SUBMISSION

To: Food Standards Australia New Zealand (FSANZ)

In response to: Consultation Paper – Proposal P1028 for Infant Formula

May 2016

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PREFACE

H.J. Heinz Company Australia Limited (**Heinz Australia**) and Heinz Wattie's Limited in New Zealand (**Heinz Wattie's**) are part of The Kraft Heinz Company global group of companies. Heinz Australia and Heinz Wattie's in this submission are collectively referred to as "**Heinz**".

Heinz is one of the world's leading producers of nutritious, convenient foods for every eating occasion and has been feeding families for more than 100 years. Heinz operates across the retail grocery and out of home channels, including hospitality and healthcare, and maintains #1 or #2 share in key categories including baby food, baked beans, tomato sauce and 'wet' soup.

With combined experience of over 140 years, Heinz provides a positive presence in the Australia and New Zealand grocery products industry.

Heinz offers a diverse portfolio of brands, including:

Heinz	Wattie's	Golden Circle	Kraft
HP	Lea & Perrins	Greenseas	PMU
Epicure	Farex	Tom Piper	Hamper
Imperial	Ox & Palm	Petdeli	Champ
Chef	Pacific	Crown	LOL
Craig's	Oak	Original Juice Co.	Popper
La Bonne Cuisine	Mediterranean	Little Ripper	Gourmet
Breton	Master Chef	Wild Boy	Ice Magic
The Good Taste Company		Nurture	
Cottee's (toppings, jelly and jams only)			

The Heinz product range includes:

infant food & snacks	frozen vegetables	baked beans	canned pasta
infant formula	fruit drinks	ketchup & sauces	soup
fruit juice	cordial	bottled water	corned beef
jams, jelly & toppings	frozen meals	canned seafood	canned fruit & vegetables

Heinz is an active member of the Infant Nutrition Council (**INC**), New Zealand Food & Grocery Council (**NZFGC**) and the Australian Beverages Council Limited (**ABCL**). Heinz representatives hold positions on various working groups, and Heinz contributes by preparing submissions, providing opinions and sharing information, and strives to keep abreast of current and upcoming regulatory issues.

Infant Feeding

Heinz fully supports and believes that breast milk provides the ideal nutrition for babies and breast feeding provides numerous benefits for both mothers and babies. However, when breast milk is not available, an infant formula product is the only suitable and safe alternative for the first 12 months of an infant's life.

The Heinz portfolio of products includes Heinz Nurture infant formula products.

Heinz is a member of the Infant Nutrition Council (**INC**) that represents the infant formula industry in Australia and New Zealand. Heinz supports the aim of the *WHO International Code of Marketing of Breast-milk Substitutes* (**WHO Code**) and the local applications. Heinz is a signatory to the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (**MAIF Agreement**), and as a member of INC has adopted *The Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand* (**INC Code of Practice**).

The aim of the WHO Code, the MAIF Agreement and the INC Code of Practice is *'to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution'.*

EXECUTIVE SUMMARY

Heinz welcomes the opportunity to make submissions in response to the Food Standards Australia New Zealand (**FSANZ**) Consultation Paper – Proposal P1028 (**Proposal P1028**).

The Heinz Nurture infant formula product range consists of powdered infant formula products which are cows' milk protein based. Heinz's submissions address the questions in Proposal P1028 that are relevant to Heinz's products accordingly.

As a member of the INC, Heinz supports the separate written submissions prepared by the INC in response to Proposal P1028. In particular, Heinz supports the INC submissions regarding industry feedback to the FSANZ preliminary views.

OVERALL POSITION

Heinz supports the review of Standard 2.9.1 in the Australian New Zealand Food Standards Code (**the Code**) for the general purposes of addressing regulatory concerns and providing clarity on the infant formula standard.

In addition, Heinz considers it desirable for the Code to be reviewed in light of the United Nations Codex Alimentarius (**Codex**) and for appropriate provisions of the Code to be aligned with corresponding provisions of the Codex. Heinz considers that this alignment would have a net positive impact for both consumers and the infant formula industry in Australia and New Zealand. Consumers would benefit as a result of the Code reflecting the world leading scientific views and evidence that underpin the Codex. The infant formula industry would benefit by having reduced regulatory barriers to international trade.

Heinz notes that the scope of Proposal P1028 is limited to infant formula for infants 0-12 months. Heinz considers that many of the issues raised by Proposal 1028 are also relevant to follow-on formula for infants 6 -12 months and for infant formula products for special dietary use (IFPSDU).

Heinz notes that follow-up formula is currently being reviewed by the Codex Committee on Nutrition and Foods for Special Dietary Uses. Heinz accepts that consideration of follow-on formula could be deferred until completion of the Codex Committee's review.

Heinz believes however that the scope of Proposal P1028 should be broadened to include IFPSDU in order to minimise regulatory complexity and timing issues that are otherwise likely to result from the

non-inclusion of IFPSDU.

CONSULTATION PAPER

Transition Period

Heinz considers that it would be appropriate for any future amendments to Standard 2.9.1 to be subject to a transition period of at least three years to provide a reasonably sufficient time to implement changes necessary to comply with new regulations. Heinz further submits that the transition period and gazettal of any changes should take into consideration the timing of the future proposed reviews of follow-on formula and IFPSDU. Heinz considers this to be an appropriate course as it will minimise the number of packaging changes which will in turn provide greater consistency of information and more clarity and certainty for caregivers using infant formula.

Label change costs

Changes to infant formula product labelling invariably involves substantial resource, time and financial costs to Heinz (and other industry participants) across multiple organisational departments. The magnitude of these costs to Heinz will depend on the nature and extent of the required change. Heinz has not yet quantified these costs, however they would include, without limitation, costs for trials, new artwork and packaging costs, packaging write-off, ingredient and finished goods write-off, costs associated with communicating the change to caregivers (as permissible), and people and procurement costs.

