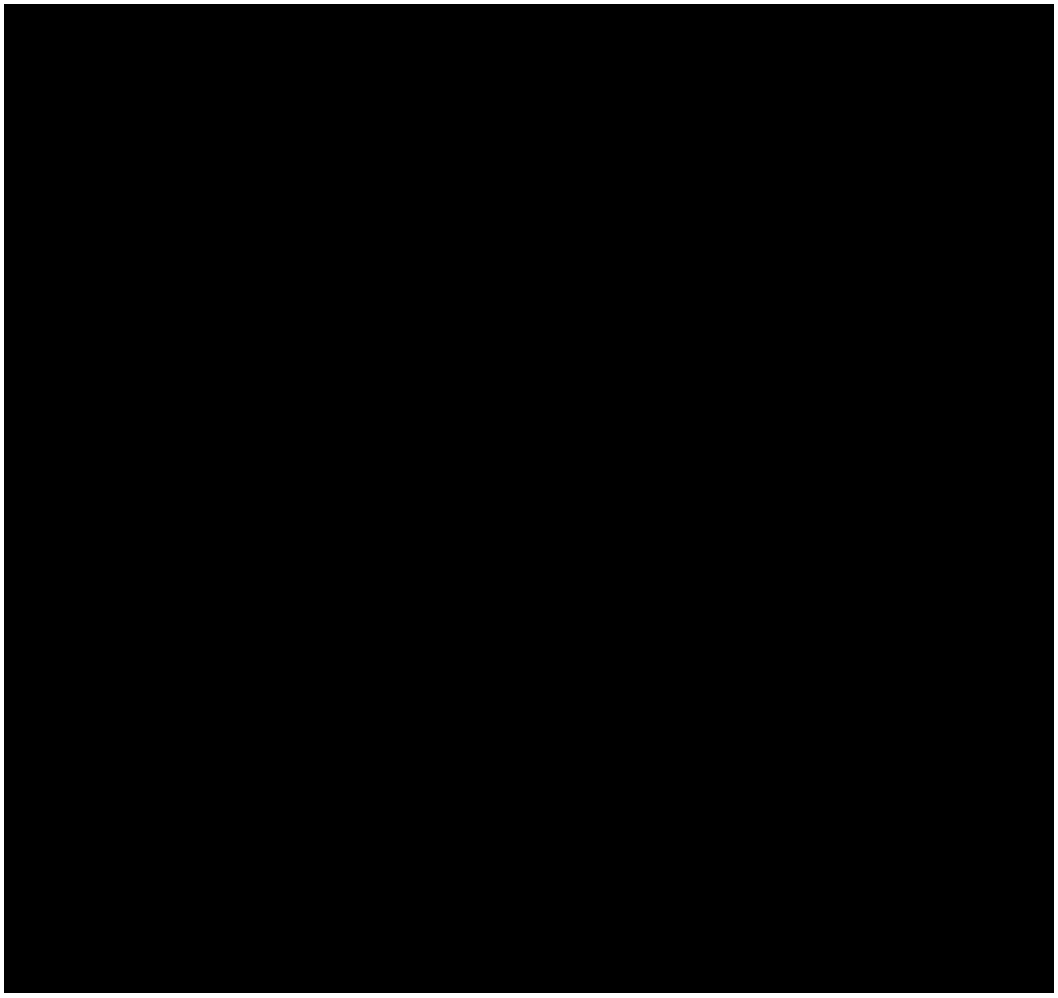
Complementary Medicines Australia *Submission to FSANZ Proposal P1028 – Infant Formula*

7 July 2021



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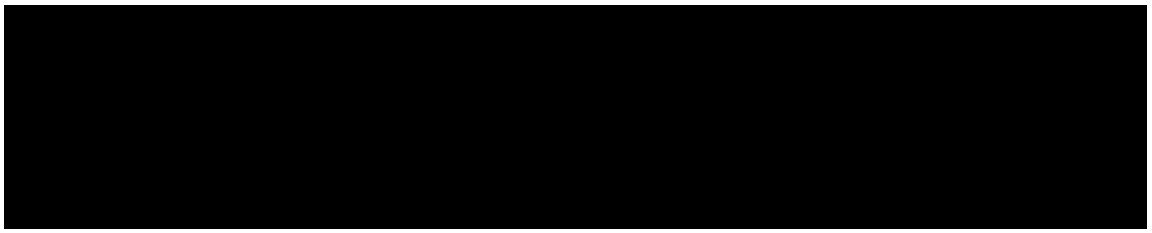
Complementary Medicines Australia

Complementary medicines Australia (CMA) appreciates the opportunity to provide feedback on FSANZ Proposal P1028-Infant Formula.

CMA is the peak body representing a thriving medicines and health food products sector supporting Australian jobs, research, manufacturing, and exports by meeting community demand for preventative and complementary healthcare. CMA represents sponsors, manufacturers, suppliers and retailers of complementary medicines, nutritional food products, sports supplements, infant formula and other concentrated foods for health purposes. CMA supports access through appropriate and balanced risk-based regulation, while contributing to skilled local employment, health enhancement and preventative health strategies to help Australians live healthier lives.

CMA supports the ongoing review of Food Standards in order to maintain currency; to align with comparable overseas regulation where practicable; and to ensure safety of consumers. Wherever possible, CMA supports a reduction in regulatory burden on industry in alignment with the Government's Modern Manufacturing Strategy, which aims to create a competitive business environment, build scale, and boost supply chain resilience by removing unnecessary regulation and reducing business compliance costs.



Proposal P1028

Proposal P1028 focuses on issues relating to the safety and food technology of infant formula, from manufacture of the product to preparation by caregivers. The purpose of the Proposal is to revise and clarify standards relating to infant formula (for use from birth to <12 months of age) comprising category definitions, composition, labelling and representation of products. The aim of this proposal is to ensure regulation of infant formula is clear and reflects the latest scientific evidence.

FSANZ has provided that, although the standards for infant formula are, on the whole, functioning adequately, there is scope to improve the clarity of some standards, and to consider the application of Ministerial policy guidance and alignment with international regulations.

Comments relating to questions 6-9 of the consultation document

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?

Industry may have to re-assess all ingredients (for carry over) in their formulations and potentially retest ingredients and/or finished goods (for contaminants). Sourcing compliant replacement ingredients may also impose a trade barrier. As a result, reformulations of current products may be necessary.

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

CMA has received advice from members that reformulation of individual products and product lines can be significant. Any required reformulation would therefore impose significant costs for businesses, particularly for businesses where numerous products are concerned and for small to medium enterprises (SMEs).

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?

There is potential for businesses of all sizes to be impacted if a new permission does not align with international regulations or standards.

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

Additional food additive preparations used in infant formula include:

- Ascorbyl palmitate: A fat-soluble form of ascorbic acid (vitamin C) as an antioxidant to protect lipids from peroxidation, used to increase the shelf life of a product.
- Tocopherols concentrate, mixed: Acts as an antioxidant and preservative, to inhibit lipid oxidation.

[redacted]

Food additives

Food class system for food additive permissions

CMA supports Option 3. - Simplify the approach by reducing the number of subclasses, which harmonises permissions with the Codex food standards and in some cases European regulations to improve international consistency and to maintain importation of infant formula products, especially Infant formula products for special dietary use (IFPSDU) which generally are not manufactured in Australia and New Zealand. This approach can more clearly limit the use of food additives, is consistent with how Schedule 15 already functions and will be harmonised with international food additive provisions.

Carry-over principle for food additives and infant formula products

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

In order to ensure compliance of products with the proposed carry over provisions, industry will have to reassess formulation ingredients, including sub-ingredients (e.g., carriers). As outlined in response to question 6., sourcing a replacement ingredient that is compliant may also impose a trade barrier and result in the costly reformulations of current products.

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

Please refer to the response to question 7.

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

The impact of the proposed changes to the carry-over principle would affect businesses of all sizes equally.

CMA conditionally supports the proposal to ensure consistency with food additive permissions in the Code with relevant international infant formula and IFPSDU regulations, by prohibiting the use of carry-over provisions for food additives ***unless*** permissions exist for such food additives used in raw materials and ingredients used to produce infant formula and IFPSDU. These permissions should necessarily and explicitly encompass provisions for additives in ingredients and raw materials; preparations of food additives or nutrients; and processing aids in ingredients.

In addition, to prevent the use of undesirable additives being 'carried-over', a clarified definition of 'carry-over' and a list of prohibited food additives for use in Infant Formula could provide additional clarity for industry and compliment the above permissions and those outlined in Schedule 15-5.

As a number of food additives are permitted and required in ingredients that are used in the production of infant formula, this approach would avoid international disadvantage and trade disruption for industry.

Harmonisation of food additive permissions

2.4.2 Acidity regulators

CMA supports FSANZ's view that the use of substances specified in the consultation paper as acidity regulators is justified. However, as some of these substances are used as a nutrient, there is a redundant additional compliance check for maximum levels (MLs) as maximum levels for composition already exist.

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

CMA supports the proposal to align with Codex and EU by introducing a lower maximum permitted level (MPL) of 7500 mg/kg for powdered products and to retain the 9000 mg/kg for liquid products

2.4.4 Starch sodium octenylsuccinate (INS 1450)

CMA supports the proposal to permit starch sodium octenylsuccinate use in infant formula for special dietary uses with the restriction of only being used for products containing hydrolysed protein and/or amino acids.

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

While CMA notes there are some stakeholder concerns with the industry proposed level of 10,000 mg/L, we do not support the current permission of 1000 mg/kg Locust bean (carob bean) gum in infant formula being further restricted for use only in 'products for reduction of gastro-oesophageal reflux'. As stated in the consultation paper, studies in infants at concentrations up to 6000 mg/L locust bean gum, 3300 mg/L cold soluble locust bean gum galactomannans or 4500 mg/L hot soluble locust bean gum galactomannans did not report any serious adverse events, indicating that use in infant formula at the current MPL is unlikely to be of toxicological concern.

2.4.6 Pectins (INS 440)

CMA supports the proposal to permit pectins in the Code for IFPSDU at a MPL of 5000 mg/L (mg/kg), in order to not restrict access to specific types of IFPSDU which may be solely sourced from Europe into the Australian and New Zealand markets.

2.4.7 Xanthan gum (INS 415)

CMA supports permitting xanthan gum in infant formula products up to 1200 mg/L. This limit is shown to have a safe history of use and would align the ML with the EU regulation and ensure importation of IFPSDU. However, should FSANZ find the level of 1200mg/L unsuitable, CMA would support permitting 1000 mg/L to align with JECFA's risk assessment which concluded that no safety concerns were associated with this limit.

2.4.8 Guar gum (INS 412)

CMA supports the permission for IFPSDU from birth onwards to contain 10,000 mg/L in liquid products containing hydrolysed proteins, peptides or amino acids.

2.4.9 Sodium alginate (INS 401)

CMA supports the proposal to align with the EU and permit sodium alginate in the Code for IFPSDU at a MPL of 1000mg/L (mg/kg), specifically for products suitable for infants from four months onward in special food products with adapted composition, required for metabolic disorders and for general tube-feeding.

2.4.10 Sodium carboxymethylcellulose (INS 466)

CMA supports the permission of a ML of 10,000 mg/kg sodium carboxymethylcellulose, limited to IFPSDU products from birth onwards for the dietary management of metabolic disorders to align with EU.

2.4.11 Sucrose esters of fatty acids (INS 473)

CMA supports the proposal to permit use of sucrose esters of fatty acids for IFPSDU containing hydrolysed proteins, peptides and amino acids up to 120 mg/L (mg/kg), which will avoid restriction of access to specific types of IFPSDU which may be solely sourced from Europe into the Australian and New Zealand markets.

2.4.12 Diacyltartaric and fatty acid esters of glycerol (472e)

CMA does not support removal of permissions for Diacyltartaric and fatty acid esters of glycerol for use as an emulsifier in IFPSDU based on a protein substitute with a MPL of 400 mg/kg. While FSANZ note that evidence of safety and technological need and justification will be required for such a permission, the removal of the permission in the absence of any safety concerns may be unsuitable. This will result in the unnecessary and costly reformulation of products containing the substance, without robust justification.

Clarifications to the Code

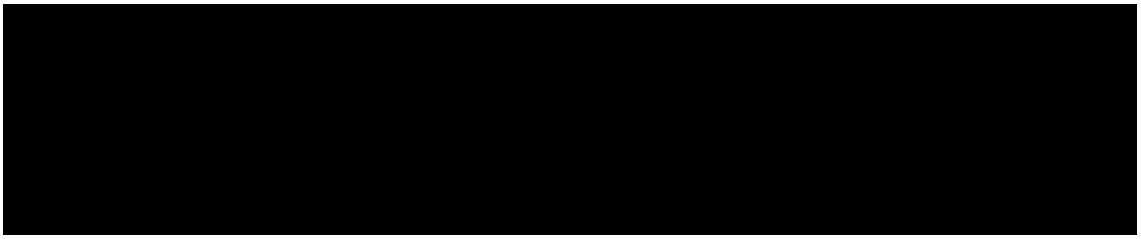
2.5.1 - CMA supports an amendment to the Code to correct what everyone understands to be an error and address the MPL for hydroxypropyl starch for soy-based infant formula; reducing from 25,000 mg/L to 5000 mg/L to be consistent with the original intent of P93, and to be consistent with Codex.

2.5.2- CMA supports clarifying permissions that allows carrageenan use in all liquid infant formula, including soy-based products.

2.5.3 – CMA supports the removal of the condition statements, as section 1.3.1—6 applies to all food classes and food additives and there is no need to make a special case for infant formula.

Updates to nomenclature and INS numbers

CMA does not support updates to nomenclature and INS numbers, as these changes will have impacts on all other food classes with labelling and cost impacts, which have not been consulted on with industry. Any major change to update food additive nomenclature and INS numbers would need to be part of a dedicated proposal where any proposed changes would be widely consulted upon.



Contaminants

Maximum levels for contaminants

3.3.1 Acrylonitrile

CMA supports the proposal of no change to the ML of 0.02 mg/kg for acrylonitrile listed in Schedule 19—5. The ML for acrylonitrile is for all foods, which includes to infant formula products.

3.3.2. Aluminium

CMA does not support a single ML of 0.05 mg/100 mL for all infant formula. As aluminium is a naturally occurring substance in the environment, a ML for aluminium is considered suitable however, CMA supports the current permissions for MLs for aluminium in soy based and all other infant formula of no more than 0.1 mg/100mL and a higher limit of 0.05 mg/100mL, respectively.

CMA supports moving the ML for aluminium from Standard 2.9.1 to Standard 1.4.1 and Schedule 19.

3.3.3. Arsenic

CMA supports the proposal not to include a ML in the Code for arsenic (inorganic) or 'arsenic, total' for infant formula products in the Code. While this approach is consistent with Codex, innovation in Infant Formula may result in use of protein sources (e.g., rice) which contain relatively high amounts of organic arsenic. Though this has been identified by FSANZ as relatively low risk, CMA supports FSANZ's continuous monitoring and review relating to future consideration of an ML for inorganic arsenic (for rice that may be used as an ingredient in infant formula).

3.3.4. Cadmium

CMA supports Option 1: To not establish an ML for infant formula in the Code on the basis that dietary exposures to cadmium in infant formula are not considered likely to be of health concern, noting that no data is available for soy-based infant formula.

3.3.5. Lead

CMA supports the proposal to reduce the ML for lead from 0.02 mg/kg to 0.01 mg/kg in infant formula and apply this level on a ready-to-feed basis. This is consistent with the ML in the Codex.

CMA supports FSANZ's view in relation to additional MLs for lead in specification of food additives for use in infant formula, that there is no need for FSANZ to amend the Code since JECFA monographs are accepted as primary sources in Schedule S3—2 and would need to be met for food additives added to infant formula, along with MLs for lead in final infant formula.

3.3.7. Melamine

CMA supports the proposal not to establish an ML for Melamine in the Code.

3.3.8 Tin and inorganic tin compounds

CMA notes that FSANZ's view is that there is no case for the exemption of infant formula per se from the scope of the tin ML (250mg/kg) in Schedule 19 and therefore, the general contaminant definition for tin as a metal in Schedule 19 should be applied to infant formula. However, in light of the issues raised in previous submissions, that there is no definition of canned foods in the Code, the inclusion of a statement to this effect in Standard 2.9.1 would assist in clarifying this requirement.

3.3.9 Vinyl chloride

CMA supports the proposal to retain the current ML for vinyl chloride, which continues to align with the guideline level (GL) in Codex STAN 193-1995.

3.3.10 Mycotoxins: Aflatoxins B1 and M1

CMA supports the proposal not to establish a ML or MLs for aflatoxins and specific aflatoxins M1 and B1, and supports the view that the Codex Code of Practice CAC/RCP 45-1997 is a useful risk management tool for manufacturers of IFPSDU products to reduce potential contamination of aflatoxins in infant formula products.

3.3.11 Mycotoxins: Ochratoxin A

CMA supports the proposal not to establish an ML for ochratoxin A, as it has been established that it is considered unlikely that levels of ochratoxin A in infant formula in Australia are a health concern.

3.3.12 Polycyclic aromatic hydrocarbons

CMA supports the proposal not to establish an ML for PAHs, as there is no identified public health and safety concern from polycyclic aromatic hydrocarbons (PAHs) in infant formula or (IFPSDU).

3.3.13 Perchlorate

CMA supports the proposal not to establish an ML for perchlorate.

3.3.14 Chloropropanol, glycidol and their esters

CMA supports the proposal not to set any MLs for chloropropanols and their fatty acid esters in the Code based on the preliminary risk assessment.

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

CMA supports the approach to apply MLs that are established for infant formula to an as consumed form in mg/kg.

Contaminant definition

CMA supports the consideration of a definition for 'contaminant' (potentially aligning with Codex) via the future review of Standard 1.4.1.

Other issues raised by submitters on contaminants

CMA supports the proposal to develop a food packaging information guide to provide a consolidated and comprehensive source of information for industry; address the gaps in awareness and knowledge for SMEs; provide general information on safety issues with CMPF for consumers; and describe the obligations on food businesses (particularly SMEs) to use safe packaging materials.

[redacted]

Lactic acid producing micro-organisms

CMA supports the retention of the permission for L-lactic acid producing microorganisms in infant formula products and considers the base 'safe and suitable' requirement to be sufficient in managing the risk of some pathogenic L(+) lactic acid producing microorganisms.

We note that Codex also refers to L(+) lactic acid producing cultures without further qualification however, if deemed necessary, CMA supports the clarification that only non-pathogenic L(+) lactic acid producing microorganisms be used. In addition, the development and provision of a list of either permitted or prohibited microorganisms, which is regularly updated and based on scientific evidence for safety and suitability in infant formula could provide greater clarity for industry.

Labelling for safe preparation and use

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?

Please see response to Directions for preparation and use.

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?

CMA is not aware of further data on infant illnesses that can be attributed to incorrect preparation as a result of unclear labelling or warning statements on products.

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

CMA has received feedback from industry that in general, voluntary label changes are not made incrementally and on a regular basis, but rather consolidated to minimise the financial and resource impact.

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)?

Proposed label changes would not incur additional costs, however, as stated in question 16 voluntary label changes are not made incrementally, rather consolidated to minimise the impact.

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)?

CMA have received feedback from industry that there would be significant costs for changes not made at the same time as voluntary changes.

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

CMA has received feedback from industry that other considerations may include write-off of tins on hand, destruction of tins and other environmental and commercial impacts.

[redacted]

Directions for preparation and use

CMA supports the proposal to maintain without change the mandatory requirement for directions:

- to prepare bottles individually (paragraph 2.9.1—19(3)(a)), and
- Instructing that if a bottle of made-up formula is to be stored before use, it must be refrigerated and used within 24 hours (paragraph 2.9.1—19(3)(b)).

In relation to the proposed amendments to infant formula labelling:

- revise the direction for water used to reconstitute powdered infant formula to include the word 'cooled' (paragraph 2.9.1—19(3)(c)).
- revise the direction instructing to discard unfinished formula to include the text 'within 2 hours' (paragraph 2.9.1—19(3)(e)).

CMA is of the view that sufficient information is available in relation to directions for the preparation and use of infant formula, which can be found not only on the label of the product, but also via product websites and Government and non-Government organisations, which offer best practice information and resources for the preparation and handling of formula.

The consultation paper states that caregivers understand there is a need to use cooled water to make up formula. Similarly, the eye-tracking study referred to in the consultation paper found that, of the 30 study participants, 25 reported discarding unfinished feeds within 60 minutes. While some evidence suggests these practices are not always followed, additional labelling information may be unlikely to encourage those care-givers who are not already following directions, to do so.

CMA supports the proposal not to apply the following directions to ready-to-drink infant formula:

- that 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)).

Standardised wording or pictures for directions for preparation and use

CMA supports the 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, consistent with Codex CXS 72-1981.

Other safe preparation and storage issues

CMA supports the proposal to maintain existing date marking requirements for infant formula products.

Storage instructions for infant formula

CMA 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.

Measuring scoop

CMA 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. CMA also supports FSANZ proposal not to apply this requirement to concentrated infant formula and ready-to-drink formula from the direction to only use the enclosed scoop.

Legibility requirements for warning statements

CMA supports the proposal not to change the existing legibility requirements for generic or specific warning statements on infant formula labels. CMA considers the existing requirements are appropriate to ensure prescribed warning statements on infant formula product labels are able to be read by caregivers. These legibility requirements also afford industry some flexibility in how warning statements are presented.

Warning statements about following instructions exactly

CMA supports the proposal to maintain the existing requirement for a warning statement on ready-to-drink infant formula labels about following instructions exactly (paragraph 2.9.1—19(1)(c)).

CMA does not support the inclusion of new additional bolded warning statement text

- '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'.

The labelling instructions on Infant Formula are quite clear about the risks of not preparing exactly according to the label. It may be appropriate, following advice of a healthcare professional, to add to the formula however, it is not necessary for this additional text to be provided on the label.

Warning statement that 'breast is best'

CMA supports the proposal to retain the existing 'breast is best' warning statement as currently required by paragraph 2.9.1—19(1)(d).

Prescribed name

CMA supports the proposal to maintain the requirement to use the prescribed name 'Infant formula' as the name of the food on the labels of infant formula, consistent with Codex specifications.

Statement that infant formula product may be used from birth

CMA supports the proposal 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.

Statement about age to offer foods in addition to formula

CMA supports the proposal to maintain the existing labelling statement indicating that infants from the age of 6 months should be offered foods in addition to infant formula as currently required by paragraph 2.9.1—19(4)(c).

Statement on protein source

CMA does not support the proposal to clarify the 'source' of protein in section 2.9.1—23 to refer to the origin of the protein (e.g., cows' milk) and not the protein fractions (e.g., whey protein or casein).

[redacted]

The provision of additional information should not be mandatory. The headline level of macronutrients necessary for maintaining health (e.g., protein, carbohydrates etc.) are already declared in addition to relevant allergen information.

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

CMA does not support the proposal to maintain the requirement for the co-location of the protein source statement and the name of the product. The FSANZ consultation paper provides that focus group participants generally had no issues with the location of the protein source statement; and that the Codex Infant Formula standard does not prescribe the location of the protein source statement. 'Supporting Document 4' states that front of package labelling of protein source information may assist consumers when they have reason to use it (e.g., health/safety concerns); and that in the event the protein source information is not labelled on the front of package consumers resort to the ingredient list. However, consumers who are choosing a product based on health/safety concerns are likely to read the ingredients list regardless of whether a statement appears on the front of the label.

As a mandated position of the protein source statement appears not be of great concern to care givers, and as there are significant cost and trade implications of prescribing the location on the label, CMA is in favour of avoiding additional and unnecessary regulatory burden wherever possible.

CMA appreciates the opportunity to provide a submission to this consultation. Please do not hesitate to contact us for further feedback on specific technical matters or industry implementation considerations.

[redacted]