INFANT NUTRITION COUNCIL
AUSTRALIA & NEW ZEALAND

7 July 2021

INC SUBMISSION ON PROPOSAL P1028 REVIEW OF INFANT FORMULA: Consultation Paper No.1/2021

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents the majority of companies marketing and/or manufacturing infant formula products and toddler milk drinks (formulated supplementary foods for young children) in Australia and New Zealand. INC aims to:

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

INC is a responsible group that voluntarily restricts its marketing practices for infant formula products to support government policies for the protection and promotion of breastfeeding.

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

We welcome the opportunity to provide written comment to Food Standards Australia New Zealand (FSANZ) in response to the *Proposal P1028 Review of Infant Formula: Consultation Paper No.1/2021.*

Yours sincerely

Jan Carey
Chief Executive Officer

PROPOSAL P1028 REVIEW OF INFANT FORMULA
Consultation Paper No.1/2021

Submission from the Infant Nutrition Council Australia & New Zealand

7 July 2021

Executive Summary

The most significant concern for INC is the FSANZ proposal to change the carryover provisions. FSANZ proposes alignment with Codex and EU regulations noting that neither permit the general carry-over of food additives for infant formula and IFPSDU except where explicit food additive permissions already apply to them. The rationale from FSANZ is to ensure consistency between the Food Standards Code and relevant international infant formula and IFPSDU regulations. INC points out that Codex and EU food additive permissions for infant formula and IFPSDU are not the same.

The proposed carry-over changes add a significant degree of complexity to the assessment of carry-over compliance. Further, the changes proposed do not capture all the food additives permitted by Codex and EU in these products. This proposal introduces significant cost and these costs are unevenly spread across the market but mostly the burden will be on local manufacturers.

In relation to harmonisation of food additive permissions, INC is largely supportive but we strongly recommend that food additives that contribute essential nutrients do not have maximum levels (MLs) specified, provided that there is no exceedance of nutrient compositional limits. It is the level of the substance present that determines safe use, not whether it is added as a nutrient or food additive.

Five nutrient carriers are listed in the Codex Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979 - Section D) which are not permitted food additives for use in infant formula under the proposed changes. FSANZ considers no changes to the Food Standards Code are needed to accommodate these as they can be considered as generally permitted processing aids in the regulation. However, we believe this is a matter of interpretation and in certain circumstances they may be considered to be food additives which would render them non-permitted under the proposed changes to carry-over provisions. This is due to the Food Standard Code's approach to additives which, if the proposed carry-over provisions are applied to infant formula, puts an undue emphasis on function, rather than simply level of presence of carry-over additives that are applied by Codex and the EU. FSANZ's interpretation cannot, therefore, be relied upon on the face of the law and this is another of the several reasons INC recommends retention of the status quo for carry-over.

Retention of current carry-over provisions will avoid unwarranted time and resources being spent by industry and regulators on compliance verification checks due to the complexity that will apply if proposed changes to carry-over provisions are adopted.

We also point out that there is a barrier to compliance in terms of the permissions of vitamins and minerals since there is no equivalent in the Food Standards Code to the Codex provision of explicit reference to advisory lists (CXG 10-1979). This leaves a gap between the Food Standards Code and the Codex carry-over permissions for infant formula. Our proposed solution is to add a food additive section to Standard 2.9.1 with text that addresses this particular problem. This will not address all the problems.

In relation to contaminants, INC is generally supportive of these proposals but INC's preference remains for MLs to be stated on a powder basis.

INC's view on Lactic Acid Producing Microorganisms is that it is not necessary to amend the current voluntary permission for addition of L(+) lactic acid producing microorganisms due to the Food Standards Code overarching requirement for food to be safe and suitable. In this regard we note that Codex refers to L(+) lactic acid producing cultures without further

qualification. We do not consider it is necessary to insert ‘non-pathogenic’ as proposed but can accept this insertion if it is strongly supported by other stakeholders..

In relation to preparation, use and storage directions to manage microbiological hazards, INC proposes clarification in application of the changes INC also stresses the importance of maintaining the current flexibility in the wording applied for preparation instructions as companies also consider other important aspects for a particular formula.

This applies to the proposed inclusion of the word ‘cooled’. INC supports this, provided other similar terms could be used to indicate that boiling water should not be used directly (e.g. lukewarm). Other important aspects for a particular formula that might be considered and for which flexibility is important to include, but are not limited to, the impact of water temperature on specific, heat sensitive ingredients (e.g. probiotics) and the solubility of the powder.

For left-over formula, INC agrees with the proposal that unfinished formula be discarded ‘within 2 hours’ but flexibility to use other non-contradictory terms is needed such as ‘within one hour’ or ‘immediately after a feed’. This flexibility ensures that the statement can be changed to be consistent with both the Australian Infant Feeding Guidelines and the New Zealand Food and Nutrition Guidelines for Healthy Infants and Toddlers. It also means the statement ‘discard formula left in the bottle after a feed’, as used in the consumer researched statement in the potentially improved instructions, could be used.

INC supports proposed directions not applying to ready-to drink infant formula where they are not relevant and supports the continued flexibility in words and pictures for directions of use and preparation on infant formula products. INC recommends making it clear on the face of the law that the exact wording is not prescribed. This is particularly due to some statements including words such as ‘must’.

In relation to date-marking, INC supports retaining the existing provisions of permitting the use of ‘best before’ and ‘use-by’ dates under certain circumstances and supports the FSANZ proposal to maintain existing date marking requirements for infant formula products.

INC does not support the extension of date marking requirements for IFPSDU. As raised previously, international alignment for date marking these specialty products is important to ensure consistent, affordable supply. This includes the use of ‘expiry date’ or other similar words instead.

INC supports the proposal to maintain the existing requirements for storage instructions including the specific requirement for infant formula products, to cover the period after the package is opened. INC also supports the proposal to maintain the existing requirement for a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used, without prescribing the exact wording for this direction and to not mandate a standard scoop volume.

INC does not support updating the warning statement. There are several compelling reasons for not requiring change that are set out in the submission. If required, it would be more appropriate to include the proposed additional text in the preparation instructions since, according to FSANZ’s research, consumers read these more than the warning statement.

In relation to the statement about age to offer foods in addition to formula INC recommends updating the existing statement to include that infants from around the age of 6 months should be offered foods in addition to infant formula products to align with both the New Zealand and Australian dietary guidelines for infants and toddlers. As there may be some introduction of solids in the 5th month, the inclusion of ‘around’ would also help provide clarity for parents who may have been advised to start solids prior to 6 months by a healthcare professional.

INC does not support the proposed clarification to the source of protein statement. Further limiting the statement will in some cases limit the information and clarity that can be provided to consumers and health professionals. There is currently no evidence of consumer confusion or issues with the status quo. Limiting useful information on protein fractions such as 'partially hydrolysed', 'hydrolysed, 'amino acids' and 'a2', risks removing information that is relevant and important for both consumers and healthcare professionals.

To ensure labels are updated as much as possible as part of normal business INC proposes a transition period of 5-years from manufacture date which also allows for stock in trade. This would accommodate composition and additive changes that may be required in addition to labelling changes. If the label updates required due to changes to Standard 2.9.1 were part of other voluntary label changes to infant formula products, no extra cost would be incurred.

INC does not support prescribed warning statements and preparation instructions for IFPSDU as presented in the INC submission on IFPSDU in 2017. To do so unnecessarily constrains compliance of a category of products where the majority are imported in small, specialist quantities for use under medical supervision. Supply of IFPSDU is especially critical for these vulnerable populations. INC supports, however, regulating the intent for IFSPSDU. The approach of regulating intent rather than prescribed wording is consistent with the WHO Code, Codex Standard and EU Regulations.

In terms of implementation, INC strongly recommends avoiding misalignment between infant formula and follow-on formula requirements and rather than a separate proposal suggests a consequential amendment might be considered to ensure timely alignment.

Introduction

1. INC welcomes the opportunity to consider the issues and preliminary views proposed in the 2021 consultation paper for Proposal P1028, and to provide comment and information to Food Standards Australia New Zealand (FSANZ) relating to the Consultation paper (CP1) on the Regulation of Infant Formula.

2. INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula.

3. To ensure the best possible nutrition for non-breastfed infants, policy and regulatory instruments must ensure a balance between restrictions on use and formulation in order to protect public health, and provide flexibility and incentive for innovation for continuous improvement of infant formulas.

4. INC considers that the key elements in policies and regulations governing infant formula must allow for:

- consistency with the policy objectives outlined in other food-related policy decisions
- the provision of a safe and nutritious food
- a scientific, evidence-based approach which does not unnecessarily restrict the use of ingredients considered to be safe for use in general foods in infant formula
- flexible provisions in the food regulations, with minimal levels of prescription and complexity, to facilitate innovation and continuous improvement of infant formula to promote health and wellbeing of infants
- sufficient information to support informed choice by consumers enabling them to select products which are suitable to the dietary needs of their non-breast-fed infant
- clarity of requirements to facilitate compliance to and enforceability of the Standard, and
- cost effectiveness to minimise the potential burden on industry and enforcement agencies, and minimise unnecessary cost impact on consumers.

5. INC recommends adherence to the principles of minimum effective regulation. Any proposed changes to regulation warrant a proper evaluation including risk analysis to quantify the evidence in terms of risk to infants to ensure restrictions are not applied that are out of proportion to diminishingly small probabilities of harm.

6. In responding to CP1, we have located questions with the issues covered in the order they appear in CP1. For this reason, for example, we respond to Question 10 dealing with carry-over first followed by Question 11, 12 and then Question 2. In subsequent Consultation Papers it would be helpful if the questions followed the sequence of the issues discussed.

Comments and Responses to questions

Food Additives

2.2 Food class system for food additive permissions

7. We note FSANZ proposes, under section 2.2.4, three options in relation future regulation:
   Option 1 status quo
   Option 2 Additional Subclasses
   Option 3 Simplified approach.

8. We agree with FSANZ that Option 3 is the best way to proceed as it is consistent with international approaches.

9. The principles relating to food additive use are technological (e.g. manufacturing process, ingredients, stability, food matrix, nutrient delivery). Food additives are chosen for use by the manufacturer based on a combination of technical elements not necessarily limited to the food matrix and ingredients.

10. INC notes that the product categorisation for IFPSDU will be considered in CP3. As discussed in the INC response in 2017, the food additive framework cannot align to a product categorisation framework based upon a nutritional purpose relevant to a disorder, disease or medical condition (e.g. prematurity or low birth weight). The use of differing sub-categories that do not exist in other jurisdictions could limit the access of this population to appropriate nutrition.

2.3 Carry-over principle for food additives and infant formula

11. FSANZ notes that Codex and EU regulations do not permit the general carry-over of food additives for infant formula and IFPSDU except where explicit food additive permissions already apply to them and proposes alignment with this principle. FSANZ also notes that the critical matter in adopting this principle appears to be to ensure consistency with food additive permissions in the Food Standards Code with relevant international infant formula and IFPSDU regulations. This is not as straight forward as it may appear. For example, aligning with Codex/EU food additive carry-over provisions is somewhat confusing given that EU requirements are not the same as Codex. We cannot stress enough the complexity that will be created if the changes as proposed are implemented.

12. Consequently, the INC's very strong position is for the status quo to be maintained as there is no market failure. Locally manufactured products and imported products coexist in the market due to the broader carry-over arrangements that have been reflected in the Food Standards Code for 20 years.

13. Furthermore, the amount that is allowed under the carry-over provision is far less than the permitted level for an ingredient since:
    a. the amount under the carry-over provisions cannot be greater than the amount that would be introduced by the use of the raw material or ingredient.
    b. For example, if 10mg/100g is allowed for an ingredient X and the percentage of ingredient X is 10% of the final infant formula powder, only 1mg/100g will be in the final powder. Furthermore, the powder is reconstituted with water before an infant consumes it, so the amount an infant will take in will be further significantly reduced and therefore only a very minimal amount will be consumed.

14. Changing the carry-over provisions as proposed will have significant impacts on some manufacturers, requiring them to undertake research for substitutes, product reformulations and storage stability trials to assess the impact on product storage stability. This cost may not necessarily be applied to imported products because, as we note above, the status quo is a broader permission than the EU or Codex positions. The extent of the impact would depend on the individual imported product and the current approach of the manufacturer. As well, the changes proposed do not capture all the food additives permitted by Codex and EU in these products. See response to Question 6.

15. We support FSANZ's interpretation about processing aids not falling within the proposed carryover provisions and would want this to be made very clear in the Standard should the proposed provisions proceed.

Question 10. What would be the practical steps involved in ensuring compliance of your products with the carry over provisions proposed in this paper?

16. The practical steps needed to ensure compliance with the proposed revised carry-over permissions are complex and would take a significant period of time to achieve. The descriptions do not necessarily convey this work and the range of alternatives and testing that would be necessary. They are:

    1) Determine if any food additives currently used do not comply. if yes, then:

    2) Research if alternative ingredients are available which will comply with new food additive carry-over provisions

    3) Reformulate test amounts of product making trial batches and undertake storage trials to assess impact on storage stability. It may be necessary to evaluate multiple alternatives to achieve acceptable product characteristics and shelf-life.

Question 11. Do you have any more information on how much ensuring compliance would cost per effected product?

17. If a food additive that is currently used is no longer permitted, the cost to achieve compliance with the new requirements could be very significant. Furthermore, the number of suppliers available will be reduced significantly and therefore the cost of raw materials potentially will increase just for infant formula products. Individual members are encouraged to provide information.

Question 12. Would different sized businesses be generally equally impacted from our proposed changes to the carry-over principle?

18. Infant Formula businesses will not be impacted equally. The impact to businesses will depend on the number of their product formulations impacted by the proposed changes to the carry-over provisions and the cost of steps needed in order to comply with amended requirements. As this the proposed changes may impact locally manufacturers more than overseas manufacturers, if a choice is given, companies may choose not to manufacturer infant formula products locally.

2.4 Harmonisation of food additive permissions

2.4.2 Acidity regulators

19. FSANZ proposes that the use of the acidity regulators is justified. We understand that FSANZ proposes to permit the following substances as food additives (acidity regulators) however we note FSANZ appears not to have taken into account density which should be considered if the proposals proceed.

    1) *Calcium carbonates and calcium citrates in IFPSDU at GMP* – INC supports this proposal but suggests consideration is given to extending permission for use in all infant formula at GMP given these are permitted forms of minerals for addition of calcium to infant formula. In addition, INC notes that calcium citrate and tricalcium phosphate are permitted for addition to nutrient preparations in the EU regulation[1]. These are able to be carried over into all infant formula products. These carryover permissions should be taken into consideration if FSANZ amends the current carryover principles in the Food Standards Code.

    2) *Calcium hydroxide in all infant formula at an ML of 2000 mg/kg* – INC recommends use of calcium hydroxide is permitted at GMP or provided the maximum specified for calcium in S29-10 is not exceeded. Refer to comment below regarding the redundancy of MLs set above maximum permitted nutrient levels.

    3) *Sodium carbonates, sodium hydroxide, potassium carbonates and potassium hydroxide in all infant formula at an ML of 2000 mg/kg* – INC supports use of these substances as acidity regulators but considers the application of ML proposed is redundant for sodium carbonates and sodium hydroxide given the maximum sodium level permitted in infant formula is lower than application of this ML.

    4) *Phosphoric acid, sodium phosphates, potassium phosphates and calcium phosphates in all infant formula with a ML of 450 mg/kg when calculated as phosphorus* – INC supports this proposal but again considers that the application of the ML is unwarranted. In CP1 it is noted that if sodium or potassium phosphates are used at the ML the maximum levels of sodium or potassium permitted in infant formula could be exceeded. EU applies a ML of 1000mg/kg which is well in excess of the maximum permitted phosphorus levels in infant formula of approximately 670mg/kg.

20. In the interests of achieving minimum effective regulation, INC strongly recommends that food additives that contribute essential nutrients do not have MLs specified which are set above the maximum levels specified for the nutrients concerned within the compositional requirements. It is the level of the substance present that determines safe use not whether it is added as a nutrient or food additive.

21. Including MLs for food additives that are higher than compositional maxima just adds additional (but redundant) compliance checks that need to be undertaken by product formulators, auditors and regulators that are a waste of time and resources. If a condition of use is to be applied, it should simply state the maximum level for the nutrient concerned is not to be exceeded. The proposed ML for use of calcium hydroxide as an acidity regulator falls into this category as do other examples provided above.

[1] EC/1333/2008 as amended

2.4.3 Citric acid and fatty acid esters of glycerol (CITREM (INS 472c)

22. FSANZ proposes it is appropriate to harmonise with the EU/Codex for CITREM at 9000 mg/L and to differentiate between liquid and powdered formulas by introducing a lower MPL of 7500 mg/kg for powdered product and retain 9000 mg/kg for liquid products.

23. INC supports this proposal.

2.4.4 Starch sodium octenylsuccinate (INS 1450)

24. FSANZ proposes use of starch sodium octenylsuccinate is restricted to IFPSDU with a restriction of only being used for products containing hydrolysed protein and/or amino acids.

25. INC supports the inclusion of INS 1450 in all IFPSDU to align with the EU which are wider than proposed by FSANZ. As a result, INC does not support the restriction to IFPSDU containing hydrolysed protein and/or amino acids.

26. In addition, INC notes that starch sodium octenylsuccinate is a permitted food additive for addition to certain nutrients intended to be used in all infant formula in the EU (EU No. 1333/2008 as amended by EU No. 1130/2011). These permissions should additionally be taken into consideration if FSANZ amends the carryover principles.

2.4.5 Locust bean (carob bean) gum (INS 410)

27. FSANZ proposes to retain the current permission for use in infant formula with an MPL of 1000 mg/kg. In addition, FSANZ proposes alignment with the EU permission that locust bean gum be permitted in IFPSDU only for use in 'products for reduction of gastro-oesophageal reflux' with an MPL of 10,000mg/kg.

28. INC supports the proposal:
    - to retain the current permission for use in infant formula to 1000 mg/kg
    - IFPSDU permission: from birth onwards in products for reduction of gastro-oesophageal reflux with MPL of 10,000 mg/kg to align with EU.

2.4.6 Pectins (INS 440)

29. INC notes that CP1 does not reflect the Codex permission for use of pectins as a food additive in certain infant formula in Codex Standard 72-1981 (amended 2020).

30. FSANZ proposes to permit pectins in the Food Standards Code for IFPSDU at a ML of 5000 mg/L.

31. INC supports pectins be permitted in:
    - Infant formula limited to liquid infant formula containing hydrolysed protein with ML 2000 mg/kg to align with Codex CXS 72-1981
    - IFPSDU limited to products used in case of gastro-intestinal disorders with ML 10,000 mg/kg to align with EU.

2.4.7 Xanthan gum (INS 415)

32. INC notes that CP1 does not reflect the Codex permission for use of xanthan gum as a food additive in certain infant formula in Codex Standard 72-1981 (amended 2020).

33. FSANZ proposes to align with the EU.

34. INC supports the proposal to permit xanthan gum as a thickener in IFPSDU at the ML of 1200 mg/kg, limited to powdered hydrolysed protein and/or amino acid and gastrointerinal

tract problems, protein malabsoprtion, or inborn errors of metabolism formula to align with EU. In this, in the interests of minimum efficient regulation, we recommend FSANZ gives consideration to permitting xanthan gum to apply to all IFPSDU. In addition, we suggest that xanthan gum be permitted in powdered hydrolysed protein and/or amino acid based infant formula to align with Codex.

2.4.8 Guar gum (INS 412)

35. FSANZ is seeking further information on the need for the 10-fold higher ML in the EU for specific products.

36. INC supports the permission in IFPSU from birth onwards in products containing hydrolysed proteins, peptides or amino acids.

37. INC has also sought further information from our contacts in the EU and will provide this to FSANZ if and when received.

2.4.9 Sodium alginate (INS 401)

38. FSANZ proposes there be no general permission for use in IF and proposes to align with the EU permission restricted to specific products but seeks from industry current use levels to inform the final decision.

39. INC supports the FSANZ proposal to permit addition to IFPSDU from 4 months onwards in products for dietary management of metabolic disorders with an ML of 1000 mg/kg to align with EU.

40. INC also supports the permission for formula used in general tube-feeding to be fully aligned with the EU. It is unclear whether FSANZ proposes uses in general tube-feeding as this is included in the section 2.4.9 discussion in CP1 along with a proposed approach but is not included in Table 2.17. INC supports the FSANZ proposal not to permit addition to infant formula.

2.4.10 Sodium carboxymethylcellulose (INS 466)

41. In the absence of use data from industry FSANZ proposes not to permit the use of sodium carboxymethylcellulose (INS 466) in infant formula.

42. In 2017 FSANZ proposed alignment with the EU but in CP1 the issue is confusing since 2.4.10 implies FSANZ is not going to permit sodium carboxymethylcellulose in any infant formula products whereas it is included in Table 2.17. Clarification on the intent is required. In any event, we are seeking data and will provide this to FSANZ when received.

43. INC supports the FSANZ proposal to permit addition to IFPSDU limited to products from birth onwards in products for the dietary management of metabolic disorders with ML 10,000 mg/kg to align with EU. It is likely this addition is for liquid products only.

2.4.11 Sucrose esters of fatty acids (INS 473)

44. FSANZ proposes to permit the use of sucrose esters of fatty acids in IFPSDU but only in products containing hydrolysed proteins, peptides or amino acids with an ML 120 mg/kg FSANZ has requested information from health professionals about the need for permission and from industry about current use.

45. INC supports the proposal to permit addition to IFPSDU but only in products containing hydrolysed proteins, peptides or amino acids with an ML 120 mg/kg to align with the EU.

2.4.12 Diacyltartaric and fatty acid esters (472e)

46. FSANZ proposes to remove the permission on the basis that neither the EU nor Codex permit addition and industry data provided in 2017 was not convincing enough.

47. INC supports maintaining the permission. This additive is authorised for general use in food, for example in the US under 21 CFR 184.1101 that allows its use in some infant products. There has not been any identified risk in relation to this additive and products containing it have been present in the market globally for decades. Any decision to remove this permission should be based on a risk assessment[2].

Question 2. Table 2.17 [p47] lists the proposed approach for food additives. It includes some food additives where it is proposed to align with EU regulations but FSANZ has noted that there is a lack of safety information and therefore, it is not possible to draw a conclusion on the safety of these substances at the proposed levels in the target population. In these cases (all relate to IFPSDU which are generally imported into the Australian and New Zealand market), we request further information from health professionals about the need to permit addition of these food additives to IFPSDU and information from manufacturers about industry use of these food additives in Australia and New Zealand. The food additives that this question pertains to are:

- Locust bean gum
- Pectins
- Xanthan gum
- Sodium alginate
- Sodium carboxymethylcellulose
- Sucrose esters of fatty acids

General comment

48. INC notes that in addition to locust bean gum, Codex Standard CXS 72-1981 (amended 2020) has recently been updated to permit the use of pectins and xanthan gum in some infant formula products.

Locust bean gum

49. See above, INC supports the proposal:
    - to retain the current permission for use in infant formula to 1000 mg/kg
    - IFPSDU permission: from birth onwards in products for reduction of gastrooesophageal reflux with MPL of 10,000 mg/kg to align with EU.

[2] Food and Drug Administration, HHS. Page 497:

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as an emulsifier and emulsifier salt as defined in § 170.3(o)(8) of this chapter and a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: baked goods and baking mixes as defined in § 170.3(n)(l) of this chapter; nonalcoholic beverages as defined in § 170.3(n)(3) of this chapter; confections and frostings as defined in § 170.3(n)(9) of this chapter; dairy product analogs as defined in § 170.3(n)(10) of this chapter; and fats and oils as defined in § 170.3(n)(12) of this chapter.

Pectins (440)

50. See above, INC supports the proposal to permit pectins in:
    - Infant formula limited to liquid infant formula containing hydrolysed protein with ML 2000 mg/kg to align with Codex CXS 72-1981
    - IFPSDU limited to products used in case of gastro-intestinal disorders with ML 10,000 mg/kg to align with EU.

Xanthan gum (415)

51. See above. INC supports the proposal to permit addition of xanthan gum as a thickener in IFPSDU at the ML of 1200 mg/kg, limited to powdered hydrolysed protein and/or amino acid-based formula.

Sodium alginate (401)

52. See above, INC supports the FSANZ proposal to:
    - permit addition to IFPSDU from 4 months onwards in products for dietary management of metabolic disorders with MPL 1000 mg/kg to align with EU.
    - not to permit addition to infant formula.

53. INC recommends also allowing this additive in IFPSDU used for general tube-feeding to align with the EU.

Sodium carboxymethylcellulose (466)

54. See above, INC supports the FSANZ proposal to permit addition to IFPSDU limited to products from birth onwards in products for the dietary management of metabolic disorders with ML 10,000 mg/kg to align with the EU.

55. At this time, until FSANZ has clarified anomalies within CP1 (see above), INC supports addition to infant formula.

Sucrose esters of fatty acids (473)

56. See above, INC supports the proposal to permit addition to IFPSDU in products containing hydrolysed proteins, peptides or amino acids with an ML 120 mg/kg.

For health professionals, please provide information to the following questions:

Question 3. In addition to the above list, what new evidence (if any) do you have for the potential health impacts for infants of changing any of the current permissions for any other food additives, discussed in this paper?

Question 4. In addition to the list above, can you provide any further examples of lack of alignment with EU regulations delaying important formula from reaching vulnerable infants?

Question 5. To what extent would proposed changes to current permissions and limits for Special formula address any perceived delays to vulnerable infants accessing the imported formula that they need? Please provide evidence where possible.

N/A

For industry, please provide information to the following questions:

Question 6. Would there be any practical barriers to complying with new permissions and limits as proposed in this document for any formula products that have not yet been identified? How might such barriers be overcome?

57. INC used the following decision tree to assess the impact:
    - It is already permitted as a direct additive in the Food Standards Code to Infant Formula
    - It is proposed to be permitted as a direct additive to Infant Formula in the Food Standards Code per proposals in CP1.
    - For carriers (e.g. nutrient carriers), is the substance permitted for use as a processing aid in the Food Standards Code?

58. We note that all GMP additives and substances in Schedule 18 are permitted for use as processing aids in the Food Standards Code and that CP1 (p20) states that carriers can be considered as processing aids. For any food additives permitted for use in infant formula by Codex and the EU that do not clearly go through one of the three avenues above, INC proposes changes be made to the Standard to bridge the gaps identified.

59. There is a barrier to compliance in terms of the permissions of vitamins and minerals that also can serve an additive function. Under Codex, there is an explicit reference to the advisory lists (CXG 10-1979) in the additive section of the infant formula standard:

    "Only the food additives listed in this Section or in the Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children (CXG 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions: [...]"

60. There is no equivalent in the Food Standards Code, which leaves a gap between the Food Standards Code and Codex carry-over permissions for infant formula. For example, a nutrient form might not be a directly permitted additive for food category 13.1 of Schedule 15. Under the proposals, that nutrient form would not be permitted to be carried over into infant formula and IFPSDU as an additive, even when it is directly permitted in IF and IFPSDU as a nutrient. Our proposed solution is to add a food additive section to Standard 2.9.1 with the following text:

    "Only the food additives listed in the sub-food categories 13 of Schedule 15 or substances listed in Schedule 29—7[1] may be present in the foods described in Standard 2.9.1—3 as a result of carry-over from a raw material or other ingredient (including food additive) used to produce the food.'

    [1] Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes

61. Five nutrient carriers are listed in Section D of the *Codex advisory list of nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979) which are not permitted food additives for use in infant formula under the proposed changes. FSANZ considers no changes to the Food Standards Code are needed to accommodate these as they can be considered as generally permitted processing aids in the regulation. However, we believe this is a matter of interpretation and other interpretations are possible in certain circumstances which would render them non-permitted under the proposed changes to carry-over provisions. This is due to the Food Standard Code's approach to additives which, if the proposed carry-over provisions are applied to infant formula, puts an undue emphasis on function, rather than simply level of presence of carry-over additives as applied by Codex and the EU. FSANZ's interpretation cannot therefore be relied upon on the face of the law and

this is yet another of the several reasons INC recommends retention of the status quo for carry-over.

62. INC's strong preference is for retaining the status quo to avoid unwarranted time and resources being spent by industry and regulators on compliance verification checks due to the complexity that will apply if proposed changes to carry-over provisions are adopted.

Question 7. What (if any) implications might overcome any practical barriers have for production costs per product line? Please quantify where possible.

N/A

Question 8. Might smaller or else larger businesses be disproportionately impacted if a new permission does not align with international regulations or standards? If so can you specify how by providing quantitative evidence where possible?

63. As noted above, since the changes proposed do not capture all the food additives permitted by Codex and the EU the proposed changes introduce significant costs and these costs are unevenly spread across the market but mostly the burden will be on local manufacturers. The cost impact to businesses will depend on the number of their product formulations impacted by the proposed changes to changes such as the carry-over provisions and the cost of steps needed in order to comply with amended requirements.

Question 9. Are any food additive preparations (food category 0 in Schedule 15) used in infant formula products? If so, how?

64. Food category 0 in Schedule 15 includes all additives permitted at GMP, along with a list of specific substances. From the list of additives permitted at GMP, there are some that are used in the preparation of other additives that are then used in infant formula. These food additive preparations may have functions such as being an antioxidant (e.g. sodium ascorbate has antioxidant function) for another additive or mixture of additives.

65. Given that the technological function for the substances in food category 0 in Schedule 15 relate to their function in additives, rather than their function in the infant formula or IFPSDU product, we do not think it is necessary to review or re-evaluate their appropriateness as part of this consultation.

2.5 Clarifications to the Code

66. Amendments to a number of additives are proposed: to correct an error with the level proposed for hydroxypropyl starch, to expand the scope of application for carrageenan and to remove conditions applied to three starches.

67. INC has previously supported all these clarifications and confirms that is still the case.

2.6 Updates to nomenclature

68. The proposal is to not update nomenclature and INS numbers under this proposal but rather to do so under a dedicated food additives proposal raised for that purpose.

69. INC has previously supported this proposal and confirms that is still the case.

Contaminants
3.3 Maximum levels for contaminants

3.3.1 – 3.3.3 Acrylonitrile, Aluminium Arsenic

70. FSANZ proposes positions on the following contaminants:
    - acrylonitrile (no change)
    - arsenic (no ML for arsenic (inorganic) or 'arsenic, total').

71. INC supports the proposals relating to acrylonitrile and arsenic.

72. In relation to aluminium, FSANZ considers it is appropriate to retain an ML for aluminium and is proposing to set an ML of 0.05 mg/100 mL to apply to all infant formula and move the ML to Standard 1.4.1 and Schedule 19.

73. INC reaffirms its previous position that any new contaminant limit should be based upon risk to address public health concerns.

74. The toxicological understanding of aluminium has evolved since JEFCA's 2011 assessment derived a Provisional Tolerable Weekly Intake (PTWI) of 2mg/kg-bodyweight. In 2017, the EU established a Tolerable Daily Intake (TDI) for aluminium of 0.3 mg/kg-bodyweight/day[3]. It is not apparent how FSANZ has calculated the ML of 0.05 mg/100 mL from either the JECFA or EU health-based guidance value (HBGV). Nor is it apparent that current dietary exposure to aluminium from infant formula comes close to any toxicologically-based limits. Therefore, we request further information that helps demonstrate what (if any) public health benefit this ML achieves.

75. The ADS dietary information that was shared to support the ML suggests that older infants (9 months) have most of their dietary exposure to aluminium from baked goods (muffins, scones, cakes, slices). INC considers it important to recognise that infant formula is for 0 to 6 months where formula is a sole source of nutrition, and that baked goods are irrelevant to the dietary intake of this age-group. Any assessment of risk should take this into consideration.

76. Hence, INC is of the view that Standard 2.9.1 should align with Codex which does not include limits on aluminium as a contaminant metal in infant formula (Codex STAN 193-1995). The EU does not list aluminium as a contaminant metal in infant formula (nor any foods) (Commission Regulation (EC) No 1881/2006). In the US, limits for aluminium as a contaminant metal in infant formula are also not included (CFR, Chap 21, parts 106 & 107).

3.3.4 Cadmium

77. FSANZ proposes two options in relation to the ML for cadmium (Section 3.3.4). These are:
    - do not establish an ML for infant formula in the Food Standards Code on the basis that dietary exposures to cadmium in infant formula are not considered to be of health concern…
    - harmonise with the EU MLs [there are none for infant formula in Codex].

[3] https://ec.europa.eu/health/sites/default/files/scientific_committees/scheer/docs/scheer_o_009.pdf

Question 1. FSANZ has proposed two options in relation to the ML for cadmium (Section 3.3.4). FSANZ ask[s] stakeholders for views on these options.

78. INC supports Option #1: Do not establish an ML for infant formula in the Food Standards Code which aligns with Codex.

79. FSANZ should continue to take a risk-based approach to establishing MLs. If the available data demonstrates intake is unlikely to pose a concern to the population there is no need to establish a limit, as described in the paper.

80. If Option #2 is selected, we strongly encourage FSANZ to consider using a similar risk-based approach for establishing an ML rather than simply aligning to the MLs established in the EU. As currently established, the EU limits for powder are only 2X the liquid values. In practical terms, this means the limits for powder products are much stricter, therefore simply adopting the EU limits may not align to the limits FSANZ would adopt using a risk-based process. Infant formula powder is typically reconstituted using an ~7X ratio[4] [5], and by setting a single limit (as-fed) this would place the same emphasis on controlling cadmium in liquid and powder products.

3.3.5 – 3.3.14 Lead, Melamine, Tin and inorganic tin compounds, Vinyl chloride, Mycotoxins: aflatoxins B1and M1, Mycotoxins: Ochratoxin A, Polycyclic aromatic hydrocarbons Perchlorate, Chloropropanol, glycidol and their esters

81. FSANZ has proposed positions on the above contaminants:
    - lead (reduce the ML), additional MLs for lead in specification of food additives for use in IF (no change),
    - melamine (no ML)
    - tin and inorganic tin compounds (no change)
    - vinyl chloride (no change)
    - mycotoxins: aflatoxins B1and M1 (MLs not necessary)
    - mycotoxins: Ochratoxin A (ML not necessary)
    - polycyclic aromatic hydrocarbons (ML not necessary for PAHs)
    - perchlorate (ML not necessary)
    - chloropropanol, glycidol and their esters (MLs not necessary).

82. INC supports the above positions on all these contaminants.

3.4 MLs for infant formula in the dry powder form or as consumed

83. FSANZ proposes to apply MLs that are established for infant formula to an ‘as consumed’ form in mg/kg.

84. INC’s preference remains for MLs to be stated on a powder basis, however INC can accept this proposal if supported by other submitters.

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[4] EFSA Panel on Contaminants in the Food Chain (CONTAM). 2016 *Risks for human health related to the presence of 3- and 2- monochloropropanediol (MCPD), and their fatty acid esters, and glycidyl fatty acid esters in food.* doi: 10.2903/j.efsa.2016.4426

[5] EURL-SRM-Residue Observations report *Analysis of toxicologically critical pesticides and some additional SRM compounds in infant formulae and milk – Part 2: Residue findings [version 1 last update 26.04.2021]*

3.5 Contaminant definition

85. FSANZ is not proposing to change the definition of analytes but will address the issue in any future review of Standard 1.4.1.

86. INC supports this proposal.

4 Lactic acid producing microorganisms

87. FSANZ considers that the Standard should be clarified for addition of L(+) lactic acid producing microorganisms.

Question 13. Does the current permission for L(+) lactic acid producing microorganisms need to be clarified? For example, some L(+) lactic acid producing microorganisms are pathogenic. Do these need to be explicitly excluded (or non-pathogenic specifically permitted) or is the base 'safe and suitable' requirement considered sufficient to manage this risk?

88. FSANZ is not proposing to amend the current voluntary permission which allows for addition of L(+) lactic acid producing microorganisms for purposes other than acidification. The risk assessment FSANZ undertook has not identified any risks for healthy full term infants from this provision provided the L(+) lactic acid producing microorganisms are non-pathogenic and non-toxigenic. FSANZ proposes that the current permission is strengthened by the inclusion of the term 'non-pathogenic'.

89. INC's view is that it is not necessary to amend the current voluntary permission for addition of L(+) lactic acid producing microorganisms due to the Food Standards Code overarching requirement for food to be safe and suitable. In this regard, we note that Codex refers to L(+) lactic acid producing cultures without further qualification. However, if other stakeholders have a strong preference for amending this provision to include the term 'non-pathogenic' as shown below, this could be accepted by INC even though unnecessary.

    2.9.1—6 Addition of lactic acid producing microorganisms

    Non-pathogenic L(+) lactic acid producing microorganisms may be added to infant formula product.

5 Labelling

5.3 Preparation, use and storage directions to manage microbiological hazards

5.3.1 Directions for preparation and use

90. INC supports many of the following proposals but maintaining the current flexibility in the application of words, terms or phrases proposed should continue to be permitted so long as these are non-contradictory (e.g. lukewarm instead of cooled). This is important for manufacturers, reflecting the range of matters taken into account when developing directions.

Prepare bottles individually

91. FSANZ proposes retaining the direction to prepare bottles individually is appropriate and should be retained.

92. INC supports this proposal.

Storage of made up water

93. FSANZ undertook additional risk assessment of formula prepared and stored at or below 6º for 24 hrs and found that it had the same risk as formula stored for 24 hrs, if prepared with water at 20º C or less. FSANZ proposes to retain the recommended storage time of 24 hrs.

94. INC supports this position.

Water used to reconstitute powdered infant formula

95. The Food Standards Code currently requires a direction that potable, previously boiled water should be used. FSANZ proposes the revision of this direction for water used to reconstitute powder infant formula to include the word 'cooled' (paragraph 2.9.1-19(3)(c)).

96. INC supports the inclusion of the word 'cooled' as an option provided other similar terms as determined appropriate by a company could be used to indicate that boiling water should not be used directly (e.g. lukewarm).

97. Flexibility in the wording for preparation instructions is important as companies will also be considering other important aspects for a particular formula, for example, the impact of water temperature on specific, heat sensitive ingredients (e.g. probiotics) and the solubility of the powder.

98. As noted from FSANZ, this instruction is used on many labels currently and reflects both the Australia and New Zealand infant feeding guidance.

Discarding leftover formula

99. The Food Standards Code currently requires a direction of formula left in the bottle after a feed must be discarded. FSANZ proposes revision of this direction and instructing unfinished formula be discarded 'within 2 hours' (paragraph 2.9.1-19(3)(e)). The text 'within 2 hours' is new.

100. INC supports the inclusion of the text 'within 2 hours' to indicate a specified period should be included. This support is also for other similar terms that do not contradict this maximum (2 hours) as determined appropriate by a company could be used (e.g. 'within one hour' or 'immediately after a feed').

101. Flexibility in wording ensures that this statement can be changed to be consistent with the Australian Infant Feeding Guidelines that states any prepared formula at room temperature for longer than one hour should be discarded (NHMRC 2012). The New Zealand Food and Nutrition Guidelines for Healthy Infants and Toddlers state a maximum of 2 hours within feeding but that this time could be made shorter if necessary. Flexibility in wording also ensures the statement 'discard formula left in the bottle after a feed', as used in the consumer researched statement in the potentially improved instructions, could be used.

Application of preparation and use directions to concentrated and ready-to-drink formula

102. The Food Standards Code currently does not differentiate preparation instructions for powder and ready-to-drink infant formula. FSANZ proposes that the following directions do not apply to read-to-drink formula:

- for each bottle to be prepared individually (paragraph 2.9.1-19(3)(a))
- to refrigerate formula and use within 24 hours if it is made up and stored prior to use (paragraph 2.9.1-19(3)(b)

- to use potable, previously boiled water (paragraph 2.9.1-19(3)(c))

103. INC supports these directions not applying to ready-to drink infant formula as they are not relevant.

104. The Food Standards Code currently does not differentiate preparation instructions for powder and concentrate infant formula. FSANZ proposes that the direction to only use enclosed scoop (paragraph 2.9.1-19(3)(d)) does not apply to concentrate infant formula.

105. INC supports the direction 'to only use enclosed scoop' as not applying to concentrate infant formula as it is not relevant.

5.3.2 Standardised wording or pictures for directions for preparation and use

106. FSANZ considered the current approach of not prescribing the exact words or pictures for the instructions required for preparation and use of infant formula. FSANZ proposes to maintain this existing approach.

107. INC supports the continued flexibility in words and pictures and the FSANZ proposal to maintain the current approach not to prescribe the exact wording or pictures to be used for the required directions of use and preparation on infant formula products.

108. INC recommends further clarification under subsection 2.9.1—19(3) to ensure it is clear to regulators that the exact wording is not prescribed. This is particularly due to some statements including words such as 'must'.

5.4 Other safe preparation and storage issues

5.4.1 Date Marking

109. FSANZ proposes to retain the existing provisions of permitting the use of best before and use-by dates under certain circumstances.

110. INC supports the FSANZ proposal to maintain existing date marking requirements for infant formula products.

111. INC does not support the extension of above date marking requirements for IFPSDU. As raised in INC's previous submission, international alignment for date marking these specialty products is important to ensure consistent, affordable supply. INC recommends aligning to Food Products for Special Medical Purposes which allows the use of 'expiry date' or other similar words instead. This will contribute to ensuring the ongoing supply of these products to Australia and New Zealand.

5.4.2 Storage instructions for infant formula

112. FSANZ considers that the existing requirements provide clear instructions to ensure infant formulas retain safety and quality characteristics during storage and is not proposing any change.

113. INC supports the proposal to maintain the existing requirements for storage instructions including the specific requirement for infant formula products, to cover the period after the package is opened.

5.4.3 Measuring scoop

Direction regarding enclosed scoop

114. FSANZ considers there is no need to prescribe the wording of the direction to always measure the amount of powder using the scoop provided in the can.

115. INC supports the proposal to maintain the existing requirement for a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used, without prescribing the exact wording for this direction.

Standardised scoop and ratio for preparation

116. FSANZ proposes to maintain the status quo to not prescribe a standardised scoop volume or ratio of scoops to water.

117. INC supports FSANZ position to not mandate a standard scoop volume.

5.5 Warning statements

5.5.1 Legibility requirements for warning statements

118. FSANZ proposes not to change the existing legibility requirements.

119. INC supports FSANZ proposal to maintain existing legibility requirements for warning statements on infant formula labels.

5.5.2 Warning statements about following instructions exactly

120. FSANZ proposes to amend the warning statement for infant formula product in powdered form (paragraph 2.9.1-19(1)(a)) and concentrate infant formula product (paragraph 2.9.1-19(1)(b)) to include the text about not adding anything to the formula as follows:

> 'Warning- follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of [powder/concentrate] **or add anything to this formula** except on medical advice. Incorrect preparation can make your baby very ill'.

121. INC does not support updating the warning statement. There are several compelling reasons for not requiring change:

- As noted by FSANZ, there is limited evidence of adding other foods to formula and therefore limited food safety issues to address.
- Adding further text to this warning statement at 3mm size will take considerable space on already limited space on cans
- The warning statement may not be the most effective way of communicating this information. The eye-tracking data from FSANZ's consumer research reported that only 13 out of 30 participants showed attention to the warning statement. The preparation instructions received more attention with 28 out of 30 participants. The research also found that the improved preparation instructions with a statement on not adding any other food or flavouring [to the infant formula] significantly improved understanding.

122. If required, INC considers that additional text would be more appropriately included in the preparation instructions. If additional wording is required in the preparation instructions, we propose "do not change proportions of powder **and water"** or "do not add other food" as appropriate options.

5.5.3 Warning statement that 'breast is best'

123. FSANZ proposes to retain the existing 'breast is best' warning statement.

124. INC supports the proposal to maintain the existing 'breast is best' warning statement.

5.6 Product identification

5.6.1 Prescribed name

125. FSANZ proposes to maintain the current requirements for the prescribed name 'infant formula'.

126. INC supports the proposal to maintain the current requirements for the prescribed name 'infant formula'.

5.6.2 Statement that infant formula may be used from birth

127. FSANZ proposes to maintain the requirement for the existing statement indicating that the infant formula product may be used from birth in the case of infant formula.

128. INC supports the proposal to maintain the requirement for the existing statement indicating that the infant formula may be used from birth.

5.6.3 Statement about age to offer foods in addition to formula

129. FSANZ proposes to retain the existing labelling statement indicating that infant from the age of 6 months should be offered food in addition to infant formula (2.9.1—19(4)(c)).

130. INC recommends updating the existing statement that states "infants from the age of 6 months should be offered foods in addition to infant formula product" to include 'around'. The updated statement would then read:

"infants from around the age of 6 months should be offered foods in addition to infant formula products".

131. We note that the term 'around' aligns to both the New Zealand[6] and Australian dietary guidelines for infants and toddlers[7].

132. In 2002 the World Health Organisation updated its guidelines from introducing solids between 4 to 6 months of age, to "at 6 months of age". More recently, ESPGHAN (The European Society for Paediatric Gastroenterology Hepatology and Nutrition) reviewed evidence on complementary feeding and recommended solids should not be introduced before 4 months of age, but should not be delayed beyond 6 months of age[8].

133. Recent health bodies guidelines are generally consistent in outlining that weaning foods should not be delayed beyond 6 months of age, and should not be initiated prior to 4 months. In summary:

- It is not recommended to introduce solids prior to 4 months of age (17 weeks, beginning of the 5th month)
- It is not recommended to delay the introduction of solids past 6 months of age (26 weeks)
- There is some evidence of a link between delayed introduction of 'allergenic' solid foods (such as peanut butter, cooked egg, dairy and wheat) in the first year of life and increased risk of food allergy.
    - Fewtrell 2017[9] highlights emerging evidence of an allergy 'tolerance' window for egg at 4-6 months.

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[6] New Zealand Ministry of Health (2021). *Draft Dietary Guidelines for Babies and Toddlers*. 2021

[7] NHMRC (National Health and Medical Research Council) (2013). *Infant Feeding Guidelines: Summary*. 2013. Canberra: National Health and Medical Research Council

[8] Fewtrell et al (2017). Complementary Feeding: A Position Paper by the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) Committee on Nutrition. J Pediatr Gastroenterol Nutr. 2017 Jan;64(1):119-132.

[9] Ibid

134. As there may be some introduction of solids in the 5th month, the inclusion of 'around' would help provide clarity for parents who may have been advised to start solids prior to 6 months by a healthcare professional.

5.6.4 Source of protein statement

135. FSANZ proposes clarifying the 'source' of protein in paragraph 2.9.1—23(1)(a) to refer to the origin of the protein (eg cows' milk) and not the protein fractions (e.g. whey protein or casein).

136. INC does not support this clarification. As FSANZ notes, the original intent of the statement was to provide clarity for consumers to enable informed decisions. Further limiting the statement will in some cases limit the information and clarity that can be provided to consumers. There is currently no evidence of consumer confusion or issues with the status quo and the proposal simply considers there is the "potential for confusion". INC disagrees with this as there is no evidence of it.

137. Describing the true, complete and accurate description of products is required under Consumer Law and companies consider fully how to do this clearly for each product label both on front and on back of label. Clarifying that additional information on protein fractions cannot be used could be interpreted as including other useful information on protein including the following clarifications: partially hydrolysed, hydrolysed, amino acids and A2 beta casein. This information on protein is relevant and important for both consumers and healthcare professionals. For example, for a product containing hydrolysed cows' milk protein, stating 'cows' milk protein' as the protein does not provide enough information and could be considered misleading.

5.6.5 Co-location of protein source statement with the name of the food

138. FSANZ proposes to clarify the protein source adjacent to the prescribed name is not required every time that prescribed name occurs on the label and that the name of the product is the prescribed name 'infant formula'.

139. INC supports this clarification. This will assist in making it clear that the protein source information location is not prescribed and may be co-located with the prescribed name on the label wherever a company determines most appropriate.

5.7 Summary of proposed labelling risk management approach

Question 14. Do you support the amendments proposed (see section 5.7)? If not, what new evidence can you provide to support a different approach?

140. See above.

Question 15. Are you aware of any further data on infant illnesses that can be attributed to incorrect preparation as a result of unclear labelling or warning statements on products?

141. INC does not have any further data on infant illness due to incorrect preparation as a result of unclear labelling or warning statements.

Question 16. How often do you change labels on your products voluntarily for marketing or other purposes?

142. The frequency of label changes varies considerably between companies and infant formula products. Companies do not frequently change labels due to cost, the long shelf life of the product and as changes can also create consumer concern about the product recipe changes. Notably, many Infant formula products for special dietary uses (IFPSDU) are unlikely to undergo label changes for voluntary reasons as they are used in small, specialist quantities under medical supervision.

143. To ensure labels are updated as much as possible as part of normal business INC proposes a transition period of 5-years from manufacture date which also allows for stock in trade. INC considers this would be appropriate to avoid write off costs for labels and adding to unnecessary food-related wastage. The timing for change is especially important given that composition and/or additive changes may be required in addition to the labelling changes implemented, and these will be required across all infant formula products, as a result of the revised Standard.

Question 17. If the proposed changes were made at the same time as a voluntary label change, how much extra would it cost to change each product's labels (on average)?

144. There would be no extra cost for infant formula products if the label updates were part of other voluntary label changes. To ensure label changes do not incur extra cost, FSANZ must allow sufficient transition period for labels to be updated along with the other proposed changes as part of P1028. It is important to note that the proposed changes may not be limited to the label but may also require changes to off-label communications that directly reflect what is on the label e.g. websites.

145. For IFPSDU, INC supports harmonising with international regulations including labelling to reduce costs and the burden on the industry and to increase availability of these products to the Australian and New Zealand market.

Question 18. If the proposed changes could not be made at the same time as a voluntary change, how much extra would it cost to change each product's labels (on average)?

146. This information is commercially sensitive, and companies can provide it as part of their own submissions.

Question 19. Apart from any costs, would there be any other practical challenges of changing your products' labels as proposed?

147. INC does not support prescribed warning statements and preparation instructions for IFPSDU as presented in the INC submission on IFPSDU in 2017.

148. INC considers that to do so unnecessarily constrains compliance of a category of products where the majority are imported in small, specialist quantities for use under medical supervision.

149. The current Food Standards Code labelling requirements do not allow the same flexibility as Food Products for Special Medical Purposes which are similarly imported in small, specialist quantities for use under medical supervision for specific dietary purposes for vulnerable population. Hence, most manufacturers of IFPSDU customise labelling information for the Australia New Zealand market. This adds cost for the consumer and has implications for potential threats to supply. Supply of IFPSDU is especially critical for these vulnerable populations. INC supports, however, regulating the intent for IFSPSDU.

The approach of regulating intent rather than prescribed wording is consistent with the WHO Code, Codex and EU Regulations.

General question related to the Consultation paper

Question 20. In addition to your submissions from previous Consultations for this Proposal, do you have any further comments on how any of our proposed options in this paper would affect market opportunities for infant formula? Please provide evidence and quantify impacts where possible.

150. FSANZ needs to consider how changes such as those proposed for food additives and labelling requirements will be implemented. INC recommends avoiding misalignment between infant formula and follow-on formula requirements and FSANZ might explore the prospect of including 'consequential changes' in this Proposal similar to what appears to have occurred in, for example, Proposal P1044 Plain English Allergen Labelling.

Transition (not canvassed in CP1)

151. As noted above in response to Question 16, INC proposes a transition period of 5-years from manufacture date which also allows for stock in trade. INC considers this would be appropriate to avoid write off costs for labels and adding to unnecessary food-related wastage. The timing for change is especially important given that composition and/or additive changes may be required in addition to the labelling changes implemented, and these will be required across all infant formula products, as a result of the revised Standard.