RESPONSES TO QUESTIONS

Supporting Document 1: Definitions and Nutrient Composition

Q1.2 Which of the following options to amend the definition (b) of infant formula in the revised Code "satisfies by itself the nutritional requirements of infants under the age of 4 to 6 months" provides greater clarity on the role and scope of infant formula?

(1) "satisfies by itself the nutritional requirements of infants less than 6 months of age"

(2) "satisfies by itself the nutritional requirements of infants up to the introduction of appropriate complementary feeding "

(3) Option 1 or 2 followed by and, as part of a progressively diversified diet, of infants from 6 months of age

(4) no change

Heinz recommends option 4 – no change. Heinz considers the current infant formula definition in Standard 2.9.1 in the revised Code to be a clear definition and fit for purpose.

Q1.4 Do you support retaining the current minimum requirement for LA (9% total fatty acids) in infant formula? Please provide your rationale.

Heinz supports aligning with Codex Standard 72-1981 linoleic acid (LA) minimum requirement of 70mg/100kJ. This is slightly lower than the current Standard 2.9.1 of 9% total fatty acids (converted to 90mg/100kJ) minimum requirement.

Q1.5 What issues, if any, do you have with the current approach to regulation of the source of fat in infant formula? Please provide your rationale

Heinz does not have any issues with the current approach to regulation of the source of fat in infant formula.

Q1.8 What issues, if any, do you have with the current approach to regulation of the source of carbohydrate in infant formula? Please provide your rationale.

Heinz agrees with the current approach in Standard 2.9.1, not to include provisions relating to the source of carbohydrate in infant formula.

Q1.9 Should the minimum folate requirement include or exclude the contribution of naturally occurring folate? Please provide your rationale.

Heinz does not support FSANZ's preliminary view to retain the reference in Standard 2.9.1 to "Folate µg". Heinz submits that the appropriate reference should be to "Folic Acid µg" to align with Codex Standard 72-1981. Further, Heinz supports the INC industry proposal that it be permissible to measure folic acid only due to the technical challenges associated with measuring both folic acid and naturally occurring folate.

Q1.10 If you consider minimum folate requirement should include natural folate, should dietary folate equivalents (DFE) be applied? Please provide a rationale in support of your view.

Heinz does not support applying dietary folate equivalents (DFE) to express the folate in infant formula as neither Codex Standard 72-1981 nor the general food Code use dietary folate equivalents (DFE).

Q1.11 Is it appropriate to amend the maximum phosphorus amount in Standard 2.9.1 to a GUL and align with the lower minimum Ca:P ratio? Please provide a rationale in support of your view.

Heinz supports the FSANZ preliminary view to amend the Standard 2.9.1 phosphorus current maximum of 25mg/100kJ to a Guideline Upper Level (GUL) of 24mg/100kJ. Alignment with the lower Codex minimum Ca:P ratio of 1:1 (currently 1.2:1) is also supported as this aligns with Codex Standard 72-1981.

Q1.12 Should the GUL amount for vitamin C be increased to 17 mg/100 kJ? If not, is the current GUL in Standard 2.9.1 appropriate? Please provide a rationale in support of your view.

Heinz supports increasing the Vitamin C GUL in Standard 2.9.1 from 5.4mg/100kJ to 17mg/100kJ as this aligns with Codex Standard 72-1981.

Q1.13 Do you support retaining the current minimum and maximum amount of iron required in infant formula? Please provide your rationale.

Heinz supports the FSANZ preliminary view and reasons in SD1 to retain the current iron minimum of 0.2mg/100kJ and maximum of 0.5mg/100kJ in Standard 2.9.1 of this important nutrient. In Codex Standard 72-1981 the minimum iron is 0.1mg/100kJ and the notes for GUL are that levels may need to be determined by national authorities.

Q1.14 Do you support raising the minimum and maximum amount of selenium required in infant formula? Please provide your rationale.

Heinz supports retaining the current minimum for selenium in Standard 2.9.1 of 0.25µg/100kJ. This is slightly higher than Codex Standard 72-1981 selenium minimum of 0.24µg/100kJ.

Q1.15 Do you support moving the maximum amount to a GUL? Please provide your rationale

Heinz supports moving the selenium maximum from 1.19µg/100kJ in Standard 2.9.1 to align with the Codex Standard 72-1981 GUL of 2.2µg/100kJ.

Q1.16 Do you support aligning with the higher Codex minimum and maximum amount for iodine and converting the maximum to a GUL? Please provide your rationale.

Heinz agrees with the FSANZ view to raise the iodine minimum and maximum amount, and converting the maximum to a GUL. This would align with Codex Standard 72-1981 iodine requirements for a minimum of 2.5µg/100kJ and GUL of 14µg/100kJ.

Q1.20 Are there any technical issues if the lower Codex minimum and maximum levels for copper were to be incorporated into the Code?

Heinz supports including the lower Codex Standard 72-1981 copper minimum of 8.5µg/100kJ and GUL of 29µg/100kJ in Standard 2.9.1

Q1.22 What is the justification to retain β-carotene as a provitamin A form?

Heinz supports retaining β-carotene as a provitamin A form for use in infant formula as this aligns with Codex Standard 72-1981. Heinz supports the FSANZ preliminary suggestion that β-carotene should not contribute to the calculated vitamin A activity.

Q1.23 What technical justification can you provide for the use of the nutrient forms listed in table 8.2 for use in infant formula?

There are differences in the permitted forms of nutrients for use in infant formula in Codex CAC/GL 10-1979 (Codex Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses Intended for Infants and Young Children) and Standard 2.9.1.

Heinz believes all the permitted nutrient forms in Codex Standard 72-1981 should be permitted in Standard 2.9.1 for reasons of consistency and potential for innovation and reformulation and reduction in international trade barriers.

The permitted nutrient forms have been evaluated by Codex for safety and appropriate for use in products for infants.

Heinz therefore supports the inclusion of the following Codex forms of vitamins, minerals in Standard 2.9.1 for nutritional use:

- Nicotinic Acid,
- Sodium D-pantothenate,
- DL-Panthenol,
- Cupric carbonate,
- Ferric citrate,
- Ferrous bisglycinate,
- Ferrous sulphate,

- Magnesium hydroxide carbonate,
- Magnesium hydroxide,
- Magnesium salts of citric acid,
- Potassium L-lactate,
- Zinc lactate and
- Zinc citrate (either zinc citrate dihydrate or zinc citrate trihydrate).

Q1.24 Do you support inclusion of a mandatory requirement for choline in infant formula? Please provide your rationale.

Heinz agrees with FSANZ preliminary view to list a mandatory requirement for choline in infant formula rather than an optional addition. The current Standard 2.9.1 choline range is 1.7-7.1mg/100kJ and the Codex Standard 72-1981 range is 1.7-12mg/100kJ with the higher upper limit as a GUL. Heinz supports the mandatory requirement for choline in alignment with Codex with a minimum of 1.7mg/100kJ and 12mg/100kJ as a GUL rather than a maximum.

Q1.25 What is the technological justification can you provide for the use of choline citrate and/or choline hydrogen tartrate in infant formula?

Heinz supports the inclusion of choline forms choline citrate and choline hydrogen tartrate in Standard 2.9.1 for alignment with Codex CAC/GL 10-1979.

Q1.27 Do you support inclusion of a mandatory requirement for L-carnitine in infant formula? Please provide your rationale.

Heinz agrees with FSANZ preliminary view that L-carnitine is listed as a mandatory substance in infant formula rather than an optional addition. The current Standard 2.9.1 L-carnitine range is 0.21-0.8mg/100kJ and the Codex Standard 72-1981 has a minimum of 0.3mg/100kJ but no set maximum amount. Heinz supports the mandatory requirement for L-carnitine in alignment with Codex with a minimum of 0.3mg/100kJ and with no set maximum amount. Heinz does not support the maximum proposed by FSANZ of 0.8mg/100kJ.

Q1.28 What is the technological justification can you provide for the use of L-carnitine hydrochloride and/or L-carnitine tartrate infant formula?

Heinz supports the inclusion of L-carnitine forms L-carnitine hydrochloride and L-carnitine tartrate in Standard 2.9.1 for alignment with Codex CAC/GL 10-1979. Heinz submits that the inclusion in Codex of these forms is sufficient evidence of safety for use in infant formula.

Q1.30 Do you support inclusion of a mandatory minimum requirement for inositol in infant formula? Please provide your rationale.

Heinz agrees with FSANZ preliminary view that inositol is included with a mandatory minimum requirement in infant formula. The current Standard 2.9.1 inositol range is 1.0-9.5mg/100kJ and the Codex Standard 72-1981 range is the same but with the higher upper limit as a GUL. Heinz supports the mandatory minimum requirement for inositol of 1.0mg/100kJ and 9.5mg/100kJ as a GUL rather than a maximum in alignment with Codex.

Q1.31 Do you supporting listing the permitted form of inositol as myo-inositol to provide clarity and consistency with Codex?

Heinz supports the listing of the permitted form of inositol as myo-inositol to provide clarity and consistency with Codex.

Q1.32 Are there any issues with the clarity of the drafting for the maximum amount of nucleotides in the revised Code?

The SD1 paper clarifies that maximum combined total for nucleotides in Standard 2.9.1 is intended to include any naturally occurring nucleotides. Heinz agrees the revised Code drafting is clearer to reflect this: *'infant formula product must not contain more than 3.8mg/100kJ of nucleotide-5'-monophosphates'*

Supporting Document 2: Safety and Food Technology

Q2.3 What evidence can you provide that could be used to estimate the prevalence of the practice of caregivers adding other foods to infant formula in Australia and New Zealand?

Heinz has received a number of enquiries from parents through its infant formula telephone careline (**Careline**) which suggest that the majority of parents follow appropriate infant formula preparation instructions printed on Heinz infant formula products. Heinz is aware of some instances where caregivers have added foods to infant formulas. In Heinz's view these instances are not prevalent and are not representative of the majority of caregivers. Heinz believes the current preparation instructions on infant formula labels along with the warning statement (as below) are clear and provide adequate and safe practical instructions for correct infant formula preparation.

> *'Warning - follow instructions exactly. Prepare bottles and teats as directed. Do not change proportions of powder except on medical advice. Incorrect preparation can make your baby very ill'*

To the extent any confusion may exist for a minority of caregivers, Heinz considers that additional warnings on label would not be the most effective way to address this issue and that health professional or health agencies would be best placed to do so.

Q2.5 What evidence can you provide that caregivers add other foods to infant formula to reduce the cost of the feed?

Heinz refers to and repeats its response to Q2.3 above.

Heinz supports retaining the current direction requirements for the preparation and use of infant formula in Standard 2.9.1-19. Heinz considers that these provisions are clear and adequate to promote safe practice when preparing infant formula.

Q2.6 What evidence can you provide that demonstrates that caregivers have difficulty finding protein source information on the labels of infant formula, and that this affects their ability to make an informed choice?

All of Heinz Nurture infant formulas are cows' milk protein based. In the required protein source statement it is also specified if it is a whey or casein dominant cows' milk protein infant formula.

Based on the enquiries Heinz has received through its infant formula telephone careline over the last 12 months, Heinz is not aware of any evidence of caregivers having difficulty finding the protein source information on labels. It is Heinz's view that the current regulations regarding protein source labelling are sufficient and appropriate for caregivers to make an informed choice.

Q2.7 What evidence can you provide that demonstrates consistent placement of the statement of protein source on the label would provide a benefit to caregivers?

Heinz has no evidence that demonstrates consistent placement of the statement of protein source on the label would provide any benefit to caregivers.

Q2.8 If so, should there be a requirement to prescribe the position of the statement of protein source on the label e.g. on the front of the package?

Heinz does not support prescription of the position of the protein source statement on infant formula labels. Heinz supports the regulations maintaining the protein source statement, immediately adjacent to the name of the product.

Q2.9 What are the cost and trade implications of prescribing the position of the statement of protein source on the label?

As noted in Q2.8 above, Heinz does not support prescription of the position of the protein source statement on infant formula labels. If contrary to Heinz's view such a change was made, this would require label updates and associated costs, with possibly repositioning other information to include the wording in the prescribed position. Heinz considers that infant formula labels already have a high number of mandatory requirements which must be included on the label space. This could also have an impact on international trade due to different regulatory requirements applying internationally.

Q2.10 What evidence can you provide on the prevalence of vitamin and mineral preparation use by Australian and/or New Zealand infants, either with or without medical supervision?

Based on the enquiries Heinz has received through its infant formula telephone Careline over the last 12 months, Heinz is not aware of any evidence in regards to vitamin and mineral preparation use for Australia and/or New Zealand infants, either with or without medical supervision. Heinz has no evidence on prevalence of vitamin and mineral preparation use for Australian and/or New Zealand infants.

Q2.11 Is the prevalence of vitamin and mineral preparation use higher in formula-fed infants than breastfed infants (or vice versa)?

Heinz refers to and repeats its response to Q2.10 above.

Q2.12 What data are available on intake levels of vitamins and minerals for Australian and New Zealand infants due to use of supplements (in addition to their normal diets)?

Heinz has no data available on intake levels of vitamins and minerals for Australian and New Zealand infants due to use of supplements.

Q2.14 What are the cost and trade implications of mandating advice regarding vitamin and mineral preparations on infant formula packages?

Heinz Nurture infant formula labels currently incorporate the guideline advice within the storage guide: *'If correctly stored and made-up in accordance with the directions on the label, no further vitamin and mineral preparations are necessary'*

Heinz believes that the current guidance wording is sufficient and mandated advice is not necessary. If contrary to this view a regulatory change was made, Heinz considers this would need to be

premised on a strong level of evidence, and would require label updates and associated costs. Infant formula labels already have a high number of mandatory requirements which must be included on the label space. This could also have an impact on international trade due to different regulatory requirements applying internationally.

Q2.15 Should all or only certain substances proposed for use in infant formula require pre-market assessment? Please provide your rationale for your preferred position?

Premarket assessment of substances for infant formula products was excluded from the scope of the FSANZ Proposal P1024 Nutritive Substances and Novel Foods (**Proposal P1024**). Heinz notes that Proposal P1024 also excludes Standard 2.9.2 – Food for Infants from scope (see 'Other considerations' section below for further comments on this issue).

Relevantly, Proposal P1024 provides (citations omitted):

> *"Standards 2.9.1 – Infant Formula Products and 2.9.2 – Foods for Infants are excluded from consideration in this Proposal. The Ministerial Policy Guideline on the Regulation of Infant Formula Products provides guidance on the pre-market assessment of substances added to infant formula products that will be considered separately by FSANZ as part of Proposal P1028 – Regulation of Infant Formula. Additional proposals may follow on from Proposal P1028 to address other formulae regulated by Standard 2.9.1. Standard 2.9.5 – Food for Special Medical Purposes is also excluded from this Proposal".*

Heinz supports the written submissions made by the INC in response to Proposal P1024.

Heinz further considers that Standard 2.9.1 should be included within the scope of Proposal P1024 for a number of reasons. First, Proposal P1028 only includes infant formula and not follow-on formula or IFPSDU, so any Code changes resulting from P1024 and P1028 would be unlikely to address issues specifically relating to follow-on formula and IFPSDU. Addressing these issues may require further subsequent reviews by FSANZ, which could potentially lead to regulatory inconsistency for follow-on formula/IFPSDU and other products.

Secondly, the key term 'nutritive substances' appears in Schedule 2.9.1 of the Code, so it is imperative this is reviewed and regulated alongside other general foods in Proposal P1024 for consistency.

Thirdly, Heinz notes that Proposal P1024 proposes a 6 month transition period for the new provisions. Based on this Heinz believes the review of Proposal P1024 may be completed prior to Proposal P1028 and should therefore include infant formula products in Standard 2.9.1 for timing and consistency of regulatory requirements.

Heinz supports the submissions made by the INC in response to Proposal P1024 regarding the three framework options. In particular, Heinz supports the option 3 framework for general foods also being applied to Standard 2.9.1 with appropriate differentiation to address the vulnerability of the target population.

Option 3 included four main elements as summarised:

- The first pathway permits the sale of new foods which meet the 'Eligible Food Criteria' and

don't require regulatory approval before market entry.

- The second pathway would require premarket assessment via industry self-assessment with notification before Australia or New Zealand market entry.
- The third pathway is premarket approval via a FSANZ application and regulatory assessment process.

For the premarket assessment routes the draft framework includes a description of data and dossier information requirements needed to establish safety and impact on public health of new foods.

Heinz supports all substances proposed for use in infant formula requiring premarket assessment, but does not consider that all require FSANZ premarket assessment. All pathways including Eligible Food Criteria and premarket self-assessment with notification also constitute pre-market safety considerations.

As noted in the submission made by the INC in response to Proposal P1028, the option 3 framework with differentiation is a regime that appropriately reflects the needs of a vulnerable target population and where infant formula may be the sole source of nutrition from 0 to around 6 months when breastfeeding is not undertaken. Heinz believes the option 3 framework with differentiation would also meet the requirements of the policy principles in the Ministerial Policy Guideline on the Regulation of Infant Formula Products including the specific policy principles (i) and (j) regarding pre-market assessment.

Appropriate differentiation criteria could include:

- The documentation on safety for all pathways including a focus on data relevant to the infant population.
- Clear criteria for the eligible food criteria pathway in terms of defining eligibility relevant to the infant population.
- The pre-market self-assessment via industry pathway including extensions of use and minor deviations from the eligible food criteria.
- The pre-market self-assessment via industry pathway having an option for an expert panel assessment to provide expert review of the safety assessment.

The framework could take into consideration assessment of an ingredient or product that has been conducted under a reputable overseas jurisdiction's regulatory system. Heinz further considers there should be an option for industry to select premarket approval via FSANZ application, even if the substance is eligible for the pre-market self-assessment pathway.

Q2.16 What would be the cost and trade implications of your preferred position?

As noted in Q2.15 above, Heinz supports the submissions made by the INC in response to Proposal P1024 for option 3 to be adopted by developing an alternative framework (with appropriate differentiation).

Q2.17 If only certain substances for use in infant formula should require pre-market assessment, where should the 'line' be drawn for the substances that do require pre-market assessment and those that do not? What is your rationale?

Heinz supports the submission made by the INC that future work on nutritive substances and novel foods in infant formula should be included in scope of Proposal P1024. As noted in Q2.15 above, Heinz also supports P1024 option 3 with appropriate differentiation for the vulnerable target population being applied to Standard 2.9.1. All substances for use in infant formula would therefore

require pre-market consideration in the framework pathways but not all would require FSANZ pre-market assessment.

Q2.18 If only certain substances, how would you suggest we define or characterise the group of substances that should require pre-market assessment?

Heinz refers to and repeats its response to Q2.17 above.

Q2.21 What are the cost and trade implications of reducing the ML for lead in infant formula?

The current ML for lead in infant formula products under Standard 1.4.1 is 0.02 mg/kg. The recently updated Codex Standard 193-1995 has a ML for infant formula of 0.01mg/kg as consumed.

Heinz supports lowering the ML for lead for 'ready to drink' infant formula to 0.01mg/kg for consistency with Codex.

However further consideration and research is required to establish the ML for lead in infant formula in powdered form (not as consumed).

Q2.22 What if any, issues are associated with not including the Codex ML in the Code for melamine?

Heinz is not aware of any issues associated with including the Codex ML for melamine in the Code for infant formula and including a melamine ML would bring the Code in line with Codex regulations. However Heinz also agrees that as per the FSANZ view, based on absence of associated risk, and that the Codex ML was specifically set to control illegal adulteration of infant formula, there is no rationale for the incorporation of the Codex ML for melamine into the Code.

Q2.23 Please provide comments on the recommendation to apply all MLs to a reconstituted ready-to-feed form.

Heinz preference is for MLs to be expressed as mg/kg for powdered infant formula rather than reconstituted ready-to-feed form. MLs should apply to the powdered product before being prepared with water.

Q2.24 Should the contaminant definitions for the contaminant which apply specifically to infant formula (aluminium) be addressed as part of a future review of Standard 1.4.1?

Heinz agrees that all MLs for infant formula including aluminium should be included together in Standard 1.4.1. This would make Standard 1.4.1 more usable as it is the standard referenced for contaminant/metal limits.

Heinz also agrees that the contaminant definitions specific to contaminants in infant formula are addressed as part of the future review of Standard 1.4.1.

Q2.25 Should the contaminant definition for those substances which apply to general foods, including infant formula, be considered later as part of a review of metal contaminants in standard 1.4.1?

Heinz agrees that FSANZ should consider contaminant definition as part of a future review of Standard 1.4.1.

Q2.26 What is the technological purpose for using the following 12 substances in the production of infant formula – INS 339i, 339ii, 339iii, 340i, 340ii, 340iii, 500i, 500ii, 501i, 501ii, 524 and 525? i.e.

are they best described as food additives, processing aids or permitted forms of minerals? Please explain and provide examples of how they are used in the manufacture of infant formula.

Heinz considers that the 12 substances could be used as either food additives, processing aids or as permitted forms of minerals in the manufacture of infant formula.
Heinz supports alignment with Codex for use of these substances as food additives in infant formula.

Q2.27 What justification can manufacturers and suppliers of infant formula in Australia and New Zealand provide to expand the permission for the food additive citric and fatty acid esters of glycerol (INS 472c) to all infant formula?

Heinz considers the food additive permissions for citric and fatty acid esters of glycerol (472c) should be extended from infant formula products for specific dietary use based on a protein substitute to infant formula products.

Recent safety evaluations and amendments were made to Codex Standard 72-1981 to permit citric and fatty acid esters of glycerol (472c) at maximum levels of 0.75g/100mL in powder infant formula and 0.9g/100mL liquid infant formula.

Q2.30 What, if any issues would a lack of consistency in the nomenclature of food additive names for infant formula cause?

Heinz does not agree with updating the nomenclature and INS numbers of food additive names used in infant formula with Codex. As highlighted by FSANZ a change in nomenclature would cause inconsistency with other food categories or food additives in the Code.

Heinz does not have any issues with the difference in nomenclature of food additives between Codex and the Code.

Q2.32 Should the carry-over principle for food additives apply to infant formula? Please provide your rationale.

Heinz supports the status quo and that the carry-over principle for food additives in infant formula should remain. Heinz supports alignment with Codex of permitted carry-over of food additives from a raw material or ingredient.

Supporting Document 3: Provision of Information

Q3.1 Should claims about specific ingredients be permitted on packaged infant formula?

- **If no, then why not?**
- **If yes, then how should they be regulated?**

Heinz believes that breast milk provides the best nutrition for babies. However for infants not being fed breast milk, an infant formula product is the only safe and suitable alternative until 12 months of age. For caregivers who have made a decision to use infant formula for a variety of medical, practical or personal reasons, clear and accessible labelling information on the nutritional attributes of infant formula is very important to make an informed decision on the appropriate product for their infant.

In SD3 FSANZ is seeking feedback on if there is a need for greater clarity in the Code about ingredient claims on packaged infant formula. Heinz believes that with the new Nutrition, Health and Related

Claims Standard 1.2.7 (from Jan 2016) – which prohibits nutrition content or health claims on an infant formula product - there is currently no doubt or issue of regulatory clarity on ingredient claims on packaged infant formula.

Heinz further considers that the prohibition on nutrition and health claims on infant formula labels leads to an absence of reliable information being available to formula feeding caregivers, which in turn restricts caregivers' ability to make an informed and safe choice between specific ingredients, nutrients and other differences between infant formula products.

Not all infant formulas in the market in Australia and New Zealand are the same. Variants include standard and premium infant formulas, follow-on formulas and formulas for special dietary uses. Premium or "gold" infant formula products contain additional approved ingredients such as Omega 3 DHA to further assist growth and development. Under the current regulations, the differences between these products can only be stated in the ingredients list and nutrition information panel on the product. However, not all caregivers may be aware of stated ingredients, which may not be commonly known and lead to associated confusion. The current regulatory labelling requirements are therefore not sufficient to enable an informed choice by caregivers. Heinz considers that greater attention needs to be given to resolving these issues, to ensure caregivers have ready access to information and to properly understand the differences between product variants.

In the Jigsaw Australian consumer research (**Jigsaw 2014**) (commissioned by INC), key findings highlighted that infant formula labels are not key influencers for initiating formula use, with challenges with breastfeeding being the key driver to initiating formula use within the first six months. For mothers with infants 7-12 months, the key drivers to initiate formula use were to supplement feed (i.e. still continue with breastfeeding and introduce formula feeds), and returning to work.

Under the current regulatory environment, infant formula labels and company websites can provide very limited information about the nutrients and differences between infant formula products. Heinz is concerned that a large portion of the population may obtain information from sources other than health professionals. The Jigsaw 2014 research also highlighted the main sources of information for mothers when formula feeding were health professionals (57%) and friends and family (54%). Of the mothers using online information, nearly half (45%) are visiting company websites, so this has potential to be a source of factual information. The concern is that unqualified information that is provided through other channels (including online) can be about feeding and health issues for a vulnerable infant population where infant formula may be the sole source of nutrition.

The Jigsaw 2014 research also highlighted that labels on infant formula do not provide sufficient information, with only 3% of mothers finding product labelling to be the most useful, which again highlights the opportunity for labelling to be improved. Additionally, 93% of mothers felt it was very important or important to be informed about formulation changes with the majority (85%) expecting that product packaging labels have a role in communicating product changes.

While the Jigsaw 2014 consumer research provides some insights, Heinz suggests that FSANZ seeks engagement with this particular group to support the need for informed choice from caregivers to gather further information.

Heinz submits that the Code review of infant formula regulations should reconsider and include express permissions for nutrient content and general level health claims in Standard 2.9.1 or within Standard 1.2.7. In particular, Heinz submits that permissions be considered for nutrient content and general level health claims for optional and differentiating essential nutrients.

Allowing nutrient content and general level health claims on infant formula labels would assist caregivers who have made a decision to use infant formula in making an informed and safe choice in regard to specific ingredients, nutrients and differences between infant formula products.

Q3.2 Do caregivers or health professionals find nutrition information about macronutrient subgroups to be of value for informing product choice?

Heinz refers to its response to Q3.1 above.

Heinz considers that macronutrient subgroup information is important and valuable information to health professionals, because this information enables health professionals to differentiate between products and provide appropriate and informed advice to caregivers.

In relation to caregivers, the Jigsaw 2014 research found that the information mothers look for when first making a decision about formula (having already made a decision to use infant formula), is what brand of formula to use and what ingredients are in formula. Then the main information mothers looked for on-pack to help make a decision includes nutritional/health benefits and ingredients. This research highlights the importance of ingredient and macronutrient sub-group information to caregivers when choosing a product.

Q3.3 Should the Standard include permissions to declare nutrition information about macronutrient subgroups (in addition to mandatory nutrition information currently set out in clause 16 of the existing Code and section 2.9.1–21 of the revised Code) in the nutrition information statement?

Heinz considers that Standard 2.9.1 includes permissions and does not prohibit information about macronutrient subgroups in the nutrition information statement. The Proposal P1028 SD3 paper indicates that adding macronutrient subgroups voluntarily, such as 'omega-3' indented under fat or 'whey casein ratio' indented under protein may constitute a nutrition content claim. Heinz disagrees that the voluntary use of macronutrient subgroups constitutes a claim on an infant formula label.

There are differences between the regulatory requirements for nutrition information required for general foods and infant formula products.

In the general foods the nutrition information mandatory format in Schedule 12 includes 'protein, total' and 'fat, total'. Standard 1.2.8 and Standard 1.2.7 also clarifies that voluntary information in a nutrition information panel might constitute a nutrition content claim for general foods.

However, under Standard 2.9.1-21 infant formula products require a statement of nutrition information rather than a nutrition information panel. The nutrition information makes no reference to only stating total protein or total fat. Specifically Standard 2.9.1-21(1)(a)(ii) states:

"*the average amount of protein, fat and *carbohydrate expressed in g/100 mL*";

Standard 2.9.1-24(1)(f) prohibits references to the presence of any nutrient or substance that may be used as a nutritive substance, except for a reference in a statement of ingredients or declaration of nutrition information. A nutrient could constitute both macronutrients and subgroups of macronutrients. Heinz therefore considers that Standard 2.9.1-24(1)(f)permits references to the presence of any nutrient in the nutrition information.

The macronutrient subgroup information assists caregivers in making an informed choice between infant formula products. An example of this is the whey:casein ratio of the protein, an important consideration when choosing a formula. The whey:casein ratio details are not available anywhere else on the label of an infant formula product.

Notwithstanding the above, to the extent any ambiguity may exist, Heinz would support the inclusion in Standard 2.9.1 of an express permission to declare nutrition information about macronutrient subgroups in the nutrition information statement.

Q3.4 Should it be mandatory to declare all or only specified macronutrient subgroups in the nutrition information statement? If so, which macronutrient subgroups and for what reason? For example, any subgroup of protein (whey, casein, alpha-lactalbumin etc.), or specific proteins (only whey and casein).

Heinz believes the macronutrient subgroup nutrition information is important information that assists caregivers to make an informed choice and differentiate between products.

Heinz however does not support the mandatory declaration of all or only specified macronutrient subgroups in the nutrition information statement. Heinz supports the current situation in which macronutrient subgroups can be included voluntarily in the nutrition information statement as applicable to the formulation of the infant formula product.

Q3.5 If only specified macronutrient subgroups, what principles should be applied to determine which nutrients may be declared (e.g. for those fats with a specific compositional requirement, or for those nutrients that caregivers have a general understanding of their nutritional purpose in foods).

As above Heinz does not support the mandatory declaration of specified macronutrient subgroups, but does support voluntary inclusion as applicable to the product composition to differentiate between products. Infant formula products already have many mandatory label requirements that limit available label space.

Heinz would however be supportive of the Guidelines for infant formula products in Schedule 29-10(3) including the 'guideline' format for optionally adding macronutrient subgroups in the nutrition information table for consistency i.e. order and indenting format. Heinz believes that industry should be able to voluntarily include the macronutrient subgroup information in the nutrition information for caregivers to show how products differ.

Q3.6 If nutrition information about macronutrient subgroups is provided, is there potential for caregivers of formula-fed infants to be misled about the nutritional value of formula?

Heinz considers it highly unlikely that caregivers would be misled about the nutritional value of formula by the inclusion of safe, accurate and more detailed information about macronutrient subgroups in the nutrition information.

The ability to make an informed choice is important for caregivers who make a decision to formula feed (as opposed to other foods); where formula can be the sole source of nutrition. Heinz considers that there are compelling public policy arguments for all caregivers having access to sufficiently detailed and accurate nutritional information to enable them to make safe, appropriate and justified decisions regarding the formulas they feed infants.

Q3.7 What would the cost and trade implications of mandating macronutrient subgroups or conversely expressly prohibiting them?

Heinz does not agree with mandating or expressly prohibiting macronutrient subgroups. Heinz supports the status quo (and regulatory clarity) and the voluntary addition of macronutrient

subgroups to the nutrition information statement.

However if there was a change to the regulations for macronutrient subgroups, updated infant formula labels would be required. If mandated, additional concerns would include space constraint for fitting the information onto labels, particularly for smaller cans. If prohibited this may lead to restricted innovation and increased barriers to international trade.

Q3.8 Is there any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations?

Based on the enquiries Heinz has received from its infant formula Careline over the past 12 months, Heinz is not aware of any evidence that caregivers and health professionals are confused by the differences between ingredient declarations and nutrition information declarations.

The ingredient statement on Heinz Nurture products generally includes the descriptive name of the ingredient to accord with a permitted form, together with the commonly understood vitamin name in parentheses. The nutrition information statement uses the common vitamin or mineral name.

Q3.9 Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?

Heinz does not believe that the names of ingredients should align with nutrient declarations in the nutrition information statement on infant formula labels.

The ingredient list and nutrient declarations serve different purposes. Further, it would not be possible for the nutrition information statement declarations to align with the ingredient lists.

The ingredients list includes all the ingredients used to make the infant formula as sold. Under Standard 1.2.4 (4) ingredients can be listed using a common, descriptive or generic name. If there was a more restrictive prescribed ingredient declaration this could create significant barriers to international trade. The nutrition information declaration of macronutrients, vitamins, minerals and nutritive substances is the total 'average amount' in the product. The declared amount of each nutrient may be derived from one or more of the ingredients.

Q3.10 Which base units of expression do stakeholders find to be of greatest value?

Heinz Nurture infant formula products include the base unit 'per 100mL made up formula' in the nutrition information.

Heinz supports the status quo and the use of the base unit 'per 100mL' (as consumed) in the nutrition information, as this is the most appropriate and relevant for caregivers. Heinz also supports the voluntary declaration per 100g for powdered product as sold for reasons of harmonisation with Codex Standard 72-1981.

Q3.11 Is there any evidence that caregivers are confused by the use of different base units of expression?

Based on feedback from the Heinz infant formula Careline over the past 12 months, Heinz is not aware of any evidence that caregivers are confused by the use of different base units of expression.

Q3.12 In addition to the current requirement to declare nutrition information per 100 mL as consumed, should it be mandatory or voluntary to declare per 100 g of powder (or per 100 mL for liquid formula) as sold?

Heinz does not support mandatory declaration per 100g for powdered product as sold, and believes this should remain as a voluntary declaration.

Powdered infant formula products have different bulk density and reconstitution ratios of powder to water (powder grams/mL) for preparing infant formula. Per 100g information could therefore be confusing for caregivers, as this cannot be used for comparing products.

If health professionals request Heinz Nurture infant formula nutrition information as per 100g of powder for clinical purposes, this information can be provided directly.

Q3.13 What would the cost and trade implications be of mandating these base units?

If the base units of per 100g were mandated this would require an infant formula label update and associated costs. Labels would require an extra per 100g column on the infant formula nutrition information table, in circumstances where label space is already limited. Extra time, resources and associated cost would be required to create new labels and packaging to include the additional column information.

Q3.14 Should the voluntary use of the base unit of per 100 kJ be permitted?

Heinz agrees that the voluntary use of the base unit per 100kJ should be permitted. This aligns with Codex Standard 72-1981 regulatory permissions.

Q3.15 What impacts, if any, would there be if the declaration requirements for macronutrients, micronutrients, nutritive substances, inulin-type fructans and galacto-oligosaccharides are based on 'average quantity', instead of 'average amount'?

Heinz does not foresee any impacts of changing the declaration requirements for macronutrients, micronutrients, nutritive substances, inulin-type fructans and galacto-oligosaccharides to 'average quantity', instead of 'average amount'.

Heinz infant formula labels already use the wording 'average quantity per 100mL of made up formula', so Heinz support this formalisation of using 'average quantity' term.

Q3.16 Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?

Nutrition information is important part on an infant formula label. It provides caregivers with specific product information to help make an informed decision on the appropriate product to purchase for their infant.

As noted above however, Heinz considers that more needs to be done to permit information on optional nutrients/differences between products (outside of the nutrition information table) to provide caregivers with the ability to make an informed decision. This could be particularly helpful in cases when product formulations change or optional nutritive substances are used.

Q3.17 Would a consistent approach to format across product labels assist consumer understanding of this information?

Heinz supports the current approach with the requirement of the label of an infant formula product to contain a statement declaring certain nutrition information per 100mL. This information can be in a tabular format. Heinz also supports the retention of the voluntary guidelines in Schedule 29-10 which provide a recommended format for the nutrition information.

Heinz does not believe a consistent approach to format across product labels would assist caregiver understanding. As all infant formulas differ (composition, ingredients, and preparation instructions) it is important that there is not an increased requirement for a consistent approach, which would prevent these differences being reflected. A mandated format for nutrition information could create

trade barriers.

Q3.18 If the format was prescribed, what would be the impacts including costs to industry and trade considerations of changing labels?

If format was prescribed, there would be significant costs of developing new labels and international trade barrier implications.

Q3.19 How can changes in the composition in an infant formula product be communicated to caregivers and health professionals?

The information that can be provided / communicated to caregivers on an infant formula label about composition changes is very limited. This is because any reference to nutrition information outside of the nutrition information statement or ingredients list may constitute a nutrition claim that is prohibited on infant formula.

Heinz has found that the best way to communicate a product change is by an on-lid sticker on the packaging. This can be used to communicate or notify caregivers of an upcoming product change or changed product. The Heinz Nurture website also provides a way to communicate a general change to infant formula labels and formulation. However the compositional details of the change are not currently permitted on the on-lid sticker or website. For further detailed information Heinz's provide the option of caregivers speaking to its dietitians on the Heinz Careline phone number, or their health professional.

For health professionals, changes in composition in infant formula product are communicated via direct written communication and face to face contact. However it is difficult to keep up to date and reach all relevant health care professionals.

Heinz therefore submits that allowing communication of compositional changes on an infant formula label would allow caregivers to make an informed and timely choice about the product they are purchasing and feeding to their infant.

Q3.20 What information about the change in composition would caregivers and health professionals find useful?

The Jigsaw 2014 research found that 93% of mothers said it was important or very important to be informed about formulation changes. What has changed, preparation instructions and ingredients are the key changes that would need communicating.

Heinz believes that information about a composition change should be able to be communicated via the label to health professionals and caregivers to provide informed choice. This includes formulation, ingredient, label or preparation instruction changes. Further information can then be obtained from the Heinz infant formula Careline or website.

Q3.21 What are the cost and trade implications of a standardised approach to a product reformulation on infant formula packages?

Heinz is not able to provide a cost and trade implications response as we require clarification from FSANZ of what a 'standardised approach to a product reformulation' entails.

OTHER CONSIDERATIONS

Nutritive Substances and Novel Foods – Food for Infants

Heinz notes that both Standard 2.9.1 Infant Formula Products and Standard 2.9.2 Food for Infants were excluded from the scope of Proposal P1024

Heinz supports both Standards 2.9.1 and 2.9.2 being included in the FSANZ Proposal P1024 going forward for timing and consistency (refer to Heinz response in Q2.15 above). Heinz is concerned that there is currently no scope for infant food to be considered alongside the general foods review for nutritive substances and novel foods regulations. Therefore if there are any changes to the Code, infant foods will not be included in the review or consultation and there will be potential differences in regulatory requirements. The infant food standard has specific compositional requirements on the types of additional and permitted forms of vitamins and minerals which can be added to cereal and non-cereal based food for infants. With the current regulatory permissions additional nutritive substances cannot be added to infant food to support the nutritional needs of the target population. Heinz believes that the addition of a nutritive substance in infant foods which would require pre-market assessment would be best considered under the proposed option 3 framework in Proposal P1024.

In summary Heinz supports Standard 2.9.2 (and 2.9.1) being included within Proposal P1024 for timing and consistency and that the Option 3 framework could also be applied to infant foods with appropriate differentiation to meet the needs of the target infant population.

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