Comments from the Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions.

Due date of submission – 20 October 2021

The Victorian Departments of Health and Jobs, Precincts and Regions (the departments) welcome the opportunity to respond to this consultation paper P1028– Infant formula: Regulatory Framework.

The departments recognise that breastfeeding is the normal and recommended way of feeding infants and that the regulation of infant formula has implications for breastfeeding rates (and associated infant and later life health outcomes) as well as the health outcomes of formula-fed infants. Infant formula products are essential products for a vulnerable population and careful consideration is vital to ensure that infants' health and interests are the primary focus of regulatory decisions.

The departments support the overarching regulatory approach for infant formula that is outlined in Ministerial Policy Guideline on the Regulation of Infant Formula Products (the Policy Guideline). Specifically, this guideline recognises that there is a greater level of risk to be managed with infants compared to other population groups and therefore the regulatory framework for infant formula products should include requirements commensurate with this level of risk.

General questions

- **How effective do you believe the current regulatory measures for IFPSDU are? How could they be made more effective? If you think the requirements should be changed to better manage risk, please explain how and why. Please provide supporting detail and data, where available**.

The current regulatory measures for Infant Formula Products for Special Dietary Use (IFPSDU) have operated well in enabling valid specialist medical formula for infants to be imported and made available to Australian infants with little to no regulatory barriers. This view is made based on discussions with paediatric dietitians in 2017 and 2021 that have indicated there have been no instances where they have been unable to access a special purpose product for their patients due to regulatory barriers impeding importation.

The standard has performed less well in:

- establishing a clear boundary between standard formulas for healthy infants and formulas required for the dietary management of medical conditions.
- ensuring only valid medical purpose formulas exist on the market and preventing the development and marketing of formulas which are not scientifically based nor required for the dietary management of medical conditions (such as formulas designed for hungry babies or to help sleep or to manage colic). These non-evidence based products, which are not recommended by health professionals, make misleading claims and risk impacting on breastfeeding through the medicalisation of normal infant behaviours. Published literature and anecdotal evidence from Victorian maternal child health nurses indicate that such 'special purpose' formulas and their marketing can reduce confidence in breastfeeding, appear to offer solutions for breastfeeding women that encourage formula use and lead to the belief that formula is a solution to normal infant behaviours, with associated reductions in or cessation of breastfeeding in some cases[1][2]. The adverse health outcomes and costs of using infant formula in place of breastfeeding are well established.

[1] Parry, K. et al. Understanding Women's Interpretations of Infant Formula Advertising. Birth. 2013, 40: 115–124

[2] Belamarich, P. F. et al. A critical review of the marketing claims of infant formula products in the United States. Clinical Pediatrics, 2016 55(5), 437-442

- Managing access to these formulas to ensure carers are not using them inappropriately and without medical supervision. The risks of inappropriate use extend beyond consideration of acute post-consumption risks to infants and include unnecessary reduction in or cessation of breastfeeding and unnecessary dietary restrictions once foods are introduced.

More information is provided in the sections below.

- **Do you consider that the options proposed in this paper will ensure that IFPSMP are safe, suitable and meet the nutritional requirements of the infants for whom they are intended? If not, please explain why and provide supporting data and detail, where available.**

The departments consider the options proposed in this paper for the newly named Infant Formula Products for Special Medical Purposes (IFPSMP) are a significant improvement on proposed options in the 2017 consultation on these products, however certain elements need further consideration, particularly the wording used for the definition, wording around the deviation from compositional requirements and labelling.

For example, use of the terms 'suitable' and 'meet the nutritional requirements of the infants for whom they are intended' can be open to interpretation. The regulations need to ensure that these products not only meet the nutritional requirements of infants but provide valid, targeted, nutritional modifications specific to the specified condition and that are deemed effective (based on accepted scientific evidence) in the dietary management of the intended medical condition. These distinctions are important because a formula may be considered safe, suitable and meet the essential nutritional requirements of an infant with, for example colic, but not be appropriate for, or effective, in managing colic.

These wording considerations are consistent with the EU regulations which specify, '*The formulation of Foods for Special Medical Purposes shall be based on sound medical and nutritional principles. Its use, in accordance with the manufacturer's instructions, shall be safe, beneficial and effective for the persons for which they are intended on the basis of generally accepted scientific data* (EU 2016/128 Article 2(2)) and '*The nutritional composition of FSMP for infants should be based on that of IF and FOF in order to take into account the specificities of the nutritional requirements of infants. However, taking into account that IF and FOF are intended for healthy infants, derogations should be provided for FSMP for infants when this is necessary for the intended use of the products'* (Recital 6).

More detail is provided below under each issue discussed by FSANZ in the consultation paper.

- **How effective do you believe the options proposed for IFPSMP will be? How could they be made more effective? Do they place an unreasonable cost burden on industry to achieve and/or maintain compliance? Please provide supporting detail and data, where available.**

Further comments are provided under each section below. Overall, the departments broadly support the approach to simplify the regulations and create a single category for infant formula products for special dietary uses, renamed as for special medical purposes, but are of the view that the proposed risk management strategies do not go far enough to address the reduction in protection of infants where regulation will no longer limit permitted special purpose formulas to specific, nominated conditions. With the regulations potentially permitting products for any medical condition, provisions are needed to protect infants and carers, by ensuring:

- there is a clear boundary between standard formula for healthy infants, foods for special medical purposes for other age groups, and infant formulas for the management of medical conditions (such as by ensuring there is a prescribed name for medical purpose formulas and that all formulas modified for a medical purpose, such as lactose-free, are captured)
- only valid medical purpose formulas exist on the market by ensuring the definition links the need for the products to be effective, **based on scientific evidence**, to the dietary management of the specific condition.

- There are adequate controls on the labelling, presentation, advertising and promotion of these specialised formulas in addition to access.

The recently updated Commission Delegated Regulation (EU) 2016/128 on Foods for Special Medical Purposes, which covers special purpose infant products, includes in its introduction a commentary on the recent rise in special purpose formula for infants and raises concerns about potential abuses, the inappropriate targeting of consumers, consumer confusion about the nature of products, and misclassification of products as the basis for the need for greater restrictions on the labelling, presentation, advertising, and promotional and commercial practices. This supports our view that inadequate regulatory controls will lead to an undesirable proliferation and marketing of special purpose infant formulas.

The departments consider that FSANZ's proposed approaches, with the departments' suggested amendments, represent a reduction in regulatory burden for industry to achieve and/or maintain compliance compared with the status quo. This results from simplifying the regulations for IFPSDU, permitting a broader range of medical purpose products and by aligning more closely with EU regulations.

2 Novel Foods and Nutritive Substances

2.1 Pre-market assessment requirements

Summary positions: The departments do not support deferring consideration of the pre-market assessment requirements of nutritive substances and novel foods for infant formula and combining with Proposal P1024.

The departments support clarifying the existing permissions for novel foods in Schedule 25 in relation to infant formula products, infant foods and supplementary foods for young children

FSANZ is proposing deferring assessment and decision on pre-market assessment requirements for nutritive substances and novel foods in all infant formula products and instead combining this issue with P1024 – nutritive substances and novel foods, noting these substances in infant formula will fall to 'safe and suitable' provisions. This is a significant change in approach from the position of previous consultations on both P1028 and P1024. **The departments do not support this approach for the following reasons:**

1. It would undermine P1028 and introduce regulatory ambiguity into the revised Standard. Pre-market assessment of nutritive substances and novel foods in infant formula is a fundamental part of Standard 2.9.1 and P1028. FSANZ's indication that it will not be resolved in P1028 will introduce uncertainty in the revised Standard that does not currently exist and the Standard will be unable to function effectively. The review of infant formula regulations has already been underway for 9 years, there is clear regulatory precedence and policy direction on pre-market assessment of these substances and P1024 is currently on hold indefinitely. Delaying this further will impose significant burden on industry and enforcement agencies alike, and potentially place infant health at risk.
2. There is clear ministerial policy direction. FSANZ indicates in its paper that *'As a first step, we considered that the principles for the overarching regulatory approach for infant formula needed to be established. The regulatory approach could range from an all-encompassing prohibition to open permission, or involve a graduated approach commensurate with the risk posed by a substance to infant health'*. FSANZ has been given clear policy direction by food ministers regarding the regulatory framework and approach regarding permissions for infant formula products. Pre-market assessment of nutritive substances and novel foods in infant formula has been consistently required in the Code since infant formula regulations were created 20 years ago. The issue was a significant part of discussions in the development of the Policy Guideline, which was created for the Review of Standard 2.9.1. This Policy Guideline reaffirmed the intention that new types, forms, sources or levels of substances used in infant formula (which includes nutritive substances and novel foods) cannot be added before a pre-market assessment has been conducted by FSANZ. Creating a new set of principles that are at odds with the current regulatory

framework for Standard 2.9.1 and the policy guideline developed for this work is both unnecessary and problematic.

In 2017 FSANZ indicated some of the industry interpreted subclause 6(1)(b), which permits substances naturally present in an ingredient of the infant formula product, to mean that a nutritive substance that occurs naturally in milk can be extracted, purified and separately added to formula, either at the level naturally found or at higher levels for a nutritive purpose without seeking pre-market approval. The departments' view is that the intention of subclause 6(1)(b) was to prevent the unintentional requirement that the individual components of milk would need to undergo pre-market assessment, even though milk itself is a permitted ingredient. The Code has been clear **that a nutritive substance cannot be added to infant formula unless it is expressly permitted**; an interpretation that allows substances to be isolated and added for a specific purpose without pre-market assessment is inconsistent with this intention. The departments believe it would be simple to clarify that if a substance is naturally present in the ingredient when it is added to infant formula, it is permitted (subject to safety and any other conditions), but that if a manufacturer chooses to isolate a specific ingredient and add it separately for a nutritive, health or technological purpose, then a pre-market assessment is required to assess safety and suitability, in accordance with the Policy Guideline. This is also consistent with the operation of the Code more broadly where, for example, a component of a permitted food additive or processing aid cannot be automatically isolated and added to formula for a nutritive purpose without first undergoing pre-market assessment.

3. Consideration together with P1024 is problematic. Given the inherent risk with infant formula products and the target population, the regulatory framework for nutritive substances and novel foods for general foods cannot be applied to infant formula. A nutritive substance that may be considered low risk in the general food supply and able to be added without pre-market assessment, would not necessarily be considered low risk for infant formula. A novel food for infant formula may not be novel when considered in the context of the general food supply. It is unlikely that clarifying the regulatory approach for permissions of substances for infant formula will introduce inconsistencies for the general food supply, as indicated by FSANZ, given the regulatory framework for infant formula is specifically different. P1024 already has considerable complexity which has resulted in its review taking a decade and currently placed on hold. Adding another level of complexity with infant formula will divert the focus from the key issues and be likely to delay work further. The added delays for both P1028 and P1024 are likely to cause concern for both industry and food ministers.
4. Safe and suitable provisions are inadequate for infant formula and do not incorporate the range of regulatory elements set out in the Policy Guideline.

2.2 Novel Foods – Schedule 25

FSANZ has indicated that a number of novel foods currently listed in Schedule 25 that were not specifically assessed for addition to infant formula, infant foods and Formulated Supplementary Foods for Young Children, do not have conditions restricting their use in these products. FSANZ considers that the status of these novel substances as either clearly permitted or prohibited in IFP, infant food and FSFYC should be clarified according to their original assessments. FSANZ proposes to add conditions to achieve the original intention of the assessments for these novel foods which is to restrict them from use in infant formula, infant foods, and FSFYC. **The departments support this approach, as it is consistent with the current regulatory framework for permitting new substances in infant formula and is consistent with the Policy Guideline.** Given their suitability for addition to infant formula was not considered in the original novel food assessment, the departments consider it unlikely that industry would risk using these substances in infant formula from a compliance, enforcement and infant safety point of view and therefore considers clarifying these conditions should have no impact on current products.

Review of optional ingredients

Summary position: The regulatory framework for optional ingredient permissions in infant formula products needs to be updated to include regular reviews of optional ingredients.

As part of the regulatory framework for infant formula products, the departments consider the regulation of optional ingredients needs review.

Public health stakeholders are strongly opposed to optional ingredients in infant formula on the basis that it creates inequity of access to these infant formula products (which are an essential replacement for breastmilk), creates confusion for carers, may potentially mislead carers about the benefits of these formulas and lead mothers to consider these premium products as a benign choice over breastfeeding, potentially reducing breastfeeding rates. Premium infant formulas with optional ingredients can cost two to four times more than standard formula. Assuming optional ingredients are beneficial in moving health outcomes of formula-fed infants towards that of breastfed infants, this results in infants in lower socio-economic populations (who already have a greater risk of relatively lower health status) being unable to obtain the same quality formula and associated health outcomes as infants in higher socio-economic populations.

Industry stakeholders consider optional ingredients enable industry to innovate to improve infant formula and move health outcomes closer to breastfed infants. The departments have been advised by industry that the higher cost associated with premium formula is an important incentive which helps recover product research and development investments.

The departments consider a more balanced regulatory framework could be created for optional ingredients. This framework would involve:

- **a review by FSANZ of the evidence** supporting an optional ingredient (for example three to five years after gazettal, noting this goes beyond usual periods of exclusivity of 18 months).
- If there is sufficient evidence that a substance contributes to optimal growth and development in line with breastfed infants, **then a proposal should be raised to mandate it in infant formula products to make it available to all infants**.
- Alternatively, if the evidence does not demonstrate a role in growth and development, then a **Proposal should be raised to remove the voluntary permission**.

This framework would:

- allow industry to recuperate R&D costs
- enable more equitable access so all formula fed infants requiring these essential products can ultimately benefit from industry innovation
- protect infant health in line with policy guidelines by ensuring innovation is aimed at improving the health outcomes of formula fed infants in line with breastfed infants and minimising risks of burdening infant systems with unnecessary ingredients.

3 Specialised infant formula products

Summary position: The regulation of special purpose infant formula should sit in Standard 2.9.1 and this should include supplementary products such as bovine human milk fortifier.

3.1 Approach to regulation of IFPSDU

The departments note the discussion and consideration of whether infant formula products for special dietary use (IFPSDU) should remain in Standard 2.9.1 or moved to Standard 2.9.5 -Foods for Special Medical Purposes. **The departments support FSANZ's proposed approach to retain the regulation of IFPSDU in Standard 2.9.1 for the reason that there are a number of regulatory provisions associated with formula provided to infants and, as indicated by FSANZ, it would not be ideal to duplicate these in Standard 2.9.5.** The provisions include infant-formula specific:

- Nutrient reference composition
- food additive permissions (including carry-over principle)
- processing aids,
- novel foods,
- contaminant levels and
- labelling restrictions that are in place to protect breastfeeding rates.

3.2 Human milk fortifier and pre-term supplementary products

The departments note that cow's milk based human milk fortifiers used to supplement human milk are not overtly captured by any subcategory in Division 4 of Standard 2.9.1 or by Standard 2.9.5. FSANZ's proposed approach is to only regulate IFPSDU that are the sole or principal sources of nutrition as infant formula products in 2.9.1, whereas other infant products that serve a supplementary role are proposed to be regulated by Standard 2.9.5. FSANZ notes that in regulating these products under 2.9.5, additional provisions may need to be added with respect to reference nutrient composition, the range of permitted forms of vitamins and minerals, food additives, contaminants and microbiological limits as well as labelling. The departments note that the EU regulations have recently been updated to ensure restrictions that apply to infant formula products apply to IFPSMP, with the regulations specifically noting this has been done to address increasing promotion of products and direct targeting of consumers that is not permitted with infant formula.

The departments consider that these supplementary products for infants could be regulated under either 2.9.1 (by incorporating partial or supplementary feeding into the definition of IFPSDU) or 2.9.5 but that regulation under 2.9.5 introduces greater complexity and potentially regulatory uncertainty including:

- the need to duplicate infant-specific permissions/restrictions for food additives, processing aids, novel foods, contaminants, nutritive substances and some labelling elements,
- the regulation of specialised products for infants across two separate standards,
- how 'principal' and 'supplementary' source of nutrition will be determined, particularly when the proportion of supplementary feeds can vary, for example for formulas designed to manage the inborn error of metabolism of phenylketonuria. This formula is often provided in addition to breastfeeds or standard infant formula and the proportion of nutrition requirements it provides can vary.

If the decision is made to include supplementary products in Standard 2.9.5, the additional infant formula products-specific provisions must be introduced into 2.9.5 at the time Standard 2.9.1 is finalised to ensure regulatory continuity and the protection of infant health and safety.

4 Definitions

Summary positions:

Infant formula product: should be amended to include supplementary infant products and retain wording about the base ingredient requirements.

Infant formula: The departments consider that the proposed definition does not make it clear that infant formula is suitable for use by infants up until 12 months of age and could be interpreted as creating a regulatory requirement for follow-on formula.

Other definitions: The departments consider other definitions are not required provided sufficient risk management provisions are put in place.

4.1 Definition of infant formula product

Current definition of infant formula product in Standard 1.1.2: *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.*

Ministerial policy guideline definition: *A manufactured product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve as the principal liquid source of nourishment for infants.*

FSANZ's proposed definition: *An infant formula product means a product that is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants depending on the age of the infant.*

The departments note that FSANZ's proposed definition retains the element of being the sole or principal source of nutrition, which it acknowledges that this excludes a number of IFPSDU that are supplementary, thereby requiring these products to be regulated under Standard 2.9.5 instead. FSANZ has also removed the need for infant formula products to be based on milk or other edible food constituents of animal or plant origin on the basis that some specialised formula (such as that based on amino acids) may not be considered to be based on milk or other edible food constituents. The description of base ingredients is proposed to be moved to a compositional requirement for general IF and FOF only, with no base ingredients to be required for IFPSDU.

As discussed above, excluding specialised infant supplementary formula from Standard 2.9.1 introduces greater complexity and duplication into the Code and the regulation of infant formula. **The departments consider it would be simpler to regulate these formula products under Standard 2.9.1, with an adjustment to the definition to enable this, such as (amendment in bold):**

> *'An infant formula product means a product that is nutritionally adequate to serve by itself either as the sole or principal liquid source of nourishment for infants depending on the age or* ***medical nutrition requirements*** *of the infant',* alternatively:
>
> *An infant formula product means a product that* ***serves as a partial or sole liquid source*** *of nourishment for infants depending on the age or* ***medical nutrition requirements*** *of the infant'*

In relation to the removal of base ingredients, the departments consider that these elements were included in the definition to ensure suitable ingredients with a history of safe use in these products are used. While these base ingredients will be captured for standard infant formula products through compositional requirements, **the departments are concerned that removing any base ingredient requirