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Tēnā koe,

Proposal P1028 – Infant Formula

New Zealand Food Safety (NZFS) welcomes the opportunity to comment on the 1st Call for Submissions (CFS) for Proposal P1028 – Infant Formula.

NZFS acknowledges that breastfeeding is the recommended way to feed infants. For infants who are not breastfed, a safe and nutritious substitute for breast milk is needed. Infant formula products are the only safe and suitable alternative to breast milk.

We appreciate the significant work FSANZ has undertaken to date on this Proposal to cumulate in this substantial CFS. We also thank FSANZ staff for the opportunity to participate in workshops during the consultation period to clarify proposed approaches and discuss key issues for New Zealand.

Overall, we support the regulatory objectives and principles that FSANZ has applied to its assessment to clarify and revise the standards for the regulatory framework, composition, labelling and representation of infant formula products – with the primary consideration to protect the health and safety of formula-fed infants. We also note our general support for FSANZ's assessment of P1028 against Ministerial Policy Guidelines and the consideration of costs and benefits of this Proposal.

NZFS looks forward to reviewing the drafting for Standard 2.9.1 and associated standards in the 2nd CFS to clearly see how the various components of the standards will operate together. We request that the 2nd CFS provides a 'clean' version of the drafting, in addition to the standard approach with the explanatory statement, to show exactly how the standards will appear.

Attached is NZFS's submission with our preliminary view on each of the preferred options presented in the CFS. We also present alternative options with supporting rationale and evidence for issues that we consider require further consideration. In summary, key issues for NZFS relate to:

- The proposed regulatory framework and the operation of the 'modified infant formula product' and 'special medical purpose products for infants' categories.
- The need for sheep's milk to be recognised as a safe and suitable permitted protein source for infant formula products. Sheep's milk protein has a history of safe use in infant formula products in New Zealand, is recommended in New Zealand government healthy eating guidelines for babies and toddlers, has a comparable protein and amino acid profile to cow and goat's milk, and is permitted for use in international and overseas regulations.

[redacted]

- The need to address inconsistencies in the conversion of kcal to kJ in aligning the compositional requirements under Codex to the values for infant formula products in the Code.
- The need to reconsider how the criteria for setting compositional requirements have been applied for some micronutrients (e.g. protein in follow-on formula, thiamin, iron, vitamin E).
- The need to refine the prescribed format and wording for the NIS.

We would welcome the opportunity to work with FSANZ over the coming months ahead of the release of the 2nd CFS to help resolve these issues.

Nāku noa, nā

[redacted]

[redacted]

Attachment: NZFS Submission to Proposal P1028 – Infant Formula

1. REGULATORY FRAMEWORK

NZFS would first like to acknowledge FSANZ's work to date to design an effective, modernised and future-proof regulatory framework for the regulation of infant formula products and specialised food products for infants. It is a challenging task with the final framework required to protect the health and safety of formula-fed infants, ensure caregivers are not misled, be enforceable, allow for industry innovation and promote ease of trade.

The proposed regulatory framework for Standard 2.9.1 has two main categories – infant formula products (IFPs) and special medical purpose products for infants (SMPPi). The IFP category includes the existing infant formula and follow-on formula, and a new category of modified IFPs. The proposed SMPPi category includes the existing infant formula products for special dietary use (IFPSDU) and is extended to include other products (including supplementary products) specifically formulated to meet the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition.

We provide the following comments on the proposed regulatory framework by product category:

Infant formula and follow-on formula

The regulatory categories of 'infant formula' and 'follow-on formula' are defined in the Code and are currently working well. These categories provide a nutritionally adequate breast-milk substitute for use either as the sole or principal source of nourishment for formula-fed infants. NZFS supports retaining the categories of infant formula and follow-on formula.

Modified infant formula products

A new proposed category within IFPs is 'modified infant formula products'. These are considered low-risk products with modified protein and/or lactose content, and are specially formulated for the dietary management of transient gastrointestinal conditions. They are intended for use following advice from a health professional and can be safely consumed by a healthy infant if purchased in error.

Scope of products

NZFS supports the concept to regulate low-risk modified protein and/or lactose content products as standard IFPs. Products with these modifications are currently available and represented for the dietary management of transient gastrointestinal conditions (e.g. to help with digestion and colic).

However, the proposed modified IFP and SMPPi categories need to be clearly differentiated within the Code. This is important for both understanding and appropriate use of the regulations by manufacturers and distributors, and for enforcement purposes. It appears that some products could be regulated under either category at the manufacturer's choice. We are concerned this may result in manufacturers positioning their low-risk products as SMPPi and taking advantage of the more flexible compositional provisions granted for SMPPi (e.g. for use of novel foods and nutritive substances to address the medical purpose without need for pre-market assessment). SMPPi labelling provisions may also be viewed as more favourable than those for modified IFPs. It is proposed that SMPPi will be required to state the medical purpose for the product on label, whereas modified products will be restricted to prescribed label statements about the protein and/or lactose modification and the purported purpose of the product (e.g. references to colic, constipation, ease of digestion) would not be permitted.

We request further explanation to demonstrate how the proposed regulatory framework will prevent low-risk products being represented as SMPPi.

Definition of modified IFPs

We note that no definition is proposed for modified IFPs. We support this approach as we view these products as standard infant formula and follow-on formulas with modification to the protein and/or lactose content, and not a standalone category of products. We also appreciate the difficulty in setting a definition for modified IFPs, particularly in relation to hydrolysed proteins where there does not appear to be a specification point to separate partially and extensively hydrolysed proteins.

Without a definition for modified IFPs, other risk management aspects of the regulation (e.g. food additive permissions) will need to self-limit products produced under each of the modified IFP and SMPPi categories. We request FSANZ further strengthens and clarifies the risk management strategies applied to modified IFPs so that the intended low-risk products are captured and regulated as standard IFPs. This includes clarification as to whether the definition for SMPPi would exclude products for the dietary management of transient gastrointestinal conditions.

Label statements

We support the proposed approach for modified IFPs to restrict label statements to only the nature of the modification and not the purported purpose for the product. While we acknowledge the argument by some stakeholders for a need to communicate the purpose of the product on label to help enable informed choice, these products are intended to be used following advice from a health professional – who can then advise the caregiver on the statements (i.e. 'low/free lactose' and 'partially hydrolysed protein') to look for when purchasing an appropriate product for their infant.

Another reason for restricting label statements to only the nature of the modification is that there may not be a strong scientific basis for some of these products. These tend to be transient gastrointestinal conditions, which are experienced by many infants (both formula-fed and breast-fed infants) and will generally resolve with time without need for specific intervention. Therefore, label references to these conditions may mislead caregivers as to the need and value of these products to assist in dietary management of these transient conditions.

Prescribed name

We note that 'infant formula' and 'follow-on formula' are prescribed names and are required to appear on the label of an IFP as the name of the food. As modified IFPs are proposed to fall within the overarching IFP category, the prescribed names 'infant formula' and 'follow-on formula' should also apply to these products. The prescribed name would be required to be used alongside any other specific labelling requirements for the name of the food, such as prescribed words relating to the nature of the modification (e.g. 'lactose free').

We support this approach that modified IFPs will be labelled with the prescribed name 'infant formula' or 'follow-on formula' as it will allow these modified products to be clearly identified by caregivers and health professionals, and for enforcement purposes to check compliance with the relevant regulatory requirements.

Future of the modified IFP category

NZFS is interested to understand whether an application could be made to FSANZ in the future for a new modification to be incorporated under the modified IFP category (not relating to the protein or lactose content)? And if so, what evidence would be required to demonstrate the safety and efficacy of the modification in infant formula products for healthy formula-fed infants?

Special medical purpose products for infants (SMPPi)

The new SMPPi category is proposed to capture all products that are specially formulated to meet the medically determined nutritional requirements of infants with a diagnosed disease, disorder or medical condition. These are highly specialised products to be used under medical supervision, are not suitable for use by healthy infants, and available only through a pharmacy or health facility.

NZFS notes that many of these specialised medical products for infants are imported into New Zealand, mostly from Europe but also from the USA. It is critical that the final regulatory framework for these specialised products provides flexibility to allow continued import of these products to New Zealand, thus ensuring the supply and access to these specialised products by those infants requiring them.

SMPPI principles

We support the principles for SMPPi outlined in section 2.4.3 of the CFS being a food that:

- is specifically formulated to satisfy the medically determined nutritional requirements of infants with a diagnosed disease, disorder and medical condition;
- are to be used under medical supervision;
- must be safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data;
- may form the sole source of nutrition or not; and
- for SMPPi that form the sole source of nutrition, the composition is based on infant formula products in order to take account the specific nutritional requirements of infants, and modified as appropriate to satisfy the particular disease, disorder or medical condition.

We consider all of these principles should be incorporated into regulation for SMPPi – through the definition, compositional requirements, guiding principles or other regulatory means.

Scope of products

The proposed SMPPi category accommodates both formula-type products that may be used as the sole source of nourishment (e.g. extensively hydrolysed formulas), and those more supplementary-type products that cannot be used as the sole source of nutrition (e.g. modular liquid products and human milk fortifiers). FSANZ proposes to capture all SMPPi products in Standard 2.9.1, so that SMPPi permissions and restrictions can be applied to all products without need to duplicate in Standard 2.9.5.

NZFS supports the proposed approach to regulate all SMPPi in Standard 2.9.1 of the Code. This approach provides regulatory clarity by having all highly specialised products that may be consumed by infants from birth (whether as the sole or principal source of nourishment or not) in the same standard as IFPs that may also be consumed from birth. It will also help ensure greater control of this product category (now and into the future) to protect the health and safety of the vulnerable infants that consume these products.

Definition

FSANZ proposes to define SMPPI in the Code as:

> *A Special Medical Purpose Product for infants means a food that is*
>
> *a. specially formulated for the dietary management of infants*
>
> > *(i) by way of exclusive or partial feeding, who have special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food; and*

(ii) whose dietary management cannot be completely achieved without the use of the food; and

b. intended to be used under medical supervision; and

c. represented as being

(i) a food for special medical purposes intended for infants; or

(ii) for the dietary management of a disease, disorder or medical condition in infants.

The proposed definition for SMPPi is based on the Standard 2.9.5 definition for 'food for special medical purposes', with reference to 'infant' the defining feature. The use of the FSMP definition for SMPPi appears appropriate given the nature of the products, which are formulated for the dietary management of infants with a disease, disorder or medical condition. We also note that the proposed definition for SMPPi adequately captures both the formula-type and supplementary-type products for infants, with components of the definition referring to: *specially formulated for the dietary management of infants*, and *by way of exclusive or partial feeding*.

The definition appears to capture most of the principles for SMPPi as outlined in section 2.4.3 of the CFS. However, we note the principle: *must be safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data* is not captured in the definition. NZFS requests this principle is clearly captured in the revised regulation – whether as part of the definition or compositional requirements. The requirement for the composition of SMPPi to be based on generally accepted scientific data is essential to ensure the safety and suitability of SMPPi for the infant and to meet the medical purpose of the product.

Separately, we note paragraph (c) of the proposed SMPPi definition states:

represented as being

(i) a food for special medical purposes intended for infants; or

(ii) for the dietary management of a disease, disorder or medical condition in infants.

We would appreciate if FSANZ could please clarify the operation of parts (c)(i) and (ii) in the context of SMPPi and the Code to improve our understanding of this element of the definition.

Prescribed name

A prescribed name is not proposed for SMPPi under P1028. Use of a prescribed name can provide regulatory clarity and allows easy identification of products for enforcement purposes. However, we note FSANZ's rationale to not require a prescribed name includes the potential to create trade barriers (as many of these products are imported) and that other specific labelling requirements (such as the name of the food and the statement of medical purpose) will assist with identifying a product as SMPPi. We also note that more than 90% of SMPPi are currently imported from Europe and the labels of these products must state "food for special medical purpose".

As discussed at a jurisdictional/FSANZ workshop during the consultation period, we welcome further discussion on whether a prescribed name should be required for SMPPi. Or, alternatively given the depth and diversity of products within the category and to avoid trade barriers for imported products, whether a more flexible approach could be applied to ensure key attributes of these products are captured in the name of the food. However, it is vital that whatever approach is taken it does not impede the import of and access to SMPPi.

Access restriction

NZFS understands that FSANZ intends for access to SMPPi to be restricted to pharmacies and health facilities, in line with the approach for FSMP under Standard 2.9.5. However, we were not able to find detailed discussion on this issue in the CFS.

NZFS supports a restricted access approach for SMPPi to minimise potential risks to infants, particularly as these products need to be used under medical supervision and as they are unsuitable for use by healthy infants.

We note the higher cost of SMPPi products and that many can be accessed at a subsidised cost via prescription with a special authority number. It would appear that due to the requirement in New Zealand for a prescription to access subsidised product, that this approach provides a level of protection against inappropriate use of the product without medical supervision.

However, we note the growth in warehouse-type pharmacies and online sales, with both avenues potentially making product available for purchase with limited or no medical/pharmacist oversight as intended for these products. We welcome further discussion on this issue to ensure the health and safety of infants is protected. This could include strengthening the access restriction to avoid the sale of SMPPi online and by warehouse-type pharmacies without appropriate medical oversight or use of a prescription.

Overall approach and the way forward

Overall, NZFS supports the intent of the proposed regulatory framework for IFPs and SMPPi in the Code.

We welcome further discussion with FSANZ on the proposed regulatory framework to ensure that:

- the framework achieves clearly differentiated product categories, so that a product cannot be represented across more than one product category;
- all principles for SMPPi are adequately captured in the regulation, either through the definition, compositional requirements, guiding principles or other regulatory means;
- risk management strategies applied will assist to clearly identify SMPPi for enforcement purposes;
- the import of and access to SMPPi is not impeded, recognising that these products are relied upon for the dietary management of a disease, disorder or medical condition in infants; and
- the access restriction is applied to SMPPi to help mitigate risk of inappropriate and unsupervised use.

2. DEFINITIONS

P1028 proposed approach	NZFS preliminary view
Retain current definition for infant as: ***Infant*** *means a person under the age of 12 months.*	Support (status quo). In addition, we request the definition for 'infant' is inserted in 2.9.1 alongside the other relevant definitions from Std 1.1.2. This will provide clarity for users applying the definitions for 'infant formula', 'follow-on formula' and 'infant formula products'.
Retain current definition for infant formula products as: ***Infant formula product*** *means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant.*	Support (status quo). Though question if the definition needs to be amended if the protein source is to be restricted – is it appropriate to retain the wording "a product based on milk or other edible food constituents of animal or plant origin" in the definition? Or is it appropriate that the definition is broad and then the protein source restriction is applied elsewhere in Standard 2.9.1?
Revise the definition for infant formula to: ***Infant formula*** *means an infant formula product that:* *a. is represented as a breast milk substitute for infants; and* *b. satisfies by itself the nutritional requirements of infants under the age of 6 months.*	Support the proposed change to the definition for infant formula.
Retain the current definition for follow-on formula as: ***Follow-on formula*** *means an infant formula product that:* *a. is represented as either a breast milk substitute or replacement for infant formula; and*	Support (status quo), as not aware of any reason for this definition to be reconsidered.

b. is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months.	
To remove the definition for 'protein substitute'.	Support, as no longer needed as a specified sub-category under the proposed regulatory framework.
To remove the definition for 'soy-based infant formula'.	Support, as 'soy-based formula' is self-explanatory and is proposed to be listed as a permitted protein source for infant formula products. Also, the definition becomes redundant if the proposed changes to food additive permissions and aluminium requirements related to soy are made under P1028.
To remove the definition for 'pre-term formula'.	Support based on the rationale provided by FSANZ. Pre-term products will be captured as SMPPi, with pre-term birth a medical condition that has special medically determined nutrient requirements.
To remove the definition for 'medium chain triglycerides'	Support, as medium chain triglycerides is self-explanatory and the permission for use will be limited to SMPPi if supported by evidence.
Definition of SMPPi	See comments in the 'Regulatory Framework' section of the submission.

3. NOVEL FOODS AND NUTRITIVE SUBSTANCES

P1028 proposed approach	**NZFS preliminary view**
To exclude consideration of novel foods and nutritive substances from the scope of P1028 and consider as part of P1024.	NZFS support the approach to exclude the substantial consideration of novel foods and nutritive substances for use in infant formula products from P1028, and to instead consider the issue as part of the broader review under P1024 to prevent inconsistencies and regulatory ambiguity in the Code. However, if the regulation of novel foods and nutritive substances in IFPs is to be considered under P1024, we highlight the importance for IFPs to be considered separately to general purpose foods for the general population – to reflect that infants are a vulnerable population group and to ensure proper regard to the specific policy principles (d), (e) and (i) of the *Ministerial Policy Guideline on the Regulation of Infant Formula Products* (the Ministerial Policy Guideline). We note that P1024 is currently on hold and awaiting the outcome of the FSANZ Act Review. The regulation of novel foods and nutritive substances in IFPs is an important issue, and we request FSANZ prioritises its work on P1024 once the FSANZ Act Review is complete.

To retain the current general prohibition on the addition of novel foods and nutritive substances to foods, including infant formula products.	Support retaining the current general prohibition on the addition of novel foods and nutritive substances to foods, including infant formula products. Noting, that a full review of this issue is proposed under P1024. The status quo to require express permission in the Code to add a novel food or nutritive substance to an IFP and the need for a pre-market assessment is generally working well, though there remains some regulatory uncertainty. We encourage FSANZ to give clarity to the current requirements wherever possible under P1028, such as the regulatory status of added L(+) producing microorganisms and the need for pre-market assessment for new plant-based protein sources.
To amend Schedule 25 to include conditions for α-cyclodextrin, γ-cyclodextrin, diacylglycerol oil (DAG oil), isomaltulose, D-tagatose, and trehalose that restricts these substances from being used in infant formula products.	Support the proposed clarification in Schedule 25 to expressly prohibit the use of these novel foods in infant formula products. We note that these prohibitions may need to be extended to include SMPPi depending on the outcome of permissions for use of novel foods and nutritive substances in SMPPi.

4. SAFETY AND FOOD TECHNOLOGY

Food additives

NZFS supports the principles developed by FSANZ to guide consideration of the risk management approach for food additives, namely:

(1) the protection of infant health and safety
(2) the number of food additives used in infant formula products should be the least number necessary to achieve the required technological functions
(3) consideration of harmonisation with international standards.

It is noted that CCNFSDU has recently finalised a framework for appraising the technological need for food additives, which is applicable to infant formula products[1].

P1028 proposed approach	**NZFS preliminary view**
To use a simplified structure for food classes for food additive permissions applied to infant formula	Support the proposed approach to reduce the number of subclasses for food additive permissions – with the subclasses named 'infant formula products' and 'special medical purpose products for infants'

[1] https://www.fao.org/fileadmin/user_upload/codexalimentarius/committee/docs/INF_NFSDU20_e.pdf

and related products in the table to section 5 of Schedule 15, and that condition statements will be used to differentiate or qualify specific food additive permissions (i.e. Option 3 in FSANZ 2021 CP1).	(or any alternative terminology once the regulatory framework is established), in line with the product category names and definitions used elsewhere in the Code. Also, we support the use of qualification notes and conditions in Schedule 15 to qualify or differentiate permissions to provide clarity and regulatory certainty.
To not permit carry-over of food additives unless a specific permission exists for that food additive in the final food.	Support the proposed approach that carry-over of food additives is not permitted unless a specific permission exists for that food additive to be used in infant formula products. This approach is consistent with the Codex General Standard for Food Additives (GSFA), which applies to infant formula products. We support the proposed approach and the need to ensure consistency with relevant international regulations and standards, in particular those of the EU and Codex. This will serve to both support New Zealand's infant formula exports and to maintain importation of infant formula products, especially special medical purpose formulas which generally are not manufactured in Australia and New Zealand. This includes any specific provisions covering the carryover of food additives.
Food additive permissions by type or substance	
FSANZ seeks information on the safety, justification and appropriateness of adopting Codex and EU MPLs for hydrolysed protein formulas within the SMPPi category.	NZFS has no information to provide to support consideration of this issue. We will consider our view when this issue is discussed further in the 2nd CFS.
Acidity regulators – to apply condition statements for calcium, sodium, potassium and phosphorus salts, where appropriate.	Support
Citric and fatty acid esters of glycerol (CITREM) (INS 472c) – to permit use in infant formula products with MPLs of 9000 mg/L for liquid products and 7500 mg/L for powdered products.	Support
Starch sodium octenylsuccinate (INS 1450) – to permit use in products based on extensively hydrolysed protein and/or amino acids at a MPL of 20000 mg/L.	Support

Locust bean (carob bean) gum (INS 410) – to retain the current permission in infant formula products at a MPL of 1000 mg/L.	Support
Locust bean (carob bean) gum (INS 410) – to permit use in SMPPi at a MPL of 5000 mg/L.	We will consider our view when this issue is discussed in the 2nd CFS, noting FSANZ's request for further information and a pending EFSA evaluation.
Pectins (INS 440) – to permit use in SMPPi at MPLs of 2000 mg/L for hydrolysed protein liquid formulas and 5000 mg/L for gastro intestinal disorder formulas.	We will consider our view when this issue is discussed in the 2nd CFS, noting FSANZ's request for further information and a pending EFSA evaluation.
Xanthan gum (INS 415) – preliminary view, to include two permissions with different MPLs for different SMPPi products.	We will consider our view when this issue is discussed in the 2nd CFS, noting FSANZ's request for further information to inform its final position.
Guar gum (INS 412) – to retain current permission in infant formula products at an MPL of 1000 mg/L.	Support (status quo).
Guar gum (INS 412) – to permit use in certain SMPPi (products containing extensively hydrolysed proteins, peptides or amino acids) at an MPL of 10000 mg/L.	We will consider our view when this issue is discussed in the 2nd CFS, noting FSANZ's request for further information and a pending EFSA evaluation.
Sodium alginate (INS 401) – preliminary view, to permit use in certain SMPPi at an MPL of 1000 mg/L.	We will consider our view when this issue is discussed in the 2nd CFS, noting FSANZ's request for further information to inform its final position.
Sodium carboxymethylcellulose (INS 466) – preliminary view, to not permit the use of sodium carboxymethylcellulose in any infant formula product or SMPPi.	We will consider our view when this issue is discussed in the 2nd CFS, noting FSANZ's request for further information to inform its final position
Sucrose esters of fatty acids (INS 473) – preliminary view, to permit use in certain SMPPi (products	We will consider our view when this issue is discussed in the 2nd CFS, noting FSANZ's request for further information to inform its final position.

containing hydrolysed proteins, peptides or amino acids) at an MPL of 120 mg/L.	
Diacyltartaric and fatty acid esters of glycerol (INS 472e) – to removed the current permission in the Code.	Support, it is not permitted by Codex or the EU, and appears to have no technological need or current use of the permission at this time.
To make the clarifications to the Code relating to hydroxypropyl starch, carrageenan and starches (INS 1413, 1414 and 1450).	Support the proposed clarifications as outlined in section 3.6 of Supporting Document 1.
To retain current nomenclature and INS numbers.	Support, as such changes would impact all food classes and is better suited to be considered under a dedicated proposal.

Processing aids

P1028 proposed approach	**NZFS preliminary view**
To retain current standards for enzyme processing aids used in dairy processing.	Support (status quo)

Contaminants

P1028 proposed approach	**NZFS preliminary view**
Maximum levels for contaminants	
Acrylonitrile - No change to the ML of 0.02 mg/L for all foods including infant formula products.	Support
Aluminium - Move ML from Std 2.9.1 to Std 1.4.1 and Schedule 19.	Support

Retain single ML of 0.05 mg/100mL for aluminium for IFP including soy-based.	
Arsenic - No ML for infant formula products. Monitor and review (for rice that may be used as an ingredient in infant formula).	Support
Cadmium - No ML to be established.	Support
Lead - Lower ML from 0.02 mg/L to 0.01 mg/L in IFP and apply to infant formula on a ready-to-feed basis.	Support
Melamine - No ML to be established.	Support
Tin & inorganic tin compounds - No change to the ML of 250 mg/L.	Support
Vinyl chloride – No change to the ML of 0.01 mg/L.	Support
Aflatoxins B1 and M1 – No ML to be established.	Support
Ochratoxin A - No ML to be established.	Support
Polycyclic aromatic hydrocarbons - No ML to be established.	Support
Perchlorate - No ML to be established.	Support
Chloropropanol, glycidol and their esters - No ML to be established.	Support
To apply MLs for infant formula to an 'as consumed' form in mg/kg.	Support approach to apply MLs for infant formula to an 'as consumed' form in mg/kg, as consistent with Codex.

Contaminant definition – no change to the definition of analytes, as common to both infant formula and other foods. Address this issue as part of a possible future review of Std 1.4.1 (potentially aligning with Codex).	Support

Lactic acid producing microorganisms

P1028 proposed approach	**NZFS preliminary view**
Retain existing permission for use of L(+) lactic acid producing microorganisms in infant formula product.	Support, in conjunction with the clarifications below.
Clarify that L(+) lactic acid producing microorganisms may be added for acidification purposes only.	L(+) lactic acid producing cultures are used for two purposes: a technological function for the purpose of acidification, or for a nutritive purpose as a probiotic. The Code currently contains an unconditional permission for the optional use of L(+) lactic acid producing microorganisms in infant formula products, which is consistent with Codex CXS 72-1981. In the draft Codex Standard for FuFOI the clause relating to permission for L(+) lactic acid producing microorganisms is clarified to state the two purposes for which they can be added: *Only L (+) lactic acid-producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final product should not contain significant amounts of viable L (+) lactic acid producing cultures, and residual amounts should not represent any health risk.* *The safety and suitability of the addition of specific strains of L(+) lactic acid-producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures to achieve the intended effect.* NZFS supports the approach to clarify that L(+) lactic acid producing microorganisms may be used for the purpose of acidification in IFPs. In addition, we agree that a permission to use L(+) lactic acid producing microorganisms for a nutritive purpose should require pre-market assessment, as the safety and suitability of specific strains cannot be extrapolated to all L(+) lactic acid producing microorganisms. However, further consideration needs

	to be given to the regulatory status of specific strains of L(+) lactic acid producing microorganisms that have been added to IFPs for a nutritive purpose and available in Australia and New Zealand for many years. Further work is required within P1028 to identify these strains and specifically permit in the Code. The revised approach by FSANZ is a deviation from previous consultation papers whereby the open permission was to be upheld, and had been interpreted to apply to all forms of L(+) lactic acid producing cultures by industry and enforcement agencies in both Australia and New Zealand. We support an approach which provides regulatory certainty for both industry and enforcement agencies, and better aligns with the approach under Codex CXS 72-1981 and the draft Codex Standard for FuFOI.
Clarify that the permission relates to only non-pathogenic or non-toxicogenic microorganisms may be used.	Support. Agree this approach provides regulatory clarity and minimises risk of pathogenic microorganisms being added to infant formula products, rather than relying on the 'safe and suitable' proviso.

Gene technology

P1028 proposed approach	**NZFS preliminary view**
Retain requirements that, unless expressly permitted, a food for sale must not be a food produced using gene technology, or have as an ingredient or component of a food produced using gene technology.	Support the status quo to require express permission for a food, ingredient or component produced using gene technology to be added to infant formula products and SMPPi.

Labelling - Safety

P1028 proposed approach	NZFS preliminary view
Directions for preparation and use	
Maintain direction to prepare bottles individually	Support (status quo).
Maintain direction instructing that if a bottle of made up formula is to be stored before use, it must be refrigerated and used within 24 hours	Support (status quo).
Maintain direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used	Support (status quo).
Revise direction for water used to reconstitute powdered formula to include the word 'cooled'	Support revised direction; as supported by FSANZ's microbiological safety assessments. We note that as the wording will not be prescribed, other words than 'cooled' could be used on label (e.g. room temperature, lukewarm).
Revise direction instructing to discard unfinished formula to include the text 'within 2 hours'	Support revised direction; as recommended by NZFS and supported by FSANZ's microbiological safety assessments. We note that as the wording will not be prescribed, the label could refer to 'within one hour' or discard 'immediately after a feed'.
For ready-to-drink formula, to not apply the direction that each bottle to be prepared individually.	Support – agree this direction is not relevant for ready-to-drink formula.
For ready-to-drink formula, to not apply the direction to refrigerate formula and use within 24 hours if it is made up and stored prior to use.	Support – agree this direction is not relevant for ready-to-drink formula.
For ready-to-drink formula, to not apply the direction to use potable, previously boiled water.	Support – agree this direction is not relevant for ready-to-drink formula.

For concentrated and ready-to-drink formula, to not apply the direction to use enclosed scoop.	Support – agree this direction is not relevant for concentrated and ready-to-drink formula.
To maintain the current approach not to prescribe the exact wording or pictures to be used for the required directions for preparation and use on infant formula products.	Support (status quo).
Date marking and storage instructions	
To maintain existing date marking requirements for infant formula products.	Support (status quo).
To maintain: • existing generic requirements for storage instructions • the specific requirement for infant formula products, to cover the period after the package is opened.	Support (status quo); related to generic storage requirements in 1.2.6—2(a) and (b), and the specific requirement in 2.9.1—22.
Statements	
To maintain existing legibility requirements for generic and specific warning statements on infant formula product labels.	Support (status quo); related to generic legibility requirements in 1.2.2—24 and –25 and specific legibility requirements in 2.9.1—20.
To require a new direction for the preparation and use of infant formula products: • for powdered and concentrated formula - not to change proportions of [powder/concentrate] or add other food except on medical advice • for ready-to-drink formula - not to dilute or add anything except on medical advice.	Partial support. Support that this information is provided as a direction for the preparation and use of infant formula products, rather than a warning statement. We agree there is a need to communicate with caregivers not to add other foods to IFPs during preparation, based on consumer evidence and the risks of such practice to infants. However, we suggest using the wording “or add anything” (as used in the ready-to-drink statement) rather than “or add other food” (as proposed for powdered and concentrated IFP), for all product formats (powdered, concentrated or ready-to-drink). Although technically foods, we question if some caregivers would consider tea, sugar or vanilla as foods. Therefore, consider the more generic wording “or add anything”

	to be more encompassing for what a caregiver might consider adding to an infant formula product. It would also capture other substances that some caregivers may add, such as probiotics.
Propose to consolidate the warning statements for powdered, concentrated and ready-to-drink infant formula products into a single prescribed warning statement applicable to all product types that states: *Warning – follow instructions exactly. Prepare bottles and teats as directed. Incorrect preparation can make your baby very ill.*	Support the proposed single prescribed warning statement applicable to all product types.
To retain the existing warning statement currently required by paragraph 2.9.1—19(1)(d) that states: *Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice.*	Support (status quo).
To maintain the requirement for 'Infant formula' and Follow-on formula' as prescribed names for these products.	Support (status quo).
To maintain the requirement for the statement indicating that the infant formula product may be used from birth.	Support (status quo); as currently required under 2.9.1— 19(4)(a).
To maintain the requirement for a statement on follow-on formula labels indicating that follow-on formula should not be used for infants aged under the age of 6 months.	Support (status quo); as currently required under 2.9.1—19(4)(b).
To maintain, as it is currently worded, the statement indicating that infants from the age of 6 months should be offered foods in addition to the infant formula product	Support (status quo), as currently required under 2.9.1—19(4)(c). We note that this provision is a safety-based statement, rather than for the purpose of providing information to caregivers about the appropriate age to introduce complementary feeding.

	We note that some stakeholders have suggested this statement should refer to 'around 6 months' rather than 'from the age of 6 months' for consistency with both the Australian and New Zealand infant feeding guidelines. However, we have concerns if the base statement were to refer to 'around 6 months', noting that the wording of this statement is not prescribed. 'From the age of 6 months' is clear, whereas 'around 6 months' could be open to interpretation and could result in other months stated on the product label (e.g. 4, 5, 6 or 7 months, or a variation thereof). This is of concern as there is a public health and safety risk if the label were to suggest introducing complementary feeding earlier or later than is recommended – as there is evidence that introduction prior to 4 months is detrimental to health, and that later than 6 months will lead to infants not meeting their nutrient requirements. Also, use of the terminology 'around' in the New Zealand infant feeding guidance is used in conjunction with reference to the signs of readiness (which this label statement does not), thus supporting a caregiver to appropriately determine the appropriate age to introduce complementary feeding for their infant.
To clarify that the 'source' of protein in section 2.9.1—23(1)(a) refers to the origin of the protein.	Support the need to clarify that the statement for 'source' of protein refers to the origin of the protein (e.g. cow's milk) and not the protein fractions (e.g. whey protein or casein). We consider this to be an important clarification for the intent of 2.9.1—23(1)(a) for enforcement purposes.
To maintain the requirement for the co-location of the protein source statement with the name of the food.	Support (status quo).
To clarify the co-located protein source statement and name of the food needs to appear in a prominent position just once on the label.	Support the clarification that the co-located protein source statement and name of the food needs to appear only once on the label, and not every time the prescribed name is used. We also support the new requirement for the co-located statements to appear in a 'prominent position'. It is important that the statements about protein source and name of food are in a prominent position to alert consumers to the appropriate formula choice for their infant's age, which is particularly important from a health and safety perspective as infant formula can be the sole source of nutrition for some infants. This requirement is also consistent with Codex STAN 1-1985, which requires the name of the food to appear in a prominent position on the label. In practise it would be desirable for these statements to appear on front of pack, however we appreciate that prescribing the location on pack in regulation is highly restrictive for a globally traded product and would go beyond what is currently required internationally. We also note that in the case of infant formula products, which are generally packaged in a round tin, 'front of pack' would be open to interpretation.

COMPOSITION

General Principles

NZFS supports FSANZ's approach that the primary objective is the protection of public health by specifying compositional requirements that support normal growth and development when infant formula is used as the sole or principal source of nutrition up to 12 months of age. We support the need to clearly indicate which foods/substances require premarket assessment to provide clarity to industry and enforcement agencies.

Support the criteria used in the 2016 nutrition risk assessment to determine if the composition would support protection of public health and safety:

- the origin of current standards
- recommendations of key expert bodies
- comparison with breastmilk substitutes
- estimation of intakes and comparison with the Australia and New Zealand Nutrient Reference Values for adequate and excessive intakes
- physiological, biochemical and functional outcomes
- identification of new or emerging scientific evidence.

Support the assessment of the composition of infant formula with the Codex CXS 72-1981, unless current requirements or the EU 2016/127 requirements are considered more appropriate to ensure infant health and safety within the Australian and NZ context. In accordance with the regulatory objectives specified by FSANZ in the CFS, we support consideration of consistency with advances in scientific knowledge, industry innovation and/or not hindering trade.

Conversion factors

In New Zealand, infant formula products that are manufactured for export-only must still comply with the compositional requirements set in the Food Standards Code. The Ministry for Primary Industries can issue an exemption from the compositional requirements of the Food Standards Code under Food Act 2014. These exemptions are nutrient and country specific. Many of the markets that New Zealand infant formula manufacturers export to have adopted the Codex Infant Formula Standard (CXS 72-1981) into their regulations and this can be limited to expression on a per 100 kcal basis.

NZFS notes that there are some inconsistencies in the conversion of kcal to kJ in Codex CXS72-1981 and suggest that these should be rectified in the Food Standards Code as they can cause issues in exporting products. Within the Codex Committee, discussions are based on the values for the composition per 100 kcal, and subsequently converted to per 100 kJ. In the draft Codex Standard for Follow-up Formula the technical calculation errors have been addressed and the Codex Secretariat has stated that consequential amendments would be made to the Codex Infant Formula Standard following adoption of the Follow-up Formula standard.

Closer alignment of the Food Standards Code infant formula compositional requirements with those of the Codex infant formula standard kcal values would result in fewer exemptions needed and facilitate trade. The submission below highlights the nutrients which are affected, Appendix 1 details the systematic approach that was taken in the revision of the Codex Standard for FuFOI to convert kcal to kJ.

Appendix 2 summarises the NZFS preliminary view on the compositional requirements for infant and follow-on formula, and rationale for alternative proposals.

Composition – Infant formula

P1028 proposed approach	NZFS preliminary view
Macronutrients	
Energy • Minimum 2500 kJ/L • Maximum 2950 kJ/L	Support after correction of the conversion factor from kcal to kJ for the maximum to 2930 kJ/L. There are no public health and safety issues identified; however, there are minor inconsistencies with international regulation. The revised values are based on more recent scientific evidence that was used to inform the revision of Codex CXS 72-1981 whereby it was agreed to establish a range of 60 kcal to 70 kcal energy per 100 mL, the EFSA scientific assessment also came to this conclusion. In the 2016 FSANZ risk assessment the evidence was reviewed and it was confirmed that alignment with Codex CXS 72-1981 and the EU regulation was appropriate. The revised values align with Codex CXS 72-1981, but are slightly different to the draft Codex FuFOI standard or EU regulations which specify a range of 250 to 293 kJ per 100 mL when converting from kcal to kJ.
Calculation of energy density	NZFS considers the Code needs to be clarified as to whether unavailable carbohydrate must be taken into account in the calculation of energy. NZFS notes: • Standard 1.1.2-2(3) The definition of carbohydrate refers only to available carbohydrate: ***carbohydrate***, other than in the definition of ***beer*** (section 1.1.2—3), means *available carbohydrate or *available carbohydrate by difference. • S29—2(1)(a) provides that the energy contributions of fat, protein and carbohydrate components "only" are to be included in the calculation. • S29-2(1)(b) states that the "relevant" energy factors set out in S11—2 • Subsection S11—2(2) Calculation of average energy content lists the energy factors for general components for both carbohydrate excluding unavailable carbohydrate and including unavailable carbohydrate Although S11-2(2) has the energy factors for both unavailable carbohydrates it remains unclear as to whether the Code calculation for energy for infant formula products should include or exclude unavailable carbohydrate, as the definition of carbohydrate means *available carbohydrate.

Protein range (cow's and goat's milk) • Minimum 0.43 g/100 kJ • Maximum 0.7 g/100 kJ	Support after correction of the conversion factor from kcal to kJ for the maximum to 0.72 g/100 kJ. There are no public health and safety issues identified; however, there are minor inconsistencies with international regulation. Although this range aligns with Codex STAN 72-1981, it does not align with the conversion factors and rounding convention that was used from kcal to kJ for the draft Codex FuFOI requirements. NZFS currently requires an exemption to export products to markets overseas due to this error in rounding. The recently revised Chinese regulation has a protein range of 0.43-0.72 g/100 kJ. NZFS supports the maximum value of 0.72 g/100 kJ based on FSANZ's nutrition risk assessment and review of current research. We note that the EFSA review concluded that there 'is evidence of a physiological need for protein intakes at 3.0 g/100 kcal in infancy' but also acknowledged that 'there are no scientific data available which allow the establishment of precise cut-off values for the maximum protein content in infant formula'.
Protein minimum of 0.54 g/100 kJ in soy-based formula	Support the proposal to require a higher minimum protein level of 0.54g/100 kJ for infant formula based on isolated soy protein. This value is supported in the context of the establishing a single nitrogen conversion factor of 6.25.
Protein sources FSANZ proposes to prescribe the sources of protein and limit these to: cow, goat, soy protein isolate and protein hydrolysates of one or more proteins normally used in infant formula.	It is of significant concern to MPI (as a wider organisation which includes NZFS) that sheep's milk protein is not one of the prescribed sources of protein proposed for use in IFPs – and we respectfully ask that this is reconsidered within P1028. We note that the rationale provided to prescribe the sources of protein is to ensure the safety and suitability of new protein sources, particularly "emerging plant-based proteins". *Plant-based protein sources* NZFS supports pre-market assessment for new sources of plant-based protein to ensure that issues related to protein digestibility and bioavailability of micronutrients is assessed, in addition to potential issues of allergenicity. In addition, it would be beneficial to understand the requirements that would need to be fulfilled for a pre-market assessment for alternative sources of protein, as these would be used a substitute base ingredient to provide the protein and amino acids that are required by Standard 2.9.1 and the assessment may differ to the considerations of a pre-market assessment for an optional ingredient. *Milk-based protein sources* MPI strongly urges FSANZ to reconsider the need for pre-market assessment of other milk-based protein particularly the use of sheep's milk protein. Sheep's milk based infant formula is currently sold in New Zealand and recommended by Ministry of Health as one of three standard dairy based protein sources.

	The current requirements in Standard 2.9.1 do not prescribe the source of protein. Following approval of A1173 the protein requirements for follow-on formula refer to protein composition for 'milk-based formula'. NZFS does not consider that milk-based formula, that is not cow's or goat's milk, should necessarily require premarket assessment. It is our interpretation that milk-based sources of protein have not required this. We note that currently protein sources have not required specification as the amino acid profile is tightly regulated to ensure the nutritional suitability. In response to the 2021 CP2, NZFS raised this issue and there does not appear to be a response to our request for FSANZ to provide the scientific justification to prescribe protein source for animal-based milks, or to exclude sheep's milk as a permitted protein source. *New Zealand context* In New Zealand sheep's milk-based infant formula has been on the market for a number of years and is considered to have a history of safe use, which would preclude it from requiring a pre-market assessment as per specific policy principle (i) of the Ministerial Policy Guideline on the Regulation of Infant Formula (the Ministerial Policy Guideline). The New Zealand Ministry of Health recommend infants are fed a standard dairy based infant formula (made from cow's, goat's or sheep's milk protein) in their *Health Eating Guidelines for New Zealand Babies and Toddler (0-2 years old)*[2]. FSANZ should have regard to the New Zealand guidelines as per the Ministerial Policy Guideline specific policy principle b), which states that the regulation of infant formula products should not be inconsistent with national nutrition policies and guidelines of Australia and New Zealand. *Sheep milk composition* FAO have published a comparison of nutrient composition of various milk types including sheep, in comparison to human milk[3]. More recent reviews have also been published[4,5]. Similar to goat milk, sheep milk contains high amino acid sequence identities with counterpart cow's milk proteins and similar protein quality as assessed by protein digestible indispensable amino acid scores (DIAAS)[6]. *International Regulation* NZFS does not support the statement that this approach aligns with international regulation. We consider FSANZ has taken a very narrow view in considering alignment with international regulations.

[2] Ministry of Health. 2021. *Health Eating Guidelines for New Zealand Babies and Toddler (0-2 years old)*. Wellington: Ministry of Health.
[3] FAO.2013. Milk and dairy products in human nutrition (fao.org). Food and Agriculture Organization of the United Nations. Rome.
[4] Pietzrak-Fiecko R and Kamelska-Sadowska. 2020. *The comparison value of human milk with other mammals' milk*. *Nutrients 12*(5), 1404; https://doi.org/10.3390/nu12051404
[5] Roy D et al. 2020. *Composition, structure and digestive dynamics of milk from different species – a review*. Front. Nutr. https://doi.org/10.3389/fnut.2020.577759
[6] Dave LA et al 2020. *The role of holistic nutritional properties of diets in the assessment of food system and dietary sustainability.* Critical Reviews in Food Science and Nutrition. https://doi.org/10.1080/10408398.2021.2012753

	FSANZ's proposed approach does not align with Codex CXS 72-1981 or the draft Codex Standard for FuFOI. The respective Codex standards state: *3.1.1. Infant formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding. The nutritional safety and adequacy of infant formula shall be scientifically demonstrated to support growth and development of infants. All ingredients and food additives shall be gluten-free.* *3.1.1 Follow-up formula for older infants is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.* It is our interpretation that the safety and suitability of ingredients must be demonstrated in ingredients other than 'milk of cows or other animals' to be used in infant formula/follow-up formula. In addition, FSANZ's proposed approach does not align with overseas regulations which do not prescribe protein sources, (other than the EU regulation 2016/127). It also does not align with other markets, such as China (GB10765-2021) which has more recently revised its infant formula regulations (2021) and explicitly permits milk-based and soy-based formula only, and other plant proteins have yet to be approved. In China there are two standards which specify milk sources (raw milk and milk powder), currently sheep, goat and cow are permitted sources of milk. *Summary* To conclude, MPI requests sheep's milk protein is listed as a permitted source of protein in Standard 2.9.1 as sheep's milk: • has a history of safe use in infant formula products in New Zealand; • is recommended in New Zealand government healthy eating guidelines for babies and toddlers; • has a comparable protein and amino acid profile to cow and goats milk; and • is permitted for use in international and overseas regulations. A clear framework for what is required for pre-market assessment for alternative protein sources (milk-based and plant based) is critically important, particularly in the case that sheep's milk is not permitted as a protein source by FSANZ.
Nitrogen conversion factor of 6.25	Support a single nitrogen conversion factor of 6.25 for all protein sources. This approach aligns with the Codex CXS 72-1981, draft Codex Standard for FuFOI and EU 2016/127 regulation which utilise a consistent nitrogen conversion factor (6.25) and prescribe different minimum protein requirements to

	accommodate the differences the protein composition of soy-based formulas. It is a pragmatic approach given the limitations identified by FSANZ during the consultation process.
Protein Quality Managed through specifying minimum amino acid requirements with breast milk as the reference protein	NZFS supports this approach which is consistent with ensuring the suitability of product for infants and basing the protein quality on the amino acid composition of breast milk as the reference protein. This approach aligns with Codex CXS 72-1981, the draft Codex Standard for FuFOI and EU 2016/127. In 2018 a FAO Expert Working Group provided advice on the use of the DIAAS and PDCAAS methods for protein quality assessment for follow-up formula for young children to the Codex Committee on Nutrition and Foods for Special Dietary Uses. It was acknowledged that while they are ideal methods the evidence base relevant for human infants is incomplete, and the DIAAS methods was not currently suitable for regulatory purposes[7]. We note that the PDCAAS and DIAAS protein scoring systems both specify that the amino acid profile of breastmilk should be used as the reference protein for infants aged 0-6 months.
Carbohydrate • Minimum NS • Maximum NS	Support. Standard 2.9.1. does not currently specify prescribed amounts of carbohydrate as the limits are controlled by the regulation of energy, protein and fat content. This approach does not align with the Codex CXS 72-1981, draft Codex Standard FuFOI and EU 2016/127 which all specify minimum and maximum values for carbohydrate. However, we note there are no public health and safety issues identified with this approach as the amounts are controlled by the regulation of energy, protein and fat content.
Carbohydrate source	Partial support. NZFS support only specifying limits on sucrose and fructose. It is not deemed necessary to establish a list of permitted carbohydrates, but only include provisions where needed for public health and safety. Standard 2.9.1. does not currently specify provisions relating to the source of carbohydrates. Codex CXS 72-1981 and the draft Codex Standard for FuFOI provide guidance and some requirements for the source of carbohydrates that can be used. Namely that lactose and glucose polymers should be the preferred carbohydrate in product and to discourage the use of sucrose and fructose, unless needed. The draft Codex Standard for FuFOI states that if sucrose and or fructose are used the sum should not exceed 20% of available carbohydrates. Draft Codex Standard for FuFOI: *9) Lactose and glucose polymers should be the preferred carbohydrates in follow-up formula for older infants based on milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by*

[7] FAO. 2018. Protein quality assessment in follow-up formula for young children and ready to use therapeutic foods. Rome. 50 pp. Licence: CC BY-NC-SA 3.0 IGO. Accessed June 2022: https://www.fao.org/publications/card/en/c/CA2487EN/

	nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrates. FSANZ's proposed approach is to align with Codex CXS 72-1981 to adopt limits on sucrose and fructose. However, it is unclear how FSANZ proposes to refer to limits on sucrose and fructose as only the draft Codex Standard for FuFOI has limits specified. We would support consideration to specify when sucrose and fructose may be added to IFP, rather than an open statement as to these sources being permitted to be used 'when necessary'. This will provide the clarity required by industry and enforcement agencies and would align with the EU approach.
Fat • Minimum 1.05 g/100 kJ • Maximum 1.4 g/100 kJ	Support after correction of the conversion factor from kcal to kJ for the minimum of 1.1 g/100 kJ. There are no public health and safety issues identified; however, there are minor inconsistencies with international regulation.
Linoleic acid • Minimum 90 mg/100 kJ • GUL 330 mg/100 kJ	Support. FSANZ proposes to retain the current minimum requirement for linoleic acid and a GUL that aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. There are no public health and safety issues identified at the levels proposed and we acknowledge that retaining the current minimum requirement ensures the nutritional adequacy and safety within the Australian and New Zealand infant population. During the revision of the draft Codex Standard for FuFOI a GUL of 330 mg/100 kJ was agreed on the basis of a history of apparent safe use which we support.
α-Linolenic acid • Minimum 12 mg/100 kJ • Maximum NS	Support the minimum requirement and conclusion that no maximum or GUL is required if the ratio is specified. ALA is an essential fatty acid and is particularly important as a precursor to DHA, as such the requirements for LA, ALA, DHA and AA are interlinked. The use of a ratio negates the need to establish an additional maximum limit for ALA as it is limited by the upper bound of the ratio and maximum established for LA. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI.
LA:ALA ratio of • Minimum 5:1	Support retaining the current requirements for LA:ALA ratio.

• Maximum 15:1	There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. Note that this approach does not align with the EU 2016/127 regulation as a maximum ALA value was specified rather than a ratio and where DHA is required in all formula. The use of a ratio ensures an appropriate balance of LA and ALA and their long chain polyunsaturated fatty acid metabolites.
Myristic, Lauric and Erucic acid – retain current provisions	Support retaining the current requirements for lauric, myristic and erucic acid. There are no public health and safety issues identified and we do not see any issues with international regulations.
Docosahexaenoic acid (DHA) (voluntary) • Minimum NS • Maximum 7.2 mg/100 kJ	Partial support, we are still considering whether the addition of DHA should be mandatory or optional. NZFS would not support an approach where DHA is not a permitted optional ingredient. NZFS notes that the EU and China now require all infant formula products to contain DHA. In the EU this decision was based on the scientific opinion of EFSA who concluded that the decision was based on its structural role in the nervous tissue and retina, and its involvement in normal brain and visual development, and the need of the developing brain to accumulate large amounts of DHA in the first two years of life, and the consideration that the intake of pre-formed DHA generally results in an erythrocyte DHA status more closely resembling that of a breast-fed infant than is achieved with ALA alone. EFSA consider DHA to be conditionally essential for infants. The minimum level recommended by EFSA was based on the level considered adequate for the majority of infants (100 mg/day), whereas the upper bound level was based on the highest observed DHA concentration in human milk (around 1% total fatty acids). In the review of the Codex Standard for FuFOI the mandatory addition of DHA was discussed in detail. It was acknowledged that is considered conditionally essential for infants by some recognised authoritative scientific bodies and the justification provided in the EFSA opinion. It was agreed to retain an optional addition of DHA in the Codex review for multiple reasons: • Limited evidence of benefits beyond infancy on any functional outcomes (e.g. neurodevelopmental outcomes, or visual acuity); • It was considered important to consider the DHA content of other complementary foods in the diet and the regional variation in intakes; • The affordability of requiring this addition; and • It was not considered appropriate to require mandatory requirements for this age group prior to the Codex CXS 72-1981.

	The rationale which led to the draft Codex Standard for FuFOI to retain permissions for DHA as optional may not apply in the Australian and New Zealand context or for consideration of infant formula, as decisions took into account contribution from complementary foods and were not based solely on nutritive reasons. *Considerations to mandate optional ingredients* The Ministerial Policy Guideline requires that compositional requirements should only be mandated in regulation where there is sufficient evidence to demonstrate that they are safe and essential for normal growth and development of infants. In FSANZ's nutrition risk assessment, three nutritive substances which are currently optional ingredients are now proposed to be mandatory for infant formula. This approach is based on consideration of whether they are deemed essential by the NHMRC nutrient reference values work and/or through the mandatory requirement in Codex CXS 72-1981. There appears to be limited evidence of benefits beyond infancy on functional outcomes for these new mandatory requirements. NZFS notes that DHA is considered conditionally essential during early development by EFSA and the FAO due to their role in normal retinal and brain development; and that the NHMRC have not reviewed this since the NRVs were first published. *DHA and AA* NZFS notes the recent articles that state that DHA levels should not be higher than AA to adequately reflect the balance of fatty acids in human milk (Hopperton 2022[8], Koletzko 2020[9]). We question whether this concept should be expressed as requirement as is provided in CXS 72-1981 and the draft Codex Standard FuFOI, rather than a %FA. We support consistency between infant and follow-on formula products for this but we were unable to see a response to this suggestion within the SD2 regarding infant formula. We seek clarity on the expression of this requirement as a %FA. It is noted that the %FA is less than the GUL but this does not necessarily equate to ensuring that AA is at levels higher than DHA when they are both optional ingredients. It is also noted that FSANZ's preferred option for EPA is to require that it is not present at higher levels than DHA. As such it is unclear why AA is to be expressed as a %FA and not directly linked to DHA as occurs in the Codex standards and for which there is a precedent for EPA and DHA.

[8] Hopperton KE et al. 2022 *Docosahexaenoic acid and arachidonic acid levels are correlated in human milk: Implications for new European infant formula r egulations*. Lipids 57(3):197-202. doi: 10.1002/lipd.12338

[9] Koletzko B et al. 2020. *Should formula for infants provide arachidonic acid along with DHA? A position paper of the European Academy of Paediatrics a nd the Child Health Foundation*. Am. J Clin. Nutr. 2020, 111, 10–16.

Long Chain Polyunsaturated Fatty Acids (LC-PUFA) and their ratios	Support retaining the current provisions for LC-PUFA, EPA, AA and their ratios. Support FSANZ 2016 nutrition risk assessment that there are no public health and safety issues identified with this approach.
Trans fatty acid • Minimum NS • Maximum 4% total fatty acid	Support retaining the current provisions for trans fatty acids. There are no public health and safety issues identified. It is noted that the approach does not align with Codex CXS 72-1981 and the draft Codex Standard for FuFOI which specify a maximum of 3% of total fatty acids. Regulatory definitions of trans fatty acids and methods of analysis are not consistent around the world. The Food Standard Code definition of trans fatty acids exclude conjugated linoleic acid (CLA), which differs to the Codex definition. We support FSANZ's conclusion that a change to the definition of trans fatty acids is outside the scope of the proposal. Lowering the maximum to 3% without changing the definition would limit the amounts of milk fats that could be used in manufacture. In the Codex standards it is acknowledged that the maximum trans fatty acid limit is intended to allow for the use of milk fat in follow-up formula for older infant.
Phospholipids • Minimum NS • Maximum 2 g/L (72 mg/100 kJ)	Support that the total phospholipid level should be restricted with limit for phospholipids of 72 mg/100 kJ. Currently Standard 2.9.1 does not specify a maximum amount of phospholipids. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI if specified as mg/100 kJ. We seek clarification for the units to be specified (i.e. per litre or per 100 kJ) noting that almost all specifications are currently per 100 kJ (with the exception of energy and some fatty acids).
Micronutrients	
Vitamin A • Minimum 14 µg RE/100 kJ • Maximum 43 µg RE/100 kJ	Support retaining the current requirements for vitamin A composition. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI.
Vitamin B_6 • Minimum 8.5 µg/100 kJ • GUL 45 µg/100 kJ	Support the proposed minimum and guidance upper level.

	The conclusion of the FSANZ risk assessment was to establish a minimum requirement of 8.5 µg/100 kJ. This value meets the nutrient requirements of infants established by the NHMRC in the first year of life; and aligns with the requirements of Codex CXS 72-1981 which FSANZ concluded are unlikely to pose a risk to infant health. Codex CXS 72-1981 is based on the vitamin B_6 content of human milk, which is highly variable dependent on maternal intakes of vitamin B_6 (10-45 µg/100 kcal). It was also concluded that a pyridoxine intake of 50 µg/day by breastfed or 104 µg/day by formula-fed infants appeared to prevent biochemical indicators of reduced status, and that an intake of 160 µg/day may be needed to reduce biochemical indicators of marginal pyridoxine status for most infants aged four to six months. Using the assumption that 500 kcal per day of formula is required for young infants this equates to a minimum requirement of 32 µg/100 kcal. In the EU a much lower value of 4.8 µg/100 kJ has been set based on the EFSA NDA opinion. The EU minimum is based on nutrient requirements of infants aged 0-6 months (100 µg/day) and B_6 content of human milk in well-nourished but supplemented mothers (20 µg/100 kcal). Similar to the EFSA opinion, the NHMRC for Australia and New Zealand recommend an adequate intake of B_6 of 100 µg per day for infants up to 6 months old and 300 µg per day for older infants aged 6-12 months. However, we consider that it is appropriate for the minimum to also take into account that higher intakes of B_6 may be required in formula fed infants to prevent biochemical indicators of reduced status.
Vitamin B_{12} • Minimum 0.025 µg/100 kJ • GUL 0.36 µg/100 kJ	Support after correction of the conversion factor from kcal to kJ for the minimum to 0.02 µg/100 kJ. In the 2016 risk assessment, FSANZ concluded that alignment with Codex CXS 72-1981 was unlikely to pose a risk to infant health as it met the criteria that it: aligned with Standard 2.9.1, was comparable to breast milk and enabled nutrient requirements to be met. We support this conclusion but request that FSANZ review the conversion factors and rounding used to set the minimum based on the agreed minimum of 0.1 µg/100 kcal in Codex CXS 72-1981. Similar to the EFSA opinion, the NHMRC for Australia and New Zealand recommend an adequate intake of B_{12} of 0.4 µg per day for infants up to 6 months old and 0.5 µg per day for older infants aged 6-12 months. Based on this a minimum of 0.1 µg/100 kcal (0.02 µg/100 kJ) is required on the assumption that infants consume an average energy intake of 500 kcal per day. In the draft Codex Standard for FuFOI a minimum of 0.1 µg/100 kcal (0.02 µg/100 kJ) has been established.
Niacin • Minimum 70 µg /100 kJ • GUL 360 µg/100 kJ	Partial support. NZFS supports the GUL of 360 µg/100 kJ but is still considering the proposed minimum value. The Code currently requires a minimum of 130 µg niacin per 100 kJ in infant formula products. This value was based on the niacin (and tryptophan) composition of breastmilk. Reducing the minimum to 70 µg/100 kJ is a significant reduction. The rationale for this reduction is provided in FSANZ's 2016 nutrition risk assessment where alignment with Codex CXS 72-1981 was deemed unlikely to pose a

	risk to infant health. The assessment calculated that intakes of niacin from formula using the minimum of 70 µg/100 kJ would equate to 1.5 mg per day, which is below the NHMRC adequate intake value for this age group. Similar to the EFSA opinion, the NHMRC for Australia and New Zealand recommend an adequate intake of 2mg per day of preformed niacin for infants up to 6 months old. Based on this a minimum of 400 µg/100 kcal (100 µg/100 kJ) is required to meet the adequate intake for infants aged 0-6 months, on the assumption that infants consume an average energy intake of 500 kcal per day. FSANZ did not consider the minimum of 70 µg /100 kJ to pose a risk to health due to a lack of evidence of risk. Considering the substantial reduction in the minimum composition and that it does not result in infants meeting the adequate intake for niacin, we would encourage FSANZ to reconsider this issue. A minimum value of 100 µg/100 kJ would enable infants to meet the adequate intake level established by the NHMRC.
Riboflavin • Minimum 14.3 µg/100 kJ • GUL 119 µg/100 kJ	Support. The proposed values align with the minimum specified in the EU 2016/127; and the GUL specified in the Codex CXS 72-1981. The minimum recommended by the EFSA NDA is based on the adequate intakes level of 300 µg/day for infants up to 6 months. Based on this a minimum of 60 µg/100 kcal (14.3 µg/100 kJ) is required to meet the adequate intake for infants aged 0-6 months, on the assumption that infants consume an average energy intake of 500 kcal per day. The average content of riboflavin in human milk is around 54-92 µg/100 kcal. The NHMRC have also set an adequate intake of 300 µg/day for infants up to 6 months. Codex CXS 72-1981 has a slightly higher minimum requirement which is based on an adequate intake of 300-400 µg/day for infants, and that typically human milk contains between 60 to 90 µg/100 kcal. The GUL set in Codex CXS 72-1981 was established based on history of apparently safe use. The current minimum in Standard 2.9.1 is 14 µg/100 kJ. Alignment with the EU 2016/127 provides equivalent riboflavin as human milk and provides infants with their adequate intake of riboflavin; and the GUL set by Codex is based on a history of apparently safe use.
Vitamin C • Minimum 1.7 mg/100 kJ • GUL 17 mg/100 kJ	Support. There are no public health and safety issues identified; and the approach can accommodate formula manufactured to the requirements in Codex CXS 72-1981 and the draft Codex Standard for FuFOI (minimum 2.4 mg/100 kJ). FSANZ proposes to retain the current minimum in Standard 2.9.1 and align the maximum with the Codex CXS 72-1981 GUL of 17 g/100kJ. A footnote for the GUL has been included in the Codex Standard which states 'This GUL has been set to account for possible high losses over shelf-life in liquid products; for powdered products lower upper levels should be aimed for.' This was reviewed at Codex recently for the draft FuFOI standard where the GUL and

	accompanying footnote were supported to take into account the significant losses in vitamin C that can occur during the shelf life of the product. We would support a similar footnote in the Code in relation to the GUL for vitamin C.
Vitamin D • Minimum 0.25 µg/100 kJ • Maximum 0.63 µg/100 kJ	Support, after correction of the conversion factor from kcal to kJ for the minimum to 0.24 µg/100 kJ. FSANZ preferred option to retain the current prescription for vitamin D of 0.25 - 0.63 µg/100 kJ. This value was considered the most appropriate range for the Australian and New Zealand population and is aligned with the minimum value in the Codex CXS 72-1981 and the draft Codex Standard for FuFOI (after correction for conversion factors). A higher minimum and maximum level was established in the EU based on their difference in vitamin D requirements for this age group, a consequence of limited exposure to sunlight. The draft Codex Standard for FuFOI has a wide range in vitamin D requirements to accommodate the variation in regional exposure to sunlight and consequential differences in requirements.
Vitamin E • Minimum 0.12 mg/100 kJ • GUL 1.2 mg/100 kJ	Partial support. NZFS supports the GUL but is still considering the proposed minimum value. The proposed minimum and GUL align with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. The minimum recommended by the EFSA NDA is based on the adequate intakes level of 3 mg α-tocopherol/day for infants up to 6 months. Based on this a minimum of 0.6 mg α-tocopherol /100 kcal (0.14 mg/100 kJ) is required to meet the adequate intake for infants aged 0-6 months, on the assumption that infants consume an average energy intake of 500 kcal per day. The NHMRC have set an adequate intake of 4 mg α-tocopherol/day for infants up to 6 months. Consumption of formula at the proposed minimum would provide an infant with 2.6 mg α-tocopherol/day. FSANZ acknowledged in 2016 that infants would not achieve the AI set by the NHMRC or EFSA but did not consider this to pose a risk to infant health as there is no evidence of adverse effect. We would encourage FSANZ to reconsider this issue as the approach does not meet the criteria set by FSANZ to provide the adequate intake to infants aged 0-6 months. NZFS could support alignment with the EU minimum of 0.14 mg/100 kJ as this would provide a greater contribution of vitamin E to meet infants requirements. In the review of the Codex Standard for FuFOI it was not considered scientifically justified for follow-up formula to have different compositional requirements to infant formula for vitamin E.
Vitamin K • Minimum 0.24 µg/100 kJ • GUL 6.5 µg/100 kJ	Support, after correction of the conversion factor from kcal to kJ for the GUL to 6 µg/100 kJ. FSANZ proposes to retain the vitamin K GUL of 6.5 µg/100 kJ and adopt the EU 2016/127 minimum for vitamin K. The proposed value enables the NHMRC adequate intake level for vitamin K to be met. There are no public health

	and safety issues identified; and the approach can accommodate formulations made to the requirements specified in Codex CXS 72-1981 and the draft Codex Standard for FuFOI. The current minimum in Standard 2.9.1 is 1 µg/100 kJ and this aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. In the review of the Codex FuFOI standard it was also concluded that lowering the minimum value to 0.24 µg/100 kJ would still enable infant to meet the WHO/FAO requirements assuming average intake of 500 kcal of formula, but a decision was made to align with Codex CXS 72-1981 as there was no scientific rationale to deviate. The GUL in the draft Codex FuFOI has been converted from 27 µg/100/kcal to 6 µg/100 kJ.
Phosphorous • Minimum 6 mg /100 kJ • GUL 24 mg /100 kJ	Support. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI.
Calcium • Minimum 12 mg /100 kJ • GUL 35 mg /100 kJ	Support. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981.
Magnesium • Minimum 1.2 mg /100 kJ • GUL 3.6 mg /100 kJ	Support. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI.
Iron • Minimum 0.2 mg /100 kJ • Maximum 0.5 mg /100 kJ	Partial support. NZFS supports the maximum after correction of conversion factor from kcal to kJ to 0.48 mg/100 kJ; but does not support the proposed minimum value. FSANZ proposes to retain the Standard 2.9.1 range of 0.2 - 0.5 mg/100 kJ. This range does not align with Codex CXS 72-1981 or EU 2016/127. NZFS reiterates our previous position, that a lower minimum requirement is suitable for infants in the first year of life. We seek clarification as to how the minimum value of 0.14 mg /100 kJ established by the EU as suitable for product for use for the whole first year of life would likely pose a risk to infant health. FSANZ has proposed a minimum composition of 0.2 mg/100 kJ for iron in cows' milk-based formula – this is far higher than that of Codex and the EU. The rationale provided is that infant formula products must be suitable for both infants aged 0-6 and 6-12 months. As iron requirements are higher at 6 months of age this approach to setting compositional requirements for older infants would lead to a divergence of approaches between FSANZ and other

	regulations globally which prioritise the requirements of younger infants in establishing compositional requirements for infant formula. FSANZ's preferred minimum of 0.2 mg/100 kJ is also higher than the minimum of 0.14 mg/100 kJ specified in EU 2016/127 for formula that is intended to be used from the first months of infancy and the whole first year of life. The EFSA assessment assumed that 75% of iron requirements should be met by complementary foods, whereas FSANZ have assumed that 50% of iron requirements should be met by complementary foods. The nutrition risk assessment then draws a conclusion that this poses a risk to infant health but it is unclear why FSANZ has determined that 50% of iron requirements should be provided by complementary foods. Support an approach to establish a minimum iron content for infant formula products that are to be used from birth for the first year of life. The New Zealand Healthy Eating Guidelines for babies and toddlers state that a commercial infant formula is the only suitable alternative to breast milk in the first year of life. We note the Ministerial Policy Guideline focuses on the composition for infants up to six months of age and request FSANZ reconsiders the minimum requirements based on the differences with international standards and the amount of iron that should be provided by complementary foods in this age group.
Folic acid • Minimum 2.5 µg/100 kJ • GUL 12 µg/100 kJ	Support, after correction of the conversion factor from kcal to kJ for the minimum to 2.4 µg/100 kJ. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. The current Standard 2.9.1 minimum value is 2 µg /100 kJ folate. Elevating the minimum requirement to 2.5 µg folic acid/100 kJ was calculated by FSANZ to meet the NHMRC adequate intake level for folate for infants.
Sodium • Minimum 5 mg/100 kJ • Maximum 14 mg/100 kJ	Support, after correction of the conversion factor from kcal to kJ for the minimum to 4.8 mg/100 kJ. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. In the EU a minimum sodium content of 6 mg/100 kJ was established, it does not seem appropriate to increase the minimum content of sodium for infant formula products when no public health and safety issues or other reasons identified to justify doing so.
Chloride • Minimum 12 mg/100 kJ • Maximum 38 mg/100 kJ	Support. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI.

Potassium • Minimum 14 mg /100 kJ • Maximum 43 mg /100 kJ	Support. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI.
Pantothenic acid • Minimum 96 µg /100 kJ • GUL 478 µg/100 kJ	Support. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. The current requirements in Standard 2.9.1 are a minimum of 70 and GUL of 360 µg/100 kJ and permitted range in the EU 2016/127 is 100 to 480 µg/100 kJ. We note that the difference in values between the EU and Codex CXS 72-1981 and the Codex draft standard for FuFOI is the same when considered on a µg/100 kcal basis.
Manganese • Minimum 0.25 µg /100 kJ • GUL 24 µg /100 kJ	Support, after correction of the conversion factor from kcal to kJ for the minimum to 0.24 µg/100 kJ. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. We note that there is no difference in values between P1028, EU 2016/127 and the draft Codex Standard for FuFOI when considered on a per 100 kcal basis.
Zinc • Minimum 0.12 mg /100 kJ • GUL 0.36 mg/100 kJ	Support. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. NZFS supports FSANZ's 2016 Nutrition Assessment with regard to the suitability of the Codex CXS 72-1981 zinc GUL. It was concluded that it may potentially exceed the UL, however there is no evidence of a risk to infant health from such intakes. This issue was considered at length in the review of the draft Codex FuFOI standard. A decision to set a GUL of 0.36 mg/100 kJ was determined after consideration that this level has a demonstrate history of safe use in infants. The Codex working group acknowledged that although intakes could lead to exceeding the tolerable upper level established by some recognised authoritative scientific bodies that any risk associated with this was deemed negligible. Furthermore, the Committee had previously noted the uncertainty of the UL for zinc for this age group (CX/NFSDU 13/35/4). It was also noted that if the GUL was to be lowered, this would result in a narrow range for formulation which industry have acknowledged would be technologically difficult to accommodate (CX/NFSDU 16/38/6).

	It is also noted that a GUL of 0.36 mg/100 kJ may be better to accommodate the higher levels of zinc in soy-based formulas.
Thiamin • Minimum 10 µg /100 kJ • GUL 72 µg /100 kJ	Support. FSANZ proposed retaining the minimum in Standard 2.9.1 (10 µg/100 kJ) and adopting the GUL used in the Codex CXS 72-1981. There are no public health and safety issues identified; and the approach can accommodate formula that has been manufactured in accordance with Codex CXS 72-1981 and the draft Codex Standard for FuFOI.
Biotin • Minimum 0.24 µg /100 kJ • GUL 2.4µg /100 kJ	Support. There are no public health and safety issues identified; and the approach can accommodate formula that has been manufactured in accordance with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. FSANZ has concluded that this range aligns closely with concentrations in human milk.
Copper • Minimum 8.5 µg /100 kJ • GUL 29 µg /100 kJ	Support. There are no public health and safety issues identified; and the approach aligns with Codex CXS 72-1981 and the Codex draft standard for FuFOI. The NHMRC and EFSA have established different levels that are deemed to be adequate intakes for infants aged 0-6 months. The 2016 nutrition risk assessment calculated that formula containing a minimum of 8.5 µg/100 kJ can provide infants with copper intakes of 465 µg/day (when taking into account the copper from potable tap water). An intake of 465 µg/day meets both the NHMRC (0.2 mg/day) and EFSA (0.3 mg/day) adequate intake level of copper for infants aged 0-6 months.
Iodine • Minimum 2.5 µg /100 kJ • GUL 14 µg /100 kJ	Support, after correction of the conversion factor from kcal to kJ for the minimum to 2.4 µg/100 kJ. There are no public health and safety issues identified with the proposed minimum and GUL; and the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. A balance of meeting iodine requirements and providing a wide enough range to ensure technological feasibility is important. The current permitted range in Standard 2.9.1 is 1.2 – 10 µg/100 kJ and the permitted range in the EU 2016/127 is 3.6 – 6.9 µg/100 kJ. NZFS is supportive of elevating the current minimum level to that specified by Codex (2.4 µg /100 kJ) to ensure that infant formula provides a significant contribution to iodine requirements and iodine status. Ideally iodine requirements would be met through consumption of average quantities of infant formula. However, NZFS notes that

	iodine requirements for infants in Australia and New Zealand are higher than those established in other countries and based on average concentration in human milk. The iodine content of human milk varies markedly according to maternal intakes and as such the WHO /UNICEF/ICCIDD do not recommend basing dietary requirements for iodine on human milk concentrations but on achieving iodine balance. This approach was also taken in the derivation of European dietary intake reference values for iodine, in which EFSA calculated that approximately 70 µg per day were adequate for the majority of infants to achieve a urinary iodine concentration of at least 100 µg/L The NHMRC have recommended an adequate intake level of 90 µg iodine/day for infants up to 6 months based on the average concentration in human milk. Formula based on the proposed minimum iodine concentration would provide younger infants with 55 µg/day, and formula based on the EU minimum would provide 70 µg iodine/day. It is also important to note that FSANZ have reviewed a series of studies which have demonstrated that formula fed infants in Australia and New Zealand receive adequate intakes of iodine when biochemical measures of iodine status are considered.
Selenium • Minimum 0.48 µg /100 kJ • GUL 2.2 µg /100 kJ	Support. There are no public health and safety issues identified; and the approach aligns with the draft Codex Standard for FuFOI which is based on more recent evidence of increased requirements for selenium.
Equivalents, conversion factors and units of expression	
Vitamin A	
To express vitamin A requirements as µg RE/100 kJ	Support (status quo), noting this aligns with Codex CXS 72-1981.
To exclude β-carotene from the vitamin A calculation	Support excluding β-carotene from the vitamin A calculation in light of uncertainty around its bioavailability from infant formula.
To retain the permission for β-carotene as a permitted form of vitamin A in section S29–7.	NZFS seeks clarification on the need to retain permission for β-carotene as a permitted form of vitamin A when it is excluded from the vitamin A calculation, and therefore does not contribute to a product's vitamin A content. We note FSANZ's view to retain the permission based on history of use and lack of safety concern. It is also a permitted form in Codex CXS 72-1981, while not to be included in the calculation.

	It is unclear what justification there is to add β-carotene as a provitamin A form. Removing this permission would have no impact on any naturally occurring β-carotene.
Folic acid	
To express folic acid/folate as µg folic acid/100 kJ (status quo).	Support (status quo).
Conversion factors – for naturally occurring folate to be excluded from the permitted range.	Support proposed change, noting the approach aligns with Codex CXS 72-1981 and the draft Codex Standard for FuFOI. Also, naturally occurring folate present in ingredients in infant formula is low or below the level of detection.
Equivalents - folic acid	Support (status quo)
Vitamin E	
To express as α-TE/100 kJ (rather than mg/100kJ).	Support proposed change to express as α-TE/100 kJ.
Conversion factors – not specified	Support (status quo)
Equivalents – dl-α-tocopherol, d-α-tocopherol concentrate, tocopherols concentrate mixed, d-α-tocopheryl acetate, dl-α-tocopheryl acetate, d-α-tocopheryl acid succinate, dl-α-tocopheryl succinate	Support (status quo)
Niacin equivalents	
To express as µg/100 kJ	Support (status quo)
Conversion factors – add niacin and any niacin provided from the conversion	Support (status quo)

of the amino acid tryptophan, using the conversion factor 1:60.	
Equivalents – niacinamide	Support (status quo)
Fatty acids (LA, ALA, DHA)	
To express as mg/100 kJ (rather than current % total fatty acids)	Support. As identified in response to DHA, we would support that arachidonic acid must be at levels higher than DHA when DHA is added to infant formula products.
Ratios	
To remove the prescribed Zn : Cu ratio of 15:1 (maximum)	Support – no public health and safety risks identified, and approach aligns with Codex CXS 72-1981 and EU 2016/127.
To retain the current LA : ALA ratio of: • 5:1 (minimum) • 15:1 (maximum)	Support – see earlier comments.
To revise the Ca : P ratio to: • 1:1 (minimum) • 2:1 (maximum)	Support – the revised ratio aligns with Codex CXS 72-1981.
To retain the current vitamin E : fatty acids ratio of: • 0.5mg : 1g (minimum) • Not specified (maximum)	Support – status quo and aligns with Codex CXS 72-1981.
To retain EPA minimum as not specified and maximum ≤ DHA	Support – status quo and aligns with Codex CXS 72-1981.

Other nutritive substances	
Choline	
To list choline as a mandatory substance	Support the proposed change to require choline as a mandatory substance, as required in Codex CXS 72-1981.
To retain current minimum of 1.7 mg/100 kJ	Support – no public health and safety risks identified, and aligns with Codex CXS 72-1981.
To adopt a GUL of 12 mg/100 kJ	Support, based on FSANZ's nutrition assessment that concluded mandatory inclusion of choline in the range in Codex is unlikely to pose a risk to infant health. Also support use of a GUL due to the absence of an UL and to maintain consistency between the Code and Codex CXS 72-1981.
To extend the permitted forms to include: • Choline • Choline citrate • Choline hydrogen tartrate As well as current permissions for: • Choline chloride • Choline bitartrate	Support additional permitted forms as listed in Codex GL 10-1979.
L-carnitine	
To list L-carnitine as a mandatory substance	Support the proposed change to require L-carnitine as a mandatory substance, as required in Codex CXS 72-1981.
To revise the minimum to 0.3 mg/100 kJ	Support, noting this minimum aligns with Codex CXS 72-1981 and EU 2016/127.

To specify a GUL of 0.8 mg/100 kJ	Support, noting this level reflects the current maximum in Standard 2.9.1 but is proposed to be expressed as a GUL to account for the natural variability of L-carnitine content in different milks. We note Codex CXS 72-1981 does not specify a maximum.
To extend the permitted forms to include: • L-carnitine hydrochloride • L-carnitine tartrate As well as the current permission for L-carnitine.	Support additional permitted forms as listed in Codex GL 10-1979, and based on safety conclusions of Codex CXS 72-1981 and Application A1102 (L-carnitine in Food).
Inositol	
To list inositol as a mandatory substance	Support the proposed change to require inositol as a mandatory substance, as required in Codex CXS 72-1981.
To retain current minimum of 1 mg/100 kJ (when used as an optional substance)	Support, noting this minimum aligns with Codex CXS 72-1981.
To specify a GUL of 9.5 mg/100 kJ	Support, noting this level reflects the current maximum in Standard 2.9.1 but is proposed to be expressed as a GUL to be consistent with Codex CXS 72-1981.
To list the permitted form of inositol as myo-inositol	Support, noting this change aligns with Codex CXS 72-1981.
Nucleotides	
To retain the current permissions for nucleotides as optional substances	Support (status quo).
To remove the current minimums for all nucleotides	Support – as aligns with approach in EU, USA and Canadian regulations. Codex approach it for levels to be determined by national authorities.

To retain current maximums for nucleotides	NZFS requests that FSANZ reconsiders two aspects relating to maximums for individual nucleotides: • We note the maximum for adenosine-5′-monophosphate (AMP) is 0.38 mg/100 kJ in the Code and 0.36 mg/100 kJ in the EU 2016/127 regulation. As FSANZ's approach for nucleotide maximum levels is to align with EU regulations, we ask FSANZ considers whether the AMP maximum should be lowered to 0.36 mg/100kJ. • We note the request by some industry submitters to increase the maximum for guanosine-5′-monophosphate (GMP) from 0.12 to 0.4 mg/100 kJ to reflect the levels of GMP naturally present in goats' milk-based formula, which may exceed the proposed maximum. The CFS response was: "FSANZ will not be increasing the maximum for GMP, as the current maximum aligns with the EU 2016/127 maximum". While the intent is to limit levels of nucleotides, we consider these levels should recognise the inherent levels in base ingredients. Provided there are no public health and safety issues, we request FSANZ reconsiders this issue beyond simply looking to align with EU regulations and the regulatory options that may be available to achieve this outcome.
To amend 2.9.1—8(b) to state: Infant formula product must not contain more than 3.8 mg/100 kJ free nucleotide-5'-monophosphates	Support
Other	
To remove current GULs for **chromium and molybdenum** in general infant formula products.	Support – this proposed change will provide regulatory clarity, as these substances are not specified as optional substances in 2.9.1 but GULs are listed in Schedule 29.
To retain current permission for **taurine** as an optional substance with a minimum of 0.8 mg/100 kJ and maximum 3 mg/100 kJ.	We will consider our view when this issue is fully assessed in the 2nd CFS, noting that FSANZ has to date not provided an assessment on taurine and is seeking further information from stakeholders. We note that Codex CXS 72-1981 lists taurine as an optional substance with no minimum and a maximum of 3 mg/100 kJ.
To retain the current permissions for **lutein** as an optional substance with a	We will consider our view when this issue is fully assessed in the 2nd CFS, noting that FSANZ has to date not provided an assessment on lutein and is seeking further information from stakeholders.

minimum of 1.5 µg/100 kJ and maximum of 5 µg/100 kJ.	We note that there are currently no specific permissions for lutein in Codex or EU regulations, though Codex does have a general provision for other ingredients to be added to provide substances ordinarily found in human milk.
To retain the current permissions for **2'-FL alone or in combination with LNnT**	Support, noting this permission was recently approved under A1155 and other applications. We note the evidence for a beneficial role of 2'-FL in the normal growth and development of infants will be reassessed in a review to be completed by FSANZ by March 2026.
To set a compositional limit for **fluoride** of 24 µg/100 kJ when prepared ready for consumption and to remove the labelling statements relating to dental fluorosis in paragraph 2.9.1—23(1)(b).	NZFS supports the approach to set a compositional limit for fluoride in infant formula products and to remove the existing labelling statements in 2.9.1—23(1)(b). We note the intent of this provision is to manage the potential risk of dental fluorosis and that there is no permission to add fluoride to infant formula products. FSANZ has proposed a compositional limit for fluoride of 24 µg/100 kJ when prepared ready for consumption. While consistent with Codex CXS 72-1981 and supported by FSANZ's safety assessment, NZFS does not believe this compositional limit is enforceable. Manufacturers will not be able to ensure that this compositional limit is not exceeded when a caregiver prepares their product at home, given the variability in fluoride levels in water across different areas of New Zealand and Australia. And similarly, enforcement agencies could not enforce a breach of this compositional limit as the fluoride content will be a combination of the fluoride content of product as sold (related to the manufacturer) and the water used to prepare the product (related to local water quality requirements). Our preference is that the compositional limit relates to the fluoride content of the product prior to reconstitution for powdered and concentrated infant formula products, and per 100 mL as sold for ready-to-drink formula. This approach is enforceable and is currently used to activate the existing labelling statements for dental fluorosis, noting that 2.9.1—23 (2) states: *(2) This subsection applies to an infant formula product that contains:* *(a) for a powdered or concentrated infant formula product—more than 17 µg of fluoride/100 kJ prior to reconstitution; or* *(b) for a ready-to-drink formula—more than 0.15 mg of fluoride/100 mL.* We are confident that FSANZ's safety assessment to date can be used – but applied differently to determine a safe compositional limit for fluoride for the various formats of infant formula products (i.e. powdered, concentrate, ready-to-drink) as sold.

Composition – Follow-on formula, where there is a deviation to the Infant Formula standard

NZFS supports the approach taken by FSANZ that follow-on formula should only deviate from infant formula where there is substantiated science to support the differences in needs between the age groups, and that both products should be regulated within Standard 2.9.1.

P1028 proposed approach	NZFS preliminary view
Macronutrients	
Protein range (cow's and goat's milk) • Minimum 0.44 g/100 kJ • Maximum 0.7 g/100 kJ	Do not support, seek clarification. The current minimum protein for follow-on formula in Standard 2.9.1 is 0.38 g/100 kJ. This was approved by FSANZ in 2019 under A1173. In the EU 2016/127 separate minimum protein composition has been established for infant formula (044 g/100kJ) and follow-up formula (0.38 g/100 kJ). Codex CXS 72-1981 specifies a minimum of 0.45 g/100 kJ for infant formula products, whereas the draft Codex Standard for FuFOI prescribes a minimum of 0.43 g/100 kJ and a lower value of between 0.38 and 0.43 g/100 kJ for formula based on non-hydrolysed milk protein when evaluated for safety by a competent national or regional authority. FSANZ has recently conducted a safety and suitability assessment of lower protein formula and we would be surprised if this was revoked without scientific justification. NZFS seeks clarification regarding the minimum protein value as to whether the proposal is to retain the recently revised minimum (0.38 g/100kJ) or align with the permitted range for infant formula (0.43g/100 kJ). The SD2 nutrition composition document refers to the decision in the 2021 CP2 regarding protein composition of follow-on formula, however follow-up formula was out of scope in that consultation paper. As such it is unclear what rationale has been used to amend the recently revised protein minimum as there is no documentation from FSANZ. Support the prescribed maximum after correction of the conversion factor from kcal to kJ to 0.72 g/100 kJ. There are no public health and safety issues identified as there is no physiological need for protein from follow-on formula in excess of 0.72 g/100 kJ. This approach aligns with Codex CXS 72-1981, the draft Codex Standard for FuFOI, and EU 2016/127
Protein range (soy) • Minimum 0.54 g/100 kJ	Support.

• Maximum 0.7 g/100 kJ	There are no public health and safety issues identified; This approach aligns with Codex CXS 72-1981, the draft Codex Standard for FuFOI, and EU 2016/127. The current minimum protein for follow-on formula for all non-milk-based formula in Standard 2.9.1 is 0.45 g/100 kJ. FSANZ proposes to increase the minimum protein value to 0.54 g/100 kJ which is the same minimum protein proposed for soy-based infant formula in P1028. This approach aligns with the conclusion of A1173, for which it was concluded that there was insufficient evidence to apply a reduced protein minimum for soy-based formula.
Micronutrients	
Calcium • Minimum 12 mg/100 kJ • GUL 43 mg/100 kJ (note, infant formula GUL of 35 mg/100 kJ)	Support. There are no public health and safety issues identified. This approach aligns with the draft Codex Standard for FuFOI where a higher GUL was established to reflect the increase in calcium requirements for this age group, reduced intakes of formula, and that calcium intakes are often limited in the diets of this age group.
Other nutritive substances	
Choline	
To retain permission for choline as an optional substance	Support – status quo
To remove minimum and state as not specified	Support – to align with draft Codex Standard for FuFOI.
To increase maximum to 12 mg/100 kJ and express as a GUL	Support
Myo-inositol	
To retain permission for myo-inositol as an optional substance	Support – status quo and aligns with draft Codex Standard for FuFOI.
To remove minimum and state as not specified	Support – aligns with draft Codex Standard for FUFOI.

To retain maximum of 9.5 mg/100 kJ but express as a GUL	Support expression as a guidance upper limit, after correction of the conversion factor from kcal to kJ.
L-carnitine	
To retain permission for L-carnitine as an optional substance	Support
To increase minimum to 0.3 mg/100 kJ	Support – to align with proposed mandatory minimum in infant formula. Noting no minimum level is specified in the draft Codex standard for FuFOI with national authorities to determine.
To remove the current maximum and state not specified	Support – to align with draft Codex standard for FuFOI and EU 2016/127.
Nucleotides	
To retain the current permissions for nucleotides as optional permissions	Note that FSANZ has proposed the same approach for nucleotides for follow-on formula as for infant formula. Please refer to our comments in the infant formula section.
To remove the current minimums for all nucleotides	
To retain current maximums for nucleotides	
Other	
To retain current permission for **taurine** as an optional substance with a minimum of 0.8 mg/100 kJ and maximum 3 mg/100 kJ.	Note that FSANZ has proposed the same approach for lutein in follow-on formula as for infant formula. Please refer to our comments in the infant formula section.
To retain the current permission for **lutein** with a range of 1.5 – 5 µg/100 kJ	Note that FSANZ has proposed the same approach for lutein in follow-on formula as for infant formula. Please refer to our comments in the infant formula section.
To retain the current permissions for **2'-FL alone or in combination with LNnT**	Support, noting this permission was recently approved under A1155 and other applications.

	We note the evidence for a beneficial role of 2'-FL in the normal growth and development of infants will be reassessed in a review to be completed by FSANZ by March 2026.
To set a compositional limit for **fluoride** of 24 µg/100 kJ when prepared ready for consumption and to remove the labelling statements relating to dental fluorosis in paragraph 2.9.1—23(1)(b).	Note that FSANZ has proposed the same approach for fluoride in follow-on formula as for infant formula. Please refer to our comments in the infant formula section.

Composition – Infant formula products

P1028 proposed approach	**NZFS preliminary view**
Permitted forms	
Pantothenic acid – to permit additional forms, namely: D-panthenol, calcium D-pantothenate, sodium D-pantothenate.	Support. Also support that DL-panthenol should not be permitted for reasons outlined in CFS.
Vitamin D – to retain permissions for vitamin D_2 and vitamin D_3.	Support, based on the FSANZ risk assessment findings that both forms are equally effective at raising 25OHD concentration and the conclusions of the Codex draft standard for FuFOI work.
Niacin - to retain permission for niacinamide (nicotinamide) and to not permit nicotinic acid.	Support for both, including not to permit nicotinic acid based on FSANZ's conclusion that use of this form may pose a risk to infant health.
Copper - to permit cupric carbonate as an additional permitted form of copper.	Support
Magnesium – to permit additional forms, namely: magnesium hydroxide carbonate, magnesium hydroxide and magnesium salts of citric acid.	Support
Potassium – to permit potassium L-lactate as an additional permitted form of potassium.	Support

Zinc – to permit additional forms, namely: zinc lactate and zinc citrate (zinc citrate dehydrate or zinc citrate trihydrate).	Support
Iron – to permit additional forms, namely: ferric citrate, ferrous bisglycinate and ferrous sulphate.	Support
Choline – to permit additional forms, namely: choline, choline citrate and choline hydrogen tartrate.	Support
L-carnitine – to permit additional forms, L-carnitine hydrochloride and L-carnitine tartrate.	Support
Inositol – to refer to inositol as myo-inositol.	Support
Vitamin and mineral supplementation	
To remove the guideline on advice regarding additional vitamin and mineral supplementation in S29—10(2) of the Code.	Support removal of guideline advice. There has been little uptake by industry to provide this advice on label, there appears insufficient evidence of a problem to consider mandating the statement, and mandating such a statement would be inconsistent with international requirements. Also, this advice is communicated generally by the respective New Zealand and Australian infant feeding guidelines.
Measuring scoop	
To not standardise the scoop size or dilution ratio, and instead maintain existing requirement that a package of infant formula product in a powdered form must contain a scoop to enable the use of the infant formula product in accordance with the directions contained in the label on the package.	Support approach to not standardise the scoop size or dilution ratio. We agree that a standardised ratio is not common practice internationally, that bulk density and energy density between products differs, and that it would be costly to implement. We also note the additional risk management strategies in place to minimise the risk of over or under dilution of IFP during preparation, including that powdered IFP must contain a scoop in pack with a label statement that only the enclosed scoop should be used, the weight of the scoop must be declared on label, and the proportion of powder or concentrate required must be declared on label.

Modified formulas	
To regulate low lactose/lactose free and partially hydrolysed protein formulas as IFPs – and to require these formulas to meet the essential composition prescribed for infant formula products.	See our general comments on the modified IFP category under the 'Regulatory Framework' section. We will reserve our view on the composition of modified IFPs until the regulatory framework is agreed. However, if low lactose/lactose free and partially hydrolysed formulas are to be regulated within the overarching IFP category then it would appear appropriate that they must meet the essential composition prescribed for IFPs.

5. LABELLING FOR PROVISION OF INFORMATION

Labelling of ingredients

P1028 proposed approach	NZFS preliminary view
To continue to apply the generic labelling requirements for the statement of ingredients to infant formula products.	Support that generic labelling requirements for the statement of ingredients should continue to apply for infant formula products, as per Standard 1.2.4. NZFS agrees that further standardising the statement of ingredients (e.g. format, location, grouping of nutrients by type) would potentially be a barrier to trade due to loss of flexibility in labelling and not being aligned with international requirements.
To permit the optional grouping of added vitamins and minerals under the subheadings 'vitamins' and 'minerals', and within these groups the vitamins and minerals need not be listed in descending order of ingoing weight.	Support this new optional grouping of added vitamins and minerals in the statement of ingredients, and that the vitamins and minerals within these groups do not need to be listed in descending order of ingoing weight. This approach aligns with both Codex CXS 72-1981 and the draft Codex standard for FuFOI, may aid in consumer understanding of the statement of ingredients, and simplifies the ingredient list if a vitamin or mineral is added for both a food additive and nutritive substance function.
To continue to apply existing generic allergen declaration requirements to infant formula products.	Support the continued application of existing generic allergen labelling requirements (as per Standard 1.2.3) to infant formula products. We note that allergen labelling was extensively reviewed under P1044 (applicable to most foods including infant formula products), with gazettal of changes to the Code in 2021.
To continue to apply existing labelling requirements for GM foods to infant formula products.	Support the continued application of existing generic labelling requirements for GM foods (as per Standard 1.5.2—4) to infant formula products. This approach aligns with both Codex CXS 72-1981 and the draft Codex Standard for FuFOI, which apply the general Codex CXS 1-1985 requirements.

Declaration of nutrition information

P1028 proposed approach	NZFS preliminary view
To prescribe the format of the nutrition information statement (NIS) in accordance with the recommended format in the existing guideline in Schedule 29 of the Code with additional subheadings 'Vitamins', 'Minerals' to group the micronutrients and the subheading 'Additional' to group optional substances. (Example of the proposed format in section 3.3.4 of SD3) Questions to submitters: *Q1 Do you agree with FSANZ's preferred option to prescribe the format of the NIS as shown in Figure 1? Please provide the reasons for your views.* *Q2 How should the subheadings for 'Vitamins', 'Minerals' and 'Additional' be separated from other text (e.g. using lines, bolding)?*	NZFS supports prescribing the format of the NIS for infant formula products. *Prescribed format* The format for the NIP for all other pre-packaged foods is prescribed, so it is logical and consistent that the NIS for infant formula products is too. It is particularly important that nutrient content information for infant formula products is available given that these products may provide the sole or principal source of nutrition for a formula-fed infant (though we note that the strict compositional requirements for these products puts less onus on consumers to ensure adequate nutrition compared to other foods). Also, a prescribed format should mean a consistent and easy-to-use format to aid caregivers' use and understanding of this nutrition information and is supported by consumer research as the preferred option for caregivers. We appreciate that some stakeholders may have concerns about potential trade implications if the NIS format is prescribed, particularly as the format for the declaration of nutritive content is not prescribed in the relevant Codex standards (though these standards do note that the nutrition information should appear in a specific order, i.e. energy, protein, carbohydrate, fat, vitamins, minerals and other substances). Many other countries have strict content and formatting rules for nutrition declarations, and NZFS's understanding is that prescribing the NIP format and content for Australia and New Zealand (under Standard 1.2.8) for other foods has not caused WTO issues. Given our support for a prescribed NIS for infant formula products, our preferred format is: • Use of a tabular format, with font and contrast that align with general legibility requirements in section 1.2.1—24. • Use of the title 'Nutrition Information'. • A prescribed order of mandatory nutrition information. • The prescribed name of the nutrients to be declared. • Use of standardised sub headings for macronutrients, micronutrients and 'additional' substances (though note our further comments on the use of the term 'additional'). • The required unit(s) of expression. We consider that additional formatting will be required to group information in the NIS for ease of use, particularly given the significant number of nutrients that will need to be declared based on the strict

	compositional requirements for these products. We agree with the use of standardised sub-headings for macronutrients, micronutrients and 'additional' substances (though note our further comments on the use of the term 'additional'). We also suggest use of indentation (as required for sub-groups of macronutrients in the NIP for general purpose foods) and lines to group information. *Declaration of mandated nutritive substances* We ask that FSANZ clarifies whether mandated nutritive substances that are not macronutrients or micronutrients (such as proposed for choline, L-carnitine and inositol) would be required to be declared in the NIS. If so, we consider that an additional sub-heading is required in the NIS to indicate that these are essential components. An option could be to group these as 'other essential' or 'other essential substances'. Although the term 'other' was shown to be least understood by consumers, this heading was not given context of whether these 'other' components were essential or not. *Terminology for the sub-group to declare optional ingredients* The proposed NIS format in Figure 1 (section 3.3.4 of SD3) refers to a sub-group 'additional' to capture those substances permitted to be added voluntarily to infant formula products. We note that consumer research showed grouping optional ingredients was valued; that 'other' and 'optional' were least understood by caregivers, whereas the terms 'additional' and 'non-essential' were understood to mean added voluntarily by manufacturers. We consider that use of the term 'additional' could infer additional benefits, which is straying towards a claim. Based on the consumer research and potential for an implied claim, we suggest that the term 'non-essential' is used to identify those substances that are voluntarily added by manufacturers. The overall aim is to allow optional ingredients to be listed in the NIS to assist consumers to compare products, and to ensure that in doing so it does not mislead consumers. *Terminology for average quantity declaration* Also, a column heading in Figure 1 reads 'average quantity per 100ml made up formula'. Our preference is for this statement to refer to 'prepared formula' to be consistent with the preparation instructions (i.e. 'average quantity per 100ml prepared formula'; or similar depending on the unit of expression decision). Or if 'made up formula' is to be used, then a linked caption stating 'when prepared according to the instructions on the label'. *NZFS proposed format*

	Appendix 3 provides NZFS's proposed format for the NIS for infant formula products for consideration, based on our preferences outlined above.
To only permit the base unit of expression – per 100 mL as reconstituted – in the nutrition information statement.	NZFS does not support FSANZ's proposed approach to permit 'per 100 mL as reconstituted' as the only base unit of expression permitted in the NIS, and thus prohibit the voluntary use of other base units of expression. Standard 2.9.1-21 requires the label to provide nutrition information per 100 ml, and further guidance is provided in S29–10 which permits nutrition information to be presented per 100 g of powder, or 100 ml for liquid concentrate. *Choice of base unit of expression* A key use of the NIS is to provide information to the caregivers on the nutrition content of the product. It is particularly important that nutrient content information for infant formula products is available given that these products may provide the sole or principal source of nutrition for a formula-fed infant. We note that the strict compositional requirements for these products puts less onus on consumers to select formula based on the concentration of nutrients within a formula product. However, prescribing expression per 100 mL as reconstituted as does not enable caregivers to directly compare products' nutrient composition as the energy density per 100 mL differs somewhat (range: 2500-2950 kJ/100 mL) – so we question why FSANZ is proposing to permit only this unit of expression in the NIS. Similarly, per 100g powder or per 100ml concentrate as sold cannot be used to compare products as the amount of powder/concentrate used to prepare the same quantity of product differs between products. It appears the easiest option to compare nutrient content would be per 100 kJ to accommodate for the difference in energy density between products, though this unit of expression is rarely used on product labels. The primary aim is to provide a unit that provides caregivers with information on the nutrient content. The unit(s) chosen and information on pack also needs to allow for enforcement agencies to back calculate the nutrient composition of a product for compliance checks against the compositional requirements for infant formula products. *Limiting the units of expression* NZFS does not support limiting the base unit of expression to one unit alone (and thus prohibiting the use of other units).

	Codex CXS 72-1981 and the draft Codex Standard for FuFOI require two units of expression for the declaration of nutritive value – per 100 g or per 100 mL of the food as sold, as well as per 100 mL of the food ready for use when prepared according to the instructions on the label. In addition, the declaration of nutrients per 100 kilocalories (kcal) or per 100 kilojoules (kJ) is permitted. In the EU 2016/127 the unit of expression must be expressed per 100 ml of the food ready to use after preparation, and where appropriate information is also permitted to be expressed per 100 g of the food as sold. Therefore, from a trade perspective, there is no precedent for prohibiting other units of expression. In addition, no evidence was provided by FSANZ to indicate that caregivers are confused by the current requirements which permits different base units. As discussed above, NZFS supports retaining the status quo - requiring expression per 100 ml of the food ready for use when prepared according to the instructions on the label, in addition to permitting other units of expression (i.e. per 100 g of food as sold).
To use the term 'average quantity' rather than 'average amount' in declaration of nutrition information requirements, except for energy.	Support, as this provides consistency with terminology used elsewhere in the Code. 'Average quantity' is used in the NIP for general purpose foods and FSFYC, the Code defines this term, and calculation methods rely on this definition. However, we continue to seek clarity from FSANZ on the levels of nutrients that are required during shelf life (and degradation). Does 'average quantity' mean the average amount added (allowing for batch and seasonal variation), and is this average quantity required to be detected during the shelf life of the product? It is our understanding that any declared label values should be present at the end of the product's shelf life. The Code's definition of 'average quantity' (1.1.2—2) and how average quantity is to be calculated (1.1.1—6) does not address this issue.
To clarify that the calculation method for average quantity in 1.1.1—6(3)(c) will not apply to infant formula products. (Noting that other calculation methods in 1.1.1—6(3)(a) and (b) will still apply)	Support this clarification.
To maintain the requirement for the weight of one scoop to be declared (if a powdered product), and the proportion of powder or concentrate required to reconstitute the formula according to directions to be	NZFS supports maintaining the requirement to declare the weight of one scoop, and the proportion of powder or concentrate required to reconstitute the formula.

declared (if a powdered or concentrated form of infant formula) (paragraph 2.9.1—21(1)(b)). Also, to clarify this information must not be located in the nutrition information statement.	We agree that it is unnecessary to include this information as part of the NIS and consider it might be better placed with the preparation and use instructions on the label.
To permit with prescribed wording and format the voluntary listing in the NIS of: • 'Whey' and 'Casein' (indented under the macronutrient 'Protein') • 'Docosahexaenoic acid', 'Eicosapentaenoic acid' and 'Arachidonic acid' (indented under the sub-group nutrient heading 'Long chain polyunsaturated fatty acids', which is indented under the macronutrient 'Fat')	NZFS supports the proposed provision to allow additional information in the NIS to help inform product choice for caregivers and health professionals. We support the voluntary declaration of the nutrients specified, as well as the use of prescribed wording and format for these voluntary declarations to ensure that information provided is limited to key nutrients with express permission to add to an infant formula product. We also note that the voluntary declaration in the NIS of prescribed nutrients aligns with Codex and EU regulations for declaration of nutrients, including optional ingredients. This approach provides the opportunity for manufacturers to declare the whey and casein content of their product through the NIS, particularly given the clarification that they cannot be referenced in the protein source statement or elsewhere on the label.
To maintain the status quo and not align the declaration of ingredient names in the statement of ingredients and nutrient names in the NIS.	Support (status quo). NZFS is not aware of any issues with the current requirements, and therefore is not aware of reasons to change the approach. To require this would make IFPs different from all other foods with no apparent justification to do so.

Modified infant formula products

P1028 proposed approach	**NZFS preliminary view**
To apply general labelling requirements for infant formula products to modified infant formula products.	Assuming the proposed modified infant formula category is retained, we support that general labelling requirements for infant formula products should also apply to this category. This includes the prohibition on the use of claims, and therefore references to conditions such as reflux and colic would not be permitted.
For those infant formula products with modified lactose content, to maintain existing specific	Support – retain existing requirements: • 'lactose free' and 'low lactose' required to be included in the name of the food (i.e. the prescribed name).

labelling requirements for 'lactose free' and 'low lactose' infant formula products.	• to declare the amount of lactose and galactose. We recommend that these declarations should be required to be in the NIS for these products.
For those infant formula products with modified protein content that contain partially hydrolysed protein, a preliminary view to require the words 'partially hydrolysed' on label to inform caregivers on the nature of the modification. Question to submitters: *Q3 Without referencing specific conditions, how should partially hydrolysed formula be labelled to inform caregivers of the nature of the modification from other IFP?*	FSANZ has clarified that the protein source statement should refer to the origin of the protein (e.g. cow's milk) only. We consider the approach to labelling for lactose free and low lactose formulas is a good basis for labelling of partially hydrolysed protein formulas. That is, for the nature of the modification to be required in the name of the food (i.e. the prescribed name). FSANZ's preliminary view to require the words 'partially hydrolysed' on label appears consistent with approach for low/free lactose products, particularly if it is prescribed that these words are included in the name of the food. We recommend the wording is extended to 'partially hydrolysed protein', to make clear that it is the protein component that has been partially hydrolysed. To state the modification as 'partially hydrolysed protein' is accurate but is not likely to be understood by the general consumer. However, overall, given these products are intended to be used following advice from a health professional – who can then advise the caregiver on the statements (i.e. 'low/free lactose' and 'partially hydrolysed protein') to look for when purchasing an appropriate product for their infant, we consider this information will be useful.

Representations

P1028 proposed approach	**NZFS preliminary view**
To retain current provisions for prohibited representations in paragraphs 2.9.1—24(1)(a) to (e).	Support retaining the current provisions for prohibited representations (a) to (e) in 2.9.1—24. Agree these provisions support the Australian and New Zealand governments' international commitments to the WHO Marketing Code and are consistent with specific policy principles (k) and (l) of the Ministerial Policy Guideline. Also, as these representations are incorporated in the Code they are enforceable by law.
Additional NZFS comment - Prohibited representations 2.9.1—24(1)(f)	We note that 2.9.1—24(1)(f) states: *(1) The label on a package of infant formula product must not contain:* *(f) subject to subsection 2.9.1—14(2), a reference to the presence of any nutrient or substance that may be used as a nutritive substance, except for a reference in:*

	(i) a statement relating to lactose under subsection 2.9.1—14(6); or *(ii) a statement of ingredients; or* *(iii) a declaration of nutrition information under section 2.9.1—21; or* NZFS requests that FSANZ ensures that the Code, either via the above paragraph or elsewhere in the Code, provides that if a nutrient or ingredient is permitted to be declared (both mandatory and voluntary declarations) in the NIS of an infant formula product that this does not constitute a nutrition content claim. For example, the proposed permission for the voluntary listing in the NIS of whey, casein and certain long chain polyunsaturated fatty acids must be accommodated so that these declarations do not constitute a claim.
To maintain the current prohibition on nutrition content and health claims, and to not consider this issue further under P1028.	Support the current prohibition on nutrition content claims and health claims on infant formula products, and for this issue not to be considered further as part of P1028. The current prohibitions and restrictions on nutrient content claims and health claims on infant formula products in the Code are clear, including that the prohibition extends to advertising of these products. The approach to prohibit such claims is consistent with Ministerial policy guidance, and helps to ensure that infant formula products are not marketed inappropriately to caregivers as being equivalent to or better than breastmilk.
To only permit information about ingredients in the statement of ingredients (except for ingredients that are required to be declared in the NIS).	Support the proposed approach to specifically prohibit voluntary information being provided about an ingredient outside the statement of ingredient (i.e. ingredient claims), except for those ingredients that are permitted to be declared in the NIS. We note that the proposed approach mentions an exception for ingredients "that are <u>required</u> to be declared in the NIS". As some declarations in the NIS may be voluntary, as proposed for whey and casein in P1028, it is important that the drafting of this provision is not limited to only those ingredients "required" to be declared in the NIS (but also applicable to those that are expressly permitted).
FSANZ is seeking evidence and inviting stakeholder comment about stage labelling and proxy advertising specific to the labelling of IFP (0 - 12 months). Noting that labelling of FSFYC/toddler milks is out of scope. Questions to submitters:	NZFS is open to further consideration of regulatory provisions to restrict or prohibit line marketing and proxy advertising on infant formula products, and notes the background information provided by FSANZ on these issues. We note the issues of line marketing and proxy advertising for infant formula products are linked with the promotion of FSFYC – given that many of the issues relate to the use of stage labelling, colours and design across these product categories, and in some cases the proxy advertising of a FSFYC on the label of infant formula product. Ideally these issues would be considered for both product categories at

Q4 What evidence can you provide of caregivers' understanding of stage labelling on infant formula products? *Q5 What evidence can you provide about caregivers' understanding and behaviours associated with proxy advertising appearing on the labels of infant formula or follow-on formula?*	the same time, but we note that labelling of FSFYC is out of scope for P1028. We consider that there are some actions related to line marketing that would be considered within scope. We note the approach taken in the draft Codex Standard for FuFOI (sections 8.6.4 and 8.6.5), which is drafted with the intent to avoid consumer confusion through the clear differentiation in labelling between different product categories and to prevent label references to products from different product categories. These sections specifically refer to text, images, colours and statements that may be used on these products. We note that the drink for young children is captured within this standard as product for the 12-36 month was within scope of the FuFOI standard which was under review. For reference, sections 8.6.4 and 8.6.5 state: *8.6.4 Follow-up formula for older infants shall be distinctly labelled in such a way as to avoid any risk of confusion with Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, and Formula for special medical purposes intended for infants, in particular as to the text, images and colours used, to enable consumers to make a clear distinction between them.* *8.6.5 The labelling of follow-up formula for older infants shall not refer to Infant formula, Drink for young children with added nutrients or Product for young children with added nutrients or Drink for young children or Product for young children, or Formula for special medical purposes intended for infants, including numbers, text, statements, or images of these products.* In the EU a similar approach has been taken in EU 2016/127, whereby a clear distinction is required between infant formula and follow-on formula products: *6) The labelling, presentation and advertising of infant formula and follow-on formula shall be designed in such a way that it avoids any risk of confusion between infant formula and follow-on formula and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used* We note FSANZ's request for additional evidence in questions 4 and 5, however we do not have further information to provide at this time to address these questions.
To maintain the current non-regulatory approach for the notification of changes in product formulation. That is, manufacturers would continue to decide how best to inform caregivers and health care professionals about formulation changes as appropriate.	NZFS will reserve its view on the most appropriate approach for the notification of changes in product formulation until the 2nd CFS. NZFS is not opposed to further consideration of the current non-regulatory approach – but note a key issue is to ensure that provision of information about a change in formulation by manufacturers and distributors is not used as a mechanism to make nutrition content and health claims. We note that references to nutrition information outside the NIS and the statement of ingredients may constitute a

	nutrition content claims, which is prohibited on label and in advertising for infant formula products, but request that consideration is given to clarify this aspect in the Code if a non-regulatory approach is adopted. NZFS would also like to put forward an alternative approach for consideration that contains both regulatory and non-regulatory measures. The regulatory measure could restrict the information that could appear on the label of an infant formula product – to only allow a sticker stating "New formulation" to appear on packaging. This generic statement would adequately alert caregivers and health professionals to a change in formulation, and in combination with supplier contact details (mandated on pack) allows the caregiver/health professional to contact the supplier for further details if concerned. This regulatory approach ensures consumers are alerted to a formulation change without the communication of this information being used as a mechanism to make a claim. Also, stickers are a more flexible and temporary communication tool compared to a base label change, resulting in lower cost for industry and allowing the sticker to be used for a shorter period on product (noting the long shelf life of these products). The non-regulatory approach could then apply to other non-label communications about the change to formulation, noting the Code's prohibition on claims and implementation of WHO Marketing Code principles should limit any inappropriate or misleading information being communicated to caregivers and health professionals.
FSANZ does not intend to consider the issues of trade marks or online advertising further as part of Proposal P1028.	Support the approach to not consider the issues of trade marks or online advertising further as part of Proposal P1028. We acknowledge the concern of some stakeholders about use of trademarks to make claims that are prohibited on infant formula products. We note the application of trademark law is different in Australia and New Zealand. For New Zealand, we understand that while a trademark may be registered it may not be used if it contravenes another law. In relation to online advertising, we note FSANZ's view that this is an enforcement issue. We note that any statements, information, designs or representations that apply to a label also apply to advertisements (as is the case for all foods), and that for infant formula products this includes the prohibited representations (in 2.9.1—24(1)) and the prohibition on nutrient content and health claims.

6. SPECIAL MEDICAL PURPOSE PRODUCTS FOR INFANTS (SMPPi)

Note, the following comments should be read in conjunction with NZFS's earlier comments on the proposed regulatory framework, including comments on the definition of SMPPi, use of a prescribed name, and the proposed access restriction.

P1028 proposed approach	NZFS preliminary view
Composition	
For SMPPi that form the sole source of nutrition, to require the composition to meet the compositional requirements for infant formula products, unless a deviation is required to meet the medical purpose of the product based on generally accepted scientific data. and, For SMPPi that are not used as the sole source of nutrition, to require the composition to take account of the specific nutrition requirements of infants and to be specially formulated to meet the medical purpose of the product.	NZFS support that the base composition of SMPPi for use as the sole source of nutrition should meet the specific compositional requirements for infant formula products, unless there is a sound medical and scientifically supported reason to deviate to address the medical purpose of the product. It is important that the composition of SMPPi is flexible to accommodate the broad range of formulations required for the dietary management of infants with various diseases, disorders and medical conditions. We support this general approach in the standard rather than prescribing compositional requirements for specific medical conditions. A flexible approach to composition is also essential to support the continued importation of these specialised products to Australia and New Zealand – with the continued supply and access to these products critical for those vulnerable infants that require them. However, alongside this flexible approach needs to be appropriate risk management strategies to ensure the health and safety of infants using these specialised products is protected. We strongly support that the revised standard includes a statement, similar to that in EU Directive (EU) 2016/128, that requires the composition of a SMPPi product (including any modifications to meet the medical purpose) to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of the intended infant subpopulation. It is important that the manufacturer and/or supplier of the product holds the data that supports the product's composition. Although the 'safe and suitable' proviso may already be a requirement under the food acts applying in both New Zealand and Australia, it is more explicit if it is incorporated in the Code. As it is already a requirement, this is not adding to the regulatory burden on suppliers and manufacturers. If it is not made an explicit requirement, then the standard will be more difficult to enforce.
To include a permission for the addition of medium chain triglycerides to SMPPi, without limits, to	Support, where required to address a specific disease, disorder or medical condition as supported by generally accepted scientific data.

address the products medical purpose as supported by generally accepted scientific data.	
To permit the voluntary addition of molybdenum and chromium in SMPPi, without limits, to address the products medical purpose as supported by generally accepted scientific data.	Support, where required to address a specific disease, disorder or medical condition as supported by generally accepted scientific data.
To not standardise the scoop size or dilution ratio, and instead maintain the existing requirement for a direction instructing that, where a package contains a measuring scoop, only the enclosed scoop should be used.	Support
To permit the addition of novel foods and nutritive substances of the addition is made for the products medical purpose (otherwise, a pre-market assessment is required).	NZFS supports consideration of an open permission for use of novel foods and nutritive substances in SMPPi – if the regulation makes clear that the addition is only permitted to address the medical purpose of the product as based on generally accepted scientific data. This approach recognises the need for flexibility in the composition of these products to accommodate the varied medical conditions these products are formulated to address, and also the need to ensure no barriers to trade in the continued supply and access to these highly specialised products for infants that require them. We agree that pre-market assessment should be required for novel foods and nutritive substances that are to be added for any other purpose than to meet the medical purpose of the product. However, we do not want this more flexible approach to the addition of novel foods and nutritive substances for SMPPi (compared to that for infant formula products) to be used for commercial advantage. Therefore, as discussed under the 'regulatory framework' section of this submission, there needs to be clear differentiation between product categories to ensure that low-risk products cannot represent themselves as SMPPi and take advantage of the more flexible and/or potentially favourable compositional and labelling provisions.
Labelling	
To apply applicable labelling requirements from Standard 2.9.5 and 2.9.1 to SMPPi.	NZFS agrees with the approach to apply applicable specific labelling requirements from Standards 2.9.1 and 2.9.5 to SMPPi given the similarities in nature and use of SMPPi compared to IFPs and FSMP respectively.

	We note that the labelling requirements in Standard 2.9.5 were developed with the intent of balancing provision of information to enable the safe and appropriate use of FSMP while minimising potential barriers to trade. This is an important consideration for SMPPi too, given the majority of these highly specialised products are imported into Australia and New Zealand and the need to maintain continued supply and access to these products for the vulnerable infants who require them.
Application of Standard 2.9.5 labelling requirements	
To apply the mandatory labelling information required by section 2.9.5—9 to SMPPi.	NZFS supports the following mandatory labelling information be required for SMPPi, as per section 2.9.5—9: • name or description sufficient to indicate the true nature of the food; • lot identification; • information relating to irradiated food; • required advisory statements, warning statements, other statements and other declarations; • information relating to ingredients; • date marking, including allowing flexibility to use 'Expiry Date' or similar words; • directions for the use or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons; and • legibility requirements.
To apply the labelling requirements for inner packages and transportation outers in subsections 2.9.5—8(3) and (4) to SMPPi.	Support
To not apply the following generic labelling requirements to SMPPi: • name and business address • characterising ingredients and components	Support, noting the same approach is taken for FSMP.
To apply the generic requirement for food to be labelled as 'genetically modified' (in accordance with 1.5.2—4).	Support, this is a generic requirement relating to all food, including IFP and FSMP, and is also appropriate for SMPPi.

To apply the specific mandatory statements in 2.9.5—10(1) to SMPPi.	NZFS supports the following specific mandatory labelling statements be required for SMPPi, as per 2.9.5—10(1): • a statement to the effect that the food must be used under medical supervision; • a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food; • a statement indicating the medical purpose of the food, which may include a disease, disorder or medical conditions for which the food has been formulated; • a statement describing the properties or characteristics which make the food appropriate for the medical purpose; • if the food has been formulated for a specific age group - a statement to the effect that the food is intended for persons within the specified age group; • a statement indicating whether or not the food is suitable for use as a sole source of nutrition; • if the food is represented as being suitable for use as a sole source of nutrition: o a statement to the effect that the food is not for parenteral use; and o additional statements about the nutritional modifications made to the product (using compositional requirements for IFPs as the baseline reference). While we support the need for SMPPi labels to state the medical purpose of the product, it is important to make clear that this requirement should not be misused to make a health claim.
To apply generic labelling requirements relating to advisory or warning statements about the presence of bee pollen, propolis, guarana and aspartame, and the declaration of allergens (as indicated in 2.9.5—10(2) and (3).	Support
To require nutrition information expressed per given amount of food in relation to: • the minimum or average energy content;	Support

• the minimum amount or average quantity of protein, fat and carbohydrate; any vitamin, mineral or electrolyte that has been used as a nutritive substance in the food (in accordance with 2.9.5—13(a) and (b)(i) and (ii)).	
To not require a specific format for the NIS, as proposed for IFPs.	Support not requiring a prescribed format for nutrition information for SMPPi. We agree this provides the flexibility required to accommodate the differing overseas nutrition information requirements on imported products. We note that the label will have flexibility as to the presentation of the information, the unit(s) of expression used, and whether a minimum amount or average quantity is declared.
To require SMPPi to declare the amount of any other nutritive substance that has been added to the product for its intended medical purpose (in place of the requirements in 2.9.5—13(b)(iii) and (iv)).	Support the proposed approach to require declaration of any other nutritive substances that has been added to SMPPi for its intended medical purpose. We also consider this requirement should be extended to include any other nutritive substance added to SMPPi that is expressly permitted to be added (noting that it is proposed that novel foods and nutritive substances may be added to SMPPi for reasons other than the medical purpose, if approved via a pre-market assessment).
To prohibit nutrition, health and related claims on SMPPi.	Support, aligns with the Ministerial policy guidance and the approach for IFPs.
To not apply requirements in sections 2.9.5—14 and 15 for claims in relation to lactose and gluten content to SMPPi. Also, to not apply conditions for lactose free and low lactose IFP.	NZFS considers this may require further consideration. It appears appropriate, as proposed, to not apply the requirements for claims in relation to lactose and gluten content for SMPPi, as this information (if relevant) would be provided in the statement describing the properties or characteristics which make the food appropriate for the medical purpose. However, we consider it would be beneficial to require SMPPi products that have lactose or gluten content as a feature of the formulation to declare the average quantity of lactose and galactose and/or gluten per given quantity of the food as part of the nutrition information (i.e. to adapt 2.9.5—14(4) and 15(5).

Application of Standard 2.9.1 labelling requirements	
To not require a prescribed name for SMPPi (and that the prescribed names 'infant formula' and 'follow-on formula' will not apply).	NZFS would like this requirement to be considered further – please see our comments under the 'Regulatory framework' section of this submission.
To not apply the warning statements in 2.9.1—19(1)(a) to (c) instructing caregivers to follow instructions exactly when preparing IFPs – and instead apply 2.9.5—9(1)(g) for directions for the use or the storage of the food.	Support, as the broad nature and intended use of products in the proposed SMPPi category requires a more general approach to the provision of directions for use and storage instructions appropriate to the product.
To exempt SMPPi from the statement *'Breast milk is best for babies. Before you decide to use this product, consult your doctor or health worker for advice'.*	Support – appropriate that SMPPi do not carry this warning statement given the broad spectrum of products that will be captured by the SMPPi category, including supplementary-type products that are not breast milk substitutes. This statement is also not necessary given the need to use these products under medical supervision and the access restriction. Also, this approach is consistent with EU and USA regulations.
To apply 2.9.5—9(g) to SMPPi in place of the mandated directions for the preparation and use of IFP in 2.9.1—19(3).	We agree that the mandated statements for preparation and use of the IFP (e.g. each bottle should be prepared individually and potable, previously boiled water should be used) should not apply to SMPPi. These statements are not appropriate for all SMPPi as some SMPPi will not be presented in a traditional formula-type format, given the broad range of products the SMPPi category is proposed to capture. Therefore, we support applying 2.9.5—9(g) to SMPPi, which requires the label to state: *directions for the use or the storage of the food, if the food is of such a nature to require such directions for health or safety reasons.*
To not apply the age-related statements in 2.9.1—19(4)(a) to (c) – and instead to apply the requirement for a statement that the food is intended for persons within a specified age group.	We agree that the age-related statements in 2.9.1—19(4)(a) and (b) should be adequately addressed through the requirement under 2.9.5—10(1)(e), which states: *if the food has been formulated for a specific age group – a statement to the effect that the food is intended for persons within the specified age group.* This approach also provides flexibility for SMPPi that may also be used beyond 12 months of age to be labelled appropriately with intended age for use. We also agree it is not appropriate to require SMPPi to carry the 2.9.1—19(4)(c) statement that: *it is recommended that infants from the age of 6 months be offered foods in addition to the infant formula product.* As noted, this statement is inappropriate as the provision of additional foods may be

	contraindicated, and the supervising health professional is best placed to advise on introducing complementary foods as appropriate for the individual.
To not require a protein source statement in accordance with 2.9.1—23(1)(a) for SMPPi.	We note FSANZ's rationale that there is no consistent approach across international regulations for a protein source statement, and for the need to keep labelling requirements flexible to prevent trade barriers for these specialised products. If the approach is not to require a protein source statement, it will be important that SMPPi are not prevented from voluntarily making such a statement on label, particularly if this information is relevant for the medical purpose for which the product is formulated. We request FSANZ considers whether a specific permission for SMPPi to allow a voluntary protein source statement is required, or if other labelling requirements proposed for SMPPi (e.g. 2.9.5—9(1)(a) and 2.9.5—10(1)(d)) would sufficiently allow for such a statement to be made.
To not apply the prohibited representations in 2.9.1—24 to SMPPi	It appears appropriate not to apply the prohibited representations for SMPPi. We note FSANZ's rationale that SMPPi are highly specialised products for use under medical supervision and which are not marketed to caregivers of healthy infants, and that a restriction on sale is proposed for these products. FSANZ also notes that paragraphs 2.9.1—24(1)(a) to (e) do not align with EU or Codex provisions for SMPPi.

Appendix 1: Conversion factors and rounding issues

During the review of the Codex Standard for Follow-up Formula it was identified that there were inconsistencies in the conversion of the essential compositional requirements from kilocalories to kilojoules, partly due to rounding inconsistencies in the development of the Codex Standard for Infant Formula. The Codex Committee agreed during the PWG at CCNFSDU38 (recommendation 2) to amend the conversion factors in line with the International Standard Unit conversion factors and conventional rounding. The Secretariat informed the pWG that once the corrections were finalised in this standard then consequential amendments can be made for Codex Infant Formula Standard.

Within the Codex Committee, discussions are based on the values for the composition per 100 kcal, and subsequently converted to per 100 kJ. The Committee agreed to a systematic approach to determining the essential composition per 100 kJ, this approach to editorial and technical amendments was outlined in CRD5 at CCNFDU40 and summarised here.

Conversion factors

At times rounding inconsistencies occurred when using the international standard unit (ISU) conversion factors in the Codex Standard for Infant Formula. The conversion factors for kilojoules and kilocalories are: 1 kJ = 0.239 kcal; and 1 kcal = 4.184 kJ. This is currently specified in the Codex Standard for Follow-up Formula under the definition for kilocalorie.

Significant figures

Regarding the conversion to kJ, a level of specificity is required to ensure that the same minimum and maximum levels are specified as for those presented per 100 kcal. This is of particular importance for compliance purposes in those national or regional authorities which use kJ in their regulation. The proposed approach was to ensure that the converted nutrient requirements values per 100 kcal to per 100 kJ are nutritionally equivalent to a reasonable level of specificity. A systematic approach consistent for all essential composition requirements was deemed necessary.

The rounding logic that was applied aligns well with the current drafting of Codex Standard FuFOI and also with other international regulations for follow-up formula.

Rounding logic	
Values >5	Round to nearest whole number
Values 1-5	Report to 1 decimal point
Values <1	Report to 2 decimal points

A summary table for the essential compositional requirements which have been amended in the draft Codex Standard for Follow-up Formula Older Infants is provided in Table 1 of Appendix 1.

We would encourage FSANZ to consider using this, or a similar approach to convert values from kcal to kJ. This is an issue which has been identified at Codex and it is anticipated that consequential amendments will be made to the Codex Infant Formula Standard once the review of follow-up formula is completed.

Table 1 (Appendix 1): Summary of compositional requirements where there has been an amendment to the compositional requirement per kJ between the Codex CXS 72-1981 and Codex Draft Std FuFOI

Compositional requirement	Unit /100 kJ	P1028 IF	P1028 FoF	Codex CXS 72-1981	Codex Draft Std FuFOI*	Reference for the Codex decision
Energy	kJ/L	2500 - 2950	2500 - 2950	2500 - 2950	2500-**2930**	NFSDU/40 CRD/5
Protein cow's milk	g	0.43-0.7	0.43-0.7	0.45-0.7	0.43-**0.72**	NFSDU/40 CRD/5
Fat	g	1.05-1.4	1.05-1.4	1.05-1.4	**1.1**-1.4	NFSDU/40 CRD/5
Vitamin B6	µg	8.5-45	8.5-45	8.5-45	**8-42**	NFSDU/40 CRD/5
Vitamin B12	µg	0.025–0.36	0.025–0.36	0.025–0.36	**0.02** - 0.36	NFSDU/40 CRD/5
Niacin	µg	70 – 360	70 – 360	70 – 360	**72 – 359**	NFSDU/40 CRD/5
Vitamin C	mg	1.7-17	1.7-17	2.5-17	**2.4**-17	NFSDU/40 CRD/5
Vitamin D	µg	0.25-0.63	0.25-0.63	0.25-0.6	**0.24**-0.72	CCNFSDU37 pWG
Vitamin E	mgα-TE	0.12-1.2	0.12-1.2	0.12-1.2	0.12-**1.20**	NFSDU/40 CRD/5
Vitamin K	µg	0.24-6.5	0.24-6.5	1-6.5	**0.96-6**	NFSDU/40 CRD/5
Biotin	µg	0.24-2.4	0.24-2.4	0.4-2.4	**0.36-**2.4	NFSDU/40 CRD/5
Copper	µg	8.5-29	8.5-29	8.5-29	**8**-29	NFSDU/40 CRD/5
Folic acid	µg	2.5-12	2.5-12	2.5-12	**2.4**-12	CCNFSDU37 pWG
Sodium	mg	5-14	5-14	5-14	**4.8**-14	NFSDU/40 CRD/5
Manganese	µg	0.25-24	0.25-24	0.25-24	0.24-24	CCNFSDU37 pWG
Riboflavin	µg	14.3-119	14.3-119	19-119	19-**120**	NFSDU/40 CRD/5
Iodine	µg	2.5-14	2.5-14	2.5-14	**2.4**-14	CCNFSDU37 pWG.
Taurine	mg	0.8-3	0.8-3	N.S-3.0	N.S-**2.9**	NFSDU/40 CRD/5
Myo-inositol	mg	1.0-9.5	N.S. -9.5	1-9.5	N.S. -**10**	NFSDU/40 CRD/5

* bolded values are the those for which an editorial amendment has been made to the conversion factor from kilocalories to kilojoules for the Codex draft Standard for FuFOI.

Appendix 2 – Summary of NZFS preliminary views on compositional requirements for macronutrients and micronutrients

Table 1 (Appendix 2): Macronutrients: Summary of NZFS preliminary views on compositional requirements

Nutrient	Unit	P1028 follow-on formula	P1028 infant formula	Codex CXS 72-1981	Codex Draft Standard for FuFOI	NZFS view IF	NZFS view FoF	NZFS rationale
Energy	kJ/L	2500 - 2950	2500 - 2950	2500 - 2950	2510 - 2930	2510 - 2930	2510 - 2930	Support, after correction to kJ
Protein (cow)	g/100 kJ	0.43 – 0.7	0.43 – 0.7	0.45 – 0.7	0.43 – 0.72	0.43 – 0.72	0.38-0.72	Correction to kJ required, consideration of A1173
Protein (soy)	g/100 kJ	0.54 – 0.7	0.54 – 0.7	0.5 – 0.7	0.54 – 0.72	0.54 – 0.72	0.54 – 0.72	Support, after correction to kJ
Carbohydrate	g/100 kJ	NS	NS	2.2 – 3.3	2.2 – 3.3	NS	NS	Support
Total fat	g/100 kJ	1.05 – 1.4	1.05 – 1.4	1.05 – 1.4	1.1 – 1.4	1.1 – 1.4	1.1 – 1.4	Support, after correction to kJ
ALA	mg/100 kJ	12 – NS	12 – NS	12 – NS	12 – NS	12 – NS	12 – NS	Support
LA	mg/100 kJ	90 – 330*	90 – 330*	70 – 330*	72 – 335*	90 – 330*	90 – 330*	Support
DHA	mg/100kJ	NS - 7.2	NS - 7.2	NS - 0.5%^	NS – 7*	NS - 7.2	NS - 7.2	Withhold position on minimum.
AA	% total FA	NS – 1	NS – 1	≥ DHA	≥ DHA	≥ DHA	≥ DHA	Question expression as %FA
TFA	% total FA	NS - 4	NS - 4	NS – 3	NS - 3	NS - 4	NS - 4	Support
Lauric & Myristic acid	% total FA	NS	NS	NS - 20	NS - 20	NS	NS	Support
Erucic Acid	% total FA	NS - 1	NS – 1	NS – 1	NS – 1	NS - 1	NS - 1	Support
Phospholipids	g/L	NS – 2	NS – 2	NS – 2	NS – 2	NS – 2	NS – 2	Support

Table 2 (Appendix 2): Micronutrients: Summary of NZFS preliminary views on compositional requirements

Nutrient	Unit	P1028 infant formula	P1028 follow-on formula	Codex CXS 72-1981	Codex Draft Standard for FuFOI	NZFS view IF	NZFS view FoF	NZFS rationale
Vitamin A	µg RE/100 kJ	14 – 43	14 – 43	14 – 43	18 – 43	14 – 43	14 – 43	Support
Niacin	µg /100 kJ	70 – 360*	70 – 360*	70 – 360*	72 – 359*	100–359*	100– 359*	Correction to kJ, consideration of AI
Vitamin B6	µg /100 kJ	8.5 – 45*	8.5 – 45*	8.5 – 45*	8 – 42*	8.5 – 45*	8.5 – 45*	Support
Vitamin B12	µg /100 kJ	0.025–0.36*	0.025– 0.36*	0.025–0.36*	0.02 - 0.36*	0.02 - 0.36*	0.02 - 0.36*	Correction to kJ
Vitamin C	mg/100 kJ	1.7 – 17*	1.7 – 17*	2.5 – 17*	2.4 – 17*	1.7 – 17*	1.7 – 17*	Support
Vitamin D	µg /100 kJ	0.25 – 0.63	0.25 – 0.63	0.25 - 6	0.24 – 0.72	0.24 – 0.63	0.24 – 0.63	Correction to kJ
Vitamin E	mgα-TE/100kJ	0.12 – 1.2*	0.12 – 1.2*	0.12 – 1.2*	0.12 – 1.2*	0.14-1.2	0.14-1.2	Consideration of AI required
Vitamin K	µg /100 kJ	0.24 – 6.5*	0.24 – 6.5*	1 – 6.5*	0.96 – 6*	0.24 – 6*	0.24 – 6*	Correction to kJ
Zinc	mg/100 kJ	0.12 – 0.36*	0.12 – 0.36*	0.12 – 0.36*	0.12 – 0.36*	0.12 – 0.36*	0.12 – 0.36*	Support
Thiamin	µg /100 kJ	10 – 72*	10 – 72*	14 – 72*	14 – 72*	10 – 72*	10 – 72*	Support
Biotin	µg /100 kJ	0.24 – 2.4*	0.24 – 2.4*	0.4 – 2.4*	0.36 – 2.4*	0.24 – 2.4*	0.24 – 2.4*	Support
Copper	µg /100 kJ	8.5 – 29*	8.5 – 29*	8.5 – 29*	8 – 29*	8.5 – 29*	8.5 – 29*	Support
Phosphorus	mg/100 kJ	6 – 24*	6 – 24*	6 – 24*	6 – 24*	6 – 24*	6 – 24*	Support
Magnesium	mg/100 kJ	1.2 – 3.6*	1.2 – 3.6*	1.2 – 3.6*	1.2 – 3.6*	1.2 – 3.6*	1.2 – 3.6*	Support
Folic acid	µg /100 kJ	2.5 – 12*	2.5 – 12*	2.5 – 12*	2.4 – 12*	2.4 – 12*	2.4 – 12*	Correction to kJ
Sodium	mg/100 kJ	5 – 14	5 – 14	5 – 14	4.8 – 14	4.8 – 14	4.8 – 14	Correction to kJ
Chloride	mg/100 kJ	12 – 38	12 – 38	12 – 38	12 – 38	12 – 38	12 – 38	Support
Potassium	mg/100 kJ	14 – 43	14 – 43	14 – 43	14 – 43	14 – 43	14 – 43	Support
Pantothenic acid	µg /100 kJ	96 – 478*	96 – 478*	96 – 478*	96 – 478*	96 – 478*	96 – 478*	Support
Manganese	µg /100 kJ	0.25 – 24*	0.25 – 24*	0.25 – 24*	0.24 – 24*	0.24 – 24*	0.24 – 24*	Correction to kJ
Riboflavin	µg /100 kJ	14.3 – 119*	14.3 – 119*	19 – 119*	19 – 120*	14.3 – 119*	14.3 – 119*	Support
Iron	mg/100 kJ	0.2 – 0.5	0.2 – 0.5	0.1 – ~	0.24 – 0.48	0.14-0.48	0.14-0.48	Correction to kJ, reconsider minimum
Calcium	mg/100 kJ	12 – 35*	12 – 43*	12 – 35*	12 – 43*	12 – 35*	12 – 43*	Support
Iodine	µg /100 kJ	2.5 – 14*	2.5 – 14*	2.5 – 14*	2.4 – 14*	2.4 – 14*	2.4 – 14*	Correction to kJ
Selenium	µg /100 kJ	0.48 – 2.2*	0.48 – 2.2*	0.24 – 2.2*	0.48 – 2.2*	0.48 – 2.2*	0.48 – 2.2*	Support

Appendix 3 - NZFS's proposed format for the Nutrition Information Statement

NUTRITION INFORMATION	
	Average quantity per 100 mL prepared formula*
Energy	kJ
Protein	g
— Whey	g
— Casein	g
Fat	g
— Long chain polyunsaturated fatty acids	
— Docosahexaenoic acid	mg
— Eicosapentaenoic acid	mg
— Arachidonic acid	mg
Carbohydrate	g
Vitamins	
— Vitamin A	µg
— Vitamin B_6	µg
— Vitamin B_{12}	µg
— Vitamin C	mg
— Vitamin D	µg
— Vitamin E	µg
— Vitamin K	µg
— Biotin	µg
— Niacin	mg
— Folate	µg
— Pantothenic acid	µg
— Riboflavin	µg
— Thiamin	µg
Minerals	
— Calcium	mg
— Copper	µg
— Iodine	µg
— Iron	mg
— Magnesium	mg
— Manganese	µg
— Phosphorus	mg
— Selenium	µg
— Zinc	mg
— Chloride	mg
— Potassium	mg
— Sodium	mg
Other essential	
— (insert any other mandated substance to be used as a nutritive substance to be declared)	g, mg, µg
Non-essential	
— (insert any other optional substance used as a nutritive substance or inulin-type fructans and galacto-oligosaccharides to be declared)	g, mg, µg

*when prepared according to the instructions on the label