunity to work with FSANZ to address these concerns.

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14. 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.

15. 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.

16. Fonterra is also 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, Bega, 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.

17. Food safety and quality, and innovation are priorities to every part of the Fonterra business. Through its state-of-the-art research facilities in Palmerston North, New Zealand and Melbourne, Australia, and its global network of research and development facilities, Fonterra is a leader in dairy science and innovation. 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

18. Fonterra welcomes the opportunity to comment on the Proposal to investigate the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code (the Code). The key objective with respect to this proposed Standard is to achieve the correct balance between the role of food Standards in protecting the integrity of the food supply, and also supporting industry innovation.

19. Fonterra supports development of a regulatory regime for novel foods and ingredients that conforms to the following principles:

a. Promotes food safety and consumer confidence in the food supply;
b. Provides for appropriate regulatory interventions based on risk
c. Provides regulatory certainty while supporting innovation
d. Allows companies to protect intellectual property
e. Provides a credible system that can be leveraged internationally
f. Recognises safety approvals of reputable overseas jurisdictions
g. Recognises the long, safe history of use of dairy products and dairy ingredients
h. Recognises that not all concentration or extraction steps create risk (i.e. create imbalance in total daily intake of nutrients)
i. Focuses on safety, not efficacy (which is covered under a different regulatory regime)

20. We agree 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 new regime that removes this ambiguity while also aligning with the principles set out above.

21. With this in mind, Fonterra is supportive of several elements of the Proposal:

a. 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;

b. Recognition that is it appropriate to use existing products and ingredients with a history of safe use as a point of comparison for safety assessments;

c. Intent to align with international approaches; and

d. Introduction of a pathway for pre-market self-assessment as an alternative to FSANZ pre-market assessment.

22. We support a proportionate approach that allows for a 'step up' in regulatory requirements commensurate with risk and promise which allows for simplified assessments and streamlined decision making.

23. There are several points in the proposals, however, that we find concerning and that require further clarity/development in order for the proposed alternative regime to be considered viable for further development. These issues are identified below, along with our recommendations for addressing these concerns.

24. Inclusion of Infant Formula Products

25. The Proposal explicitly excludes Infant Formula Products (Standard 2.9.1), Foods for Infants (Standard 2.9.2) and Food for Special Medical Purpose (Standard 2.9.5) from this review. Fonterra notes that reviewing the current regulatory regime for nutritive substances and novel foods without consideration of these products will not support development of a regime that can be applied across the entire Food Code. We consider his particularly important when Infant Formula Products and products manufactured as Formulated Meal Replacement and Formulated Supplementary Foods (Standard 2.9.3) are often very closely tied togehter. The current nutritive substances and novel foods regime applies to all foods including those carved out of this proposal. It is not clear how the regulatory gap would be handled in a situation where some foods are covered under a different system for approvals. In addition, we note that a regulatory regime for nutritive substances has particular applicability to products under these standards: the term 'nutritive substances' is used in 6 standards in the Food Standards Code (outside the structure and definitions). All but one standard (Standard 1.3.2 Vitamins and Minerals) are in Part 2.9 including Standard 2.9.1. Consideration of the future regulation of nutritive substances cannot effectively be conducted if most of the standards that apply the term are excluded from the scope of Proposal P1024.

26. Fonterra will therefore include the issues raised in this consultation from the perspective of Standard 2.9.1, in order to provide comprehensive assessment of the proposed regime, and to ensure consistency of approach across the Food Standards Code.

27. As discussed in more detail later in our answers to specific questions, Fonterra supports the proposal of the Infant Nutrition Council (INC) that, with appropriate differentiation, the framework

proposed in Option 3 (although it requires further development as noted subsequently in this submission) should be applied to Standard 2.9.1.

28. **Recognition of the long history of safe consumption of dairy products and ingredients.**

29. We understand FSANZ is intending to identify substances that when concentrated and added to food can create health risks. It is important that FSANZ recognise that concentration itself is not necessarily risky – the focus should be on whether the finished product will significantly alter total dietary intake of nutrients. For example, 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. Addition of dairy components to a food at a concentration higher than that achievable from whole milk does not automatically create a health risk.

30. A regulatory regime that does not appropriately reflect this history of safe consumption by requiring pre-market safety assessments of dairy ingredients with low health risk, will not provide for efficient allocation of regulatory resources and would add unnecessary regulatory burden to the dairy industry. For example, as we will discuss further below, this regime as drafted would have required a full pre-market assessment for whey protein concentrate and milk protein concentrates which we do not consider justified.

31. Proposed system should account for different addition rates of ingredients

32. As noted above, the focus of safety assessments in this context should be on whether the finished product will significantly alter total dietary intake of nutrients. The basis for comparison should be what can be delivered to a final product through ingredients. This provides the ability to account for different **addition rates** of ingredients (with comparison in final product) instead of forcing a focus solely on comparison between ingredients.

33. Specifically, Fonterra seeks confirmation from FSANZ that pre-market assessment should not be required for concentrated dairy ingredients that deliver key components at level that could feasibly be achieved either through addition of other dairy ingredients at higher addition rates, or using different processing steps as an alternative to the intended product. For example:

a. 1 gram of a new dairy ingredient could deliver the same key components as 10 grams of an existing dairy ingredient;
b. High (10%) protein beverage: could be produced by processing milk through ultrafiltration to increase level of protein to ~20g per 200mL serve, or using addition of milk protein concentrate (MPC) to skim milk to achieve the same protein level.

34. Fonterra has provided separately examples of demonstrating how ingredients with different concentrations of key components can be used at different addition rates to achieve the same effect.

35. Recognition that pre-market assessment should not be required for concentrated dairy ingredients that deliver key components at level that could feasibly be achieved through addition of other dairy ingredients albeit at higher addition rates is important for dairy ingredients where (for example) lactose content may be reduced to enable formulation flexibility, but chemical components

are still the same and still inherently safe. We note that this is a very different concept from Eligible Food Criterion 4 (EFC4) which only allows for addition to within the natural variation of a food

36. Ability to use appropriate food products and ingredients for comparison of concentration

37. As identified in the discussion above, the effectiveness of the proposed regime is contingent on being able to compare concentration of nutrients in a finished product against an appropriate basis. In order for the proposed regime to provide an appropriate level of risk-based regulatory oversight, it is not sufficient from a dairy perspective to have whole milk as the only point of comparison for assessing concentration of components. It appears this is not FSANZ intent, and that the Proposal envisages "simply processed" commodities being used as a point of comparison as well. Fonterra supports this concept, although we note that further work is required to ensure the Eligible Food Criteria deliver on this intent. This lack of clarity from the Eligible Food Criteria is discussed further below, however, we thought it would be helpful to provide FSANZ with additional examples to support further consideration of appropriate bases for comparison.

38. For example:

a. 10g of MPC delivers the same protein as 286 g of whole milk. When a new ingredient is manufactured, it may be more appropriate to compare this new ingredient to what could be achieved through addition of MPC or other dairy ingredients to the final product, rather than fluid milk;
b. The example of addition of lactoferrin to yogurt in SD3 (table A3) is also relevant here. We support FSANZ intent that, when assessing whether lactoferrin added up to a certain level in yogurt is eligible under the Eligible Food Criteria, the comparison should be to what could be achieved using sweet whey powder in the final product, rather than fluid milk.

39. The examples Fonterra has provided separately demonstrating the range of dairy ingredients that can be used, for example, to provide protein in finished products are also relevant here.

40. Of specific concern for infant formula manufacture is that innovation of infant formula products generally emerges from the efforts of manufacturers to mimic breast milk as closely as possible. Therefore, for infant formula the appropriate point of comparison for concentration is not necessarily always the source commodity but could be breast milk. From this perspective, a differentiation of the Eligible Food Criteria for infant formula could be that an ingredient, when added to infant formula, may be compared to breast milk rather than necessarily the source commodity or substance.

41. Proposed Eligible Food Criteria lack clarity and certainty for dairy ingredients

42. Fonterra notes that the move to replace the current definition-based approach to determining products that require a pre-market safety assessment with the Eligible Food Criteria is intended to provide a system that is clear, objective and enforceable. In order to achieve this objective, it is important that we do not simply replace these ambiguous definitions with criteria that are equally ambiguous.

43. Detailed analysis of the proposed Eligible Food Criteria identifies that the Criteria, as currently proposed, do not provide clarity or allow an objective assessment of whether particular dairy ingredients require a pre-market assessment.

44. EFC2 provides a list of eligible commodities and list of processing techniques that will result in eligible "simply" processed commodities. Eligible commodities and simply processed commodities under EFC2 are also used as reference points to determine whether extracts and substances are considered eligible under Eligible Food Criteria 3 (EFC3) or EFC4. Evaluation of a range of current dairy products and ingredients demonstrates that the Criteria are not able to adequately identify the boundary between a simply processed commodity, an extract or a substance.

45. Dairy products are almost all produced using the criteria listed as "Processing Techniques that would be likely to meet criterion 2" (SD3 table 3, p8). This means under EFC2 as currently drafted, it is not possible to objectively evaluate when a product ceases to be "simply processed", and is considered an extract or a substance. It is also not clear what ingredients or products can be used as the basis for comparison for EFC3 or EFC4.

46. For example, in the lactoferrin example in Supporting Document 3 (SD3) p23, dried sweet whey is classified as "simply processed". It will have undergone: physical fractionation (separation of cream and skim milk; separation of curd and whey), thermal processing, mixing, enzymatic processing, filtration, evaporation and drying. It is not possible to deduce, from these criteria, why dried sweet whey is considered "simply processed" but lactoferrin (which has gone through similar processes but with additional physical fractionation and filtration steps) is not.

47. As another example, FSANZ refers to addition of permeate to milk to standardise nutrient levels due to seasonal variation (SD3, p14, paragraph 3) as an apparent example of a "substance" being added back to a source food. Permeate, however, will have only gone through two or three processing steps (physical fractionation, thermal processing and filtration) and thus, on the basis of the example noted above, it is not clear why it would be considered a "substance" rather than "minimally processed".

48. Other examples of dairy commodities that could be used as the basis for comparing concentration of dairy components for new dairy ingredients where it will be difficult to differentiate between simply processed, extract and substance under the criteria include:

a. Whole Milk Powder (WMP), which will have gone through the following processing steps: physical separation, thermal processing, mixing, crystallisation (where lactose added), evaporation and drying.
b. Whey Protein Concentrate (WPC), which will have undergone the following processing steps: physical fractionation, thermal processing, filtration (separating out milk permeate; retaining whey protein and fat; filtering out lactose and minerals), evaporation, drying.

49. The proposed structure for the Eligible Food Criteria, where EFC3 and EFC4 are assessed relative to the eligible commodities and simply processed commodities in EFC2, means that the criteria set as a whole lack clarity, objectivity and regulatory certainty in relation to dairy products.

50. We note that revising EFC2 to introduce a limit on the number of processing steps, or revising EFC3 or EFC4 to allow a fixed number of "extractions" will not resolve this problem. The

number of processing steps does not relate in any meaningful way to the safety risk associated with a food product. In addition, there is no clearly accepted meaning of what constitutes "extraction" as opposed to other processing steps such as filtration or evaporation.

51. Given the long history of safe use of dairy ingredients, our view is that an appropriately risk-based system would provide for the ability to use dairy ingredients that are currently on the market as the point of comparison for concentration. As noted above (paragraphs 31-40), comparison must also focus on an ingredient's use in a finished product, and therefore addition rate, rather than simply direct comparison between two ingredients.

52. We request FSANZ re-consider these criteria in light of the points raised above. Fonterra requests additional engagement with FSANZ, in the form of targeted consultation with the New Zealand and Australian dairy industries before drafting commences on the revised proposal, to address these weaknesses.

53. Exclusion of enzymatic processing from EFC2

54. Fonterra notes that FSANZ has proposed specifically excluding enzymatic processing from the list of eligible processes under EFC2. A blanket exclusion of enzymatic processing does not recognise the long history of safe use of certain enzymes/enzymatic processes (e.g. using rennet to separate milk into curds and whey) and is inconsistent with the approach used in Eligible Food Criteria 1 (EFC1) for microorganisms. It does not make sense that a product would automatically be ineligible under the Eligible Food Criteria if an enzyme is added directly, but the same product made using a microorganism to produce that enzyme would be eligible.

55. We note that, had this regime been in place, all whey protein ingredients would have required FSANZ pre-market assessment – including the sweet whey powder used in FSANZ own lactoferrin example (SD3, p 23). This suggests the current Proposal is not providing an appropriate risk-based framework.

56. We note that the Code already permits the use of enzymes as processing aids[1] to produce safe ingredients so excluding enzymatic processing from scope of Eligible Foods is a substantial reduction in existing permissions.

57. Fonterra requests that FSANZ revise the Proposal to include processing with enzymes with a long history of safe use under the Eligible Food Criteria. We refer to the positive list of enzymes used as processing aids in the Code[2]. This approach should be broadened by:

a. Adopting the same approach used by Codex of allowing use of "safe and suitable" enzymes e.g. Codex General standard for cheese (CODEX STAN 283-1978); and

b. Recognition of lists of approved enzymes in other jurisdictions. We note that the EU is in the process of developing a list of permitted enzymes, and that France includes a list of permitted enzymes in their list of processing aids[3]

[1] *Australia New Zealand Food Standards Code,* Standard 1.3.3 section 3.3-6, Schedule 18 clause 18-4
[2] *Australia New Zealand Food Standards Code,* Standard 1.3.3 section 3.3-6, Schedule 18 clause 18-4
[3] http://www.economie.gouv.fr/dgccrf/publications/juridiques/panorama-des-textes/Auxiliaires-technologiques

58. Expand approach to identifying eligible microorganisms under EFC1

59. We are concerned at the prospect of FSANZ basing the list of eligible microorganisms solely on the EFSA QPS list. We have reviewed the EFSA QPS list and several commonly used starters are absent from the list. This would result in a significant amount of the cheese manufactured in Australia and NZ potentially needing pre-market assessment, which is presumably not FSANZ's intention. Examples of missing microorganisms include:

a. Staphylococcus (most white mould and other specialty cheeses, salami and other)
    i. S. carnosus
    ii. S. xylosis
b. Penicillium (white mould cheese)
c. Geotricum (white mould cheese)
d. Macrococcus
e. Streptococcus salivarius
f. Micrococcus
g. Enterococcus (lots of salami and other foods)

60. We suggest that this criterion should be amended to allow for the use of microorganisms that meet a set of criteria where presence on the EFSA QPS list is only one way that eligibility could be established. These criteria could include:

a. Presence on similar lists published by other reputable Food Safety Authorities
b. Recognition in lists published by reputable scientific journals as having a long history of safe use, e.g. Journal of Food Microbiology's "Food fermentations: Microorganisms with technological beneficial use"[4]

61. Another alternative would be to adopt the Codex approach of allowing the use of "harmless" microorganisms in the General Cheese Standard (General standard for cheese (CODEX STAN 283-1978).

62. Pre-market self assessment through notification

63. As noted above, Fonterra is supportive of introduction of a pathway for pre-market self assessment by industry. This is a key element of introducing a graduated risk-management system that is proportionate with risk. The design of this pathway, however, will be crucial in determining the utility of this option for industry. Two key elements are the gateway criteria and the ability to protect intellectual property (IP).

64. Fonterra notes that FSANZ intends to develop appropriate gateway criteria if the draft framework is progressed. We look forward to working with FSANZ as these criteria are developed. As a preliminary position, Fonterra supports the gateway criteria proposed in the FSANZ presentation from the workshops for call for submissions:

a. International precedents;
b. Minor variations from eligible food criteria; and
c. Extensions of use.

65. The proposed requirement for dossiers to be made public is problematic. Publication of the full dossier would result in release of proprietary information, with no provision for companies to protect their IP. FSANZ suggests that the release of proprietary information can be managed by

[4] Bourdichon, F., et al., Food fermentations: Microorganisms with technological beneficial use, Int. J. Food Microbiol. (2012), doi:10.1016/j.ijfoodmicro.2011.12.030

timing the release of the dossier to coincide with the introduction of the product on the market. In our view this is inadequate to balance the release of all IP, which can take decades to develop and may relate to multiple products, including products not yet on the market.

66. We propose an alternative approach, similar to the US self-determined GRAS system, that would provide an appropriate balance of regulatory oversight and protection of IP. Our proposed alternative approach includes an independent expert assessment to add objectivity of assessment of safety:

a. Company X develops the dossier to use as the basis for determination;
b. The dossier is subject to an independent expert review;
c. Company X holds the dossier and independent expert review on file in house; and
d. The dossier can be requested by food authorities if required.

67. If FSANZ decide to proceed with requiring the dossier to be published on the website, then it should be acceptable for a summary or extract only to be made public, to prevent the release of all IP related to the ingredient/food.

68. Fonterra would also like to note that it is important that all three pathways (Eligible Food Criteria pathway, pre-market self-assessment with notification and pre-market approval by FSANZ) are carefully shaped to ensure they support appropriately calibrated regulatory interventions. For example, the existence of an industry self-assessment through notification pathway should not be used as rationale for progressing a regime with inadequate Eligible Food Criteria.

69. **Consistency of implementation and enforcement**

70. In order to provide the clarity, objectivity and regulatory certainty envisioned under this Proposal, consistency of implementation and enforcement across jurisdictions will be crucial. Fonterra understands that some jurisdictions have yet to establish regimes for implementing and enforcing the recently amended Health Claims regime, and note that this increases risk of inconsistency across how products will be treated in different jurisdictions.

71. Consistency between enforcement agencies in interpreting the Eligible Food Criteria and the gateway criteria for the pre-market self-assessment will be crucial under the proposed regime. For example, if a company determines a product meets the Eligible Food Criteria and markets that product across multiple jurisdictions, it should not be possible for one enforcement agency to object to this determination if another enforcement agency has already evaluated this determination and found it to be consistent with the Criteria.

72. We also note that in a situation where an application is made for FSANZ pre-market assessment for an ingredient that is not-novel or nutritive as it is an ‘eligible food’ FSANZ should not conduct the assessment. Instead, FSANZ should provide a reference letter that the ingredient is recognised as an ‘eligible food’. This approach would avoid a situation where the Eligible Food Criteria regime is potentially undermined by a FSANZ pre-market assessment. It would also support international trade by facilitating access to other markets that may question an ingredient’s approval status.

73. **Trade considerations**

74. Fonterra encourages FSANZ to consider whether the proposed changes have any implications for New Zealand and Australian exports of dairy products.

75. In Australia the current default under the Export Control (Milk and Milk Products) Orders 2005 is that: “Milk and milk products for export as food and their ingredients must not contain…a food additive, processing aid, vitamin, mineral, added nutrient, other matter or substance in contravention of the applicable requirements of the Food Standards Code”. There is an exemption where the importing country authority specifies an alternative requirement for the food additive, processing aid, vitamin, mineral, added nutrient, other matter or substance.

76. Where importing country regulations are silent, there is currently scope to export products that are not expressly permitted in the Code. We seek confirmation from FSANZ that this will continue under the proposed approach.

77. NZ legislation is similar with the requirement to seek an exemption (called a “60B exemption”) where an exported food does not meet the local regulatory requirements.

78. Whilst the requirement to seek exemptions does not change with the proposed alternative approach, the relationship between these two regime should be clarified as potential inconsistency creates significant business risks.

79. For example, Ingredient X is used in a product sold locally by Company A. Company A considers that, under the proposed regime, the product meets the Eligible Food Criteria. Company B decides to use ingredient X in an export product and determines that the ingredient does not meet the Eligible Food Criteria. As Company B is not planning to sell Ingredient X in Australia or NZ, Company B seeks and obtains a 60B exemption. This should not be considered to infer that ingredient X requires a pre-market safety assessment.

80. **Recognition of requirement for safety data**

81. For all criteria, including the approaches to microorganisms and enzymes, it is important to recognize the requirement that even for Eligible Foods, companies still have to undertake a safety assessment. If there is no available information on the ingredient, microorganism or enzyme to meet the requirements for microbiological, toxicological and nutritional safety as set out in Supporting Document 2 (SD2), a pre-market safety assessment will be required. The Eligible Food Criteria should be drafted with this requirement in mind. These criteria do not need to capture and eliminate every conceivable risk by themselves, but should work in concert with the requirement for safety data.

82. Moreover, recognising that a number of food and food ingredients have a long history of export from Australia and New Zealand, or that similar products may be consumed in other countries, toxicological data requirements (e.g. history of safe consumption), should also be able to be established on the basis of comparable global consumption.

83. **Pragmatic approach for amending lists**

84. The legal framework for approval of novel foods and ingredients should support pragmatic solutions – including being relatively easy to amend if required. Although FSANZ describes this as

a criteria-based approach, it is fundamentally based on a set of positive lists, including lists for microorganisms, eligible commodities and food classes, eligible processes and, as noted above, potentially enzymes. From a principle position, positive lists are not best practice in regulatory regimes, as despite good intentions and comprehensive consultation, accidental omissions will occur. It is also inevitable that lists become outdated over time. Given the fundamental role these lists play in the Proposal, it is critically important that there is a pragmatic process for expanding these lists once they are incorporated in the Code.

85. This is particularly important for omission of items that apply across an entire industry or group of industries, where an application by one company to amend the code via FSANZ pre-market approval is not appropriate

86. We request the FSANZ ensures there is a pragmatic process, with a timeline that is measured in weeks rather than months or years, for amending these lists before this regime is codified in the Code.

87. **Lack of key definitions**

88. The consultation documents do not provide definitions for key terms such as “extract”, “substances”, “natural range” and “pharmacological effect”. It is difficult to assess the impact of the proposed regime in the absence of these definitions. Further, we note that comprehensive definitions of these terms may be difficult to develop, and the development of a regime that relies on these terms may not provide any improvement over the current regime, where the absence of definitions for terms such as “nutritional purpose”, “normally consumed” have contributed to the uncertainty around the current regime.

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

90. If there are any queries relating to this submission, please contact Fiona Hutchinson, Senior Regulatory Manager – Advocacy (fiona.hutchinson@fonterra.com)

Yours faithfully

Group Director Food Safety Quality and Regulatory

Appendix: Responses to selected questions from FSANZ consultation documents

Refer section 3.3

How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?

Fonterra agrees that there is ambiguity in relation to the definition of nutritive substances, as identified by the New South Wales Supreme Court in their decision in 2009. The lack of clarity resulting from this definition means that for food companies like Fonterra there is no regulatory certainty over whether a pre-market safety assessment is required for a particular ingredient or product. The lack of clarity also creates a risk of differing positions between enforcement agencies on whether a particular product requires a pre-market safety assessment. There is also the possibility of companies having different positions on whether a pre-market safety assessment is required, which could result in one company seeking pre-market approval for a product that another company has determined does not require a pre-market approval, creating an uneven playing field among industry participants. This lack of regulatory certainty creates risks for businesses that may stifle innovation.

Fonterra supports a robust regulatory system which ensures food safety and consumer confidence in the food supply. We note the comments from food enforcement agencies on the difficulties associated with removing products that pose a threat to consumer safety under the current regime, and support a review that will consider options for addressing these difficulties.

As it noted in paragraphs 24-27 above, Fonterra does not support excluding Infant Formula Products (Standard 2.9.1), Foods for Infants (Standard 2.9.2) and Food for Special Medical Purpose (Standard 2.9.5) from this review. Further, we note that the term ‘nutritive substances’, outside the structure and definitions of the Food Standards Code, is used in 6 standards in the Food Standards Code. All but one standard (Standard 1.3.2 Vitamins and Minerals) are in Part 2.9 including Standard 2.9.1. Consideration of the future regulation of nutritive substances cannot effectively be conducted if most of the standards that apply the term are excluded from the scope of Proposal P1024. Finally, we note that FSANZ does not currently have a plan to address any subsequent regulatory changes in these standards, except for infant formula.

Fonterra will therefore include the issues raised in this consultation from the perspective of Standard 2.9.1, in order to provide comprehensive assessment of the proposed regime, and to ensure consistency of approach across the Food Standards Code.

Refer section 4.2.1
Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.

Fonterra supports retaining a pathway for pre-market safety assessment by FSANZ for high risk foods. A requirement for pre-market safety assessment that is appropriately targeted to foods or ingredients with a high potential for risk for consumer safety is an important element of a regulatory regime that supports consumer confidence and will be considered robust internationally.

Fonterra also supports retaining the option of seeking exclusivity for ingredients that receive a pre-market approval by FSANZ.

Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.

The problems with the status quo identified in the Proposal focus on legal clarity, uncertainty and enforcement issues.

Fonterra notes that the current system does not provide any recognition of pre-market assessments conducted by reputable agencies overseas. This requires duplication, cost and time to repeat or amend work already conducted expertly elsewhere. A revised regime should include appropriate recognition of assessments conducted by reputable agencies overseas.

For some products, such as infant formula products, there is also the issue of limiting the population base for safety assessments to Australia and New Zealand. Fonterra supports INC's recommendation that infants are considered reasonably homogeneous worldwide and as a result, the population for infant formula products should be expanded to reflect the global community of infants 0-12 months.

Refer section 4.2.2
Do you support amending the definitions of 'novel food' and 'used as a nutritive substance' in the Code? If so, FSANZ welcomes reasoned suggestions for amended definitions that will address the problems identified in sections 1 and 2.

Fonterra does not believe that it is possible to amend the definition of "used as a nutritive substance" to address the limitations that have been identified in the current approach.

Refer section 4.2.3.1
Are the EFC appropriate for identifying foods that do not need regulatory approval?

Fonterra had identified significant challenges in applying the proposed EFC to dairy ingredients and dairy products. These concerns are set out in detail in paragraphs 28-61 and 80-86 and include:

- Lack of recognition that concentration of components is not inherently risky. Concentration must be assessed relative to total dietary intake of components (rather than particular "source foods") to adequately assess risk. For this reason, the proposed regime risks failing to recognise the long history of safe consumption of dairy products and ingredients, which is necessary to provide appropriate targeting of regulatory resources to high-risk foods and ingredients.
- Eligible Food Criteria should recognise that pre-market assessment should not be required for concentrated dairy ingredients that deliver key components at level that could feasibly be achieved through addition of other dairy ingredients (albeit at higher addition rates) or alternative processing steps.
- Addition of dairy components to a food at a concentration higher than that achievable from whole milk does not automatically create a health risk. A more appropriate basis for comparison in a safety assessment is what can be delivered to a final product through typical dairy ingredients (including Milk Protein Concentrate (MPC), Whey Protein Concentrate (WPC), cream powders and sweet whey powder).
- It is not possible to determine with any certainty which dairy ingredients will be considered eligible under the "simply processed" element of EFC2.
- The proposed structure for the Eligible Food Criteria, where EFC3 and EFC4 are assessed relative to the eligible commodities and simply processed commodities in EFC2 means that the criteria set as a whole lack clarity, objectivity and regulatory certainty in relation to dairy products.
- The Eligible Food Criteria should also recognise breast milk as the appropriate benchmark for comparison for ingredients in infant formula, rather than the source commodity necessarily.
- The blanket exclusion of enzymatic processing fails to appropriately recognise the use of enzymes with a long history of safe use (such as adding rennet to milk to separate curds and whey) under the Eligible Food Criteria. These criteria should be amended to to include processing with enzymes with a long history of safe use under the Eligible Food Criteria.
- The proposed approach to determining microorganisms that will be included in the Code under EFC1 is too narrow, and will result in several common starter cultures being excluded from the list. This criterion should be amended to allow for the use of microorganisms that meet a set of criteria where presence on the EFSA QPS list is only one way that eligibility could be established.

In addition to the points raised above, Fonterra notes the following detailed comments:

- The processing terms used in the consultation document (SD3, Table 3) are very general. We assume companies will be able to develop their own lists of what constitutes these processes, e.g. ion exchange resin (to produce Whey Protein Isolate/high-fat whey/demineralised whey powder) is a filtration step.
- The consultation documents do not provide definitions for key terms such as "extract", "substances", "natural range" and "pharmacological effect". It is difficult to assess the impact of the proposed regime in the absence of these definitions.

- Further, we note that comprehensive definitions of these terms may be difficult to develop, and the development of a regime that relies on these terms may not provide any improvement over the current regime, where the absence of definitions for terms such as "nutritional purpose", "normally consumed" have contributed to the uncertainty around the current regime.
- FSANZ notes that it may be necessary to provide an additional definition of "natural range" as used in EFC3, to avoid the use of "outlier" sources that do not reflect food sources that are commonly consumed (SD3, p 14). We note that there is very wide range of seasonal and breed-based variability in the composition of bovine milk, and highlight the critical importance of adequately reflecting this variability in this regime.
- NZFSA's discussion relating to this criterion in the discussion documents (including SD3) only discusses the situation where the total level of naturally occurring and added components in the target food is no higher than that present as if the *source food* were added to the target food. This criterion, however, also provides for *products described in criterion 2* (e.g. minimally processed commodities) to be used as the basis for comparison. We note that this adds additional complexity to issues such as "natural range" and "naturally occurring" and that this should therefore be reflected in any future discussions on this criterion.
- NZFSA notes that there is a continuum between extracts and substances, queries whether the distinction between extracts and substances should be maintained, and the more appropriate baseline. Given the challenges associated with fitting dairy products adequately into to proposed framework, Fonterra's preference is to have the widest possible choice of products to use as a comparison. As a preliminary position, we consider that the approach laid out in EFC3 would be the more appropriate to use than that in EFC4, although we note that the inadequacy of the Eligible Food Criteria as currently drafted makes it impossible to offer a final view.

We request FSANZ re-consider these criteria in light of the points raised above. Fonterra requests additional engagement with FSANZ, in the form of targeted consultation with the New Zealand and Australian dairy industries before drafting commences on the revised proposal, to address these weaknesses.

Are there foods that may meet the EFC that you consider should be subject to pre-market assessment? If so, please describe the properties of these foods.

Fonterra is not aware of any foods that may meet the EFC that should be subject to pre-market assessment.

Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.

As noted above, Fonterra does not support a blanket exclusion for enzymatic processing in EFC2. This issue is discussed in full in paragraphs 53-57. We note that the Code already permits the use

of enzymes as processing aids[5] to produce safe ingredients so excluding enzymatic processing from the scope of Eligible Foods is a substantial reduction in existing permissions. Fonterra requests that FSANZ revise the Proposal to include processing with enzymes with a long history of safe use under the Eligible Food Criteria. We refer to the positive list of enzymes used a processing aids in the Code[6]. This approach should be broadened by:

a. Adopting the same approach used by Codex of allowing use of "safe and suitable" enzymes (e.g. Codex General standard for cheese (CODEX STAN 283-1978).

b. Recognition of lists of approved enzymes in other jurisdictions. We note that the EU is in the process of developing a list of permitted enzymes, and that France includes a list of permitted enzymes in their list of processing aids[7]

Fonterra also notes that the proposed approach to microorganisms under EFC1 would result in several common starter organisms being considered ineligible. This issue is discussed in more detail in paragraphs 58-61. Fonterra suggests that this criterion should be amended to allow for the use of microorganisms that meet a set of criteria where presence on the EFSA QPS list is only one way that eligibility could be established. These criteria could include:

c. Presence on similar lists published by other reputable Food Safety Authorities
d. Recognition in lists published by reputable scientific journals as having a long history of safe use, e.g. Journal of Food Microbiology's "Food fermentations: Microorganisms with technological beneficial use"[8]

Another alternative would be to adopt the Codex approach of allowing the use of "harmless" microorganisms in the General Cheese Standard (General standard for cheese (CODEX STAN 283-1978).

Finally, Fonterra also refers to the discussion under the question "Are the EFC appropriate for identifying foods that do not need regulatory approval? " and in paragraphs 28-61 that highlight challenges with the EFC as currently proposed. If these concerns are not addressed, then it is possible that the EFC may not capture a wide range of dairy ingredients and products that have a low food safety risk and should be considered eligible for the EFC pathway.

What type of information do you think should be held by food businesses to support the safety of eligible foods? Please describe the type of information and why this information would support safety.

Fonterra supports comments from the Infant Nutrition Council (INC) that a differentiating aspect of the Framework for infant formula products could be a requirement that all safety assessment dossiers should include a focus on data that is relevant to infants as the target population group, e.g. breast milk levels, history of safe use of other ingredients from the same source commodity,

[5] *Australia New Zealand Food Standards Code*, Standard 1.3.3 section 3.3-6, Schedule 18 clause 18-4
[6] *Australia New Zealand Food Standards Code*, Standard 1.3.3 section 3.3-6, Schedule 18 clause 18-4
[7] http://www.economie.gouv.fr/dgccrf/publications/juridiques/panorama-des-textes/Auxiliaires-technologiques
[8] Bourdichon, F., et al., Food fermentations: Microorganisms with technological beneficial use, Int. J. Food Microbiol. (2012), doi:10.1016/j.ijfoodmicro.2011.12.030

use of existing ingredients in infant formula formulated to current Standard 2.9.1 regulatory minimums and maximums.

Fonterra notes that this regime presents complications for its application to ingredient manufacturing as distinct from finished goods manufacturing. There is an interdependence between ingredient supplier and finished goods manufacturers in relation to the dossier and determination of eligibility. The final decision on level of use of an ingredient is made by the finished goods manufacturer, yet much of the proposed regime for assessing the need for a pre-market approval is based on the level of use of the ingredient in a final product. There may also be issues of intellectual property and interpretation of requirements from international suppliers.

Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC?

The proposed exclusions to the EFC are based on products having an impact on weight or satiety. Fonterra notes that these exclusions are not intended to capture "weight loss" foods that qualify to carry diet or low energy or similar claims (SD3, p18). These exclusions, however, also need to carefully crafted to avoid capturing normal food-health relationships for foods that do not carry diet/low energy or similar claims. For example, proteins (including dairy proteins) are have an impact on satiety and may be promoted for weight management. This type of food-health relationship should not be used as the basis to exclude ingredients from the Eligible Foods Criteria Pathway.

Fonterra notes that the definition of "pharmacological properties" will be critical in determining whether we can support this exclusion. We support the comments of the NZ Food and Grocery Council in relation to this question, including noting that:

- If 'pharmacological properties' are intended to mean 'therapeutic properties' then NZFGC suggests that the only foods that would be affected are those that are within the scope of Standard 2.9.5 since all other uses of substances are for processing or dietary purposes.
- It is also the case that 'pharmacological properties' is in part defined by the context and the sector involved. Most vitamins and minerals might be considered to have 'pharmacological properties' but in the context of the general food supply, they are micronutrients for growth.
- Fonterra could envisage support for the pre-market safety assessment of substances with pharmacological properties so long as 'pharmacological property' and all other terms used to describe characteristics were clearly defined. We note that FSANZ has recognised this as a particular issue (SD3) and that "there does not appear to be an internationally recognised consistent definition of 'pharmacological' in the literature"
- We agree that a term such as 'biologically active substance' is too broad.

Refer section 4.2.3.3
Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?

Fonterra considers that the investigation of an alternative approach to regulating nutritive substance in the Code is a viable option. The current regime does not provide clarity or regulatory certainty, and it is difficult to see how the current definitions could be amended to provide the necessary clarity. Therefore, Fonterra supports investigation of an alternative approach to regulating nutritive substances in the Code.

In particular, taking account of FSANZ's primary objective of protecting public health and safety, is the draft framework presented in option 3 a viable option? What aspects of the draft framework do you think are viable or not viable? Please provide supporting statements for your view.

Please note that although the summary of questions refers submitters to section 4.2.3.3. (Data and Dossier Requirements) only, Fonterra has interpreted this question to refer to Option 3 as a whole (i.e. Section 4.2.3: Option 3: Develop an alternative framework).

Fonterra supports further consideration of option 3 as set out in p17 of the Call For Submissions Consultation Document as a viable option.

Fonterra supports INC's comments that the framework proposed as Option 3 for general foods also being applied to infant formula products, with potential consideration of some differential elements specific to the target population. A proportionate approach to risk is a more efficient approach to managing the market entry of new food substances and, with appropriate differentiation, the framework proposed in Option 3 should therefore be applied to Standard 2.9.1.

Fonterra supports INC's proposal that the differentiation for infant formula products and ingredients is in relation to the prerequisite requirements for the Eligible Foods Pathway and the Pre-Market Assessment by Notification Pathway and the content of the data and dossier requirements for both. This would need to be designed to address the vulnerability of the target population who are consuming infant formula and the unique role of infant formula as the sole source of nutrition for infants 0-6 months where breastfeeding is not undertaken.

Fonterra supports INC's conclusion that the relevant Policy principles the Policy Guideline on the Regulation of Infant Formula Products encompass an interpretation that does not exclude the application of the Option 3 Framework including eligible food criteria and industry pre-market self-assessment.

Fonterra has also identified aspects of the proposed pre-market self-assessment pathway that require further consideration. These issues are discussed in detail in paragraphs 62-68 and cover:

- The need for suitably designed gateway criteria
- Revision of the proposal to require publication of the full dossier, to allow companies to protect their intellectual property.

Although Fonterra supports further consideration of option 3 as set out in p17 of the Call For Submissions Consultation Document as a viable option, we have identified a number of areas where improvements are required in the proposed framework in order for this approach to be considered viable. These relate to the Eligible Food Criteria in particular (as noted in our General Comments (paragraphs 28-61 and 80-86 and answers to questions on section 4.2.3.1) as well as the above comments on the self-assessment pathway. If these concerns cannot be adequately addressed, then Fonterra does not consider option 3 to be viable and will support maintenance of the status quo.

Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?

As a preliminary position, Fonterra supports foods and ingredients that meet the following criteria are being suitable for industry self-assessment:

- Products that have been subject to pre market assessment by overseas reputable or recognised authorities could be suitable for industry self assessment such as Codex (through member contributions and assessments by other international agencies such as JECFA), EU and USFDA (GRAS substances).
- Extensions of use
- Minor deviations from the EFC

As is noted in paragraph 68, Fonterra would also like to note that it is important that all three pathways (Eligible Food Criteria pathway, pre-market self-assessment with notification and pre-market approval by FSANZ) are carefully shaped to ensure they support appropriately risk-based regulatory interventions. For example, the existence of an industry self-assessment through notification pathway should not be used as rationale for progressing a regime with inadequate Eligible Food Criteria.

Please provide details of how a self-assessment pathway may or may not provide benefits to industry.

An appropriately calibrated pre-market self-assessment pathway would also for is a central element of an appropriately calibrated risk-management regime. Such a pathway would allow for lower-risk products that do not fit within the EFC but have sufficient information available to allow industry to establish that a product is safe for consumption to be assessed under an alternative regime to FSANZ pre-market assessment. Fonterra supports FSANZ comments that such as regime may provide greater control over time for market for new foods. We also note that the introduction of such a regime will allow regulatory attention be focussed on higher risk foods, allowing for more efficient allocation of regulatory resources.

As noted above and in paragraphs 62-68 the self-assessment pathway will need to be appropriately calibrated in order to deliver these benefits. Development of suitable gateway criteria and revising

the proposed approach to publicly releasing commercially sensitive details will be necessary for this pathway to offer any benefit to industry.

Would notification and publication of dossiers provide enough regulatory oversight and consumer confidence in relation to the safety of new foods? Please support your answer with detail of why you believe this is the case.

Fonterra does not support publication of the dossier under a pre-market self-assessment pathway. Complete comments on this issue are provided in paragraphs 65-67. Fonterra does not consider that publication of the dossiers is the best approach to provide regulatory oversight and consumer confidence in the industry self-assessment pathway. We propose an alternative approach, similar to the US self-determined GRAS system, which would provide an appropriate balance of regulatory oversight and protection of IP:

- Company X develops the dossier to use as the basis for determination;
- The dossier is subject to an independent expert review;
- Company X holds the dossier and independent expert review on file in house; and
- The dossier can be requested by food authorities if required.

Refer section 6.2

Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.

Fonterra supports retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ. We note that the FSANZ pre-market approval process may require the release of commercially sensitive information including IP, and that the ability to seek exclusive permission is a partial mitigation against the potential losses associated with such a release. We note that similar exclusivity provisions are provided in overseas regimes, such as the EU novel foods regime.

Fonterra notes that the provision of exclusivity may require further consideration in relation to a situation where FSANZ receives a request for pre-market approval with exclusivity for two identical (or near identical) products at the same time.

Can you identify any issues that may arise if exclusive permissions are available for FSANZ approved foods, but not available for industry self-assessed foods? Would the self-assessment process for non-eligible foods provide a trade-off against the lack of an exclusive permission for self-assessed foods (section 4.2.3)?

Fonterra refers to our comments above and in paragraphs 65-67 on the requirement for industry to be able to protect IP through either making the dossier available to regulatory agencies only, or being required to release only a summary of the dossier. In this situation, the self-assessment

pathway provides a suitable trade-off against the lack of an exclusive permission for self-assessed foods.

If FSANZ proceeds with requiring public release of the entire dossier per the current proposal, then Fonterra considers that the self-assessment process does not provide an adequate trade-off against the lack of an exclusive permission for self-assessed foods. For this reason, Fonterra strongly recommends the approach set out in paragraph 66, which provides a more appropriate balance between protection of IP and regulatory oversight of the self-assessment pathway.

Refer section 7.1

Do you support a cut-off date? Please provide reasons for your view.

Fonterra supports a cut-off date if products under Standards 2.9.1, 2.9.2 and 2.9.5 are included under the same regulatory regime. We note that a cut-off date has been used in the EU and US. If Standards 2.9.1, 2.9.2, and 2.9.5 are brought under the same regulatory regime at the same time, there could be a significant gap arising from differing regulatory regimes would result in considerable uncertainty over how these products are to be treated.

Do you see a need for grandfathering provisions? Please provide reasons for your view.

Fonterra supports grandfathering provisions to remove doubt about substances currently in the market, particularly those currently defined as 'nutritive substances'.

Do you see a need for a stock in trade provision? Please provide reasons for your view.

Fonterra considers the usual 12 month stock-in-trade provision is appropriate.

Refer section 7.2.3

Do you have any concerns regarding the proposed 6 month transition period? Please explain your concerns, noting the length of time the development of any future standard is likely to take and will therefore be clearly signposted before changes are made to the Code.

Fonterra notes that a transition period of 12 months is would be considered more appropriate for a regulatory regime of this level of significant. We recognise, however, that regulators are seeking to address the problems with the current regime as soon as possible. In light of this, Fonterra notes that a short transition period (such as 6 months) would require extensive guidance to be in place before the commencement of the transition period.

There should also be recognition that special treatment may be required for products that were already in the process of application preparation since the investment in application preparation is a significant cost in its own right (outside the application fees and charges arrangements).

Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?

Given the possibility of a short (6 month) transition period for this regime, Fonterra notes that it will be important for FSANZ to work with a wide range of peak bodies to ensure industry is familiar with the requirements and guidance for the new provisions. Fonterra suggests this could include the

Dairy Australia, the Dairy Companies Association of New Zealand, the Infant Nutrition Council and the Food and Grocery Council's of Australia and New Zealand.

In addition to peak bodies, FSANZ should also be prepared to work directly with companies that have been in the process of preparing applications in the lead up to, and during, the transition process as these companies are at greatest risk of experiencing confusion, delays and additional costs over the transition period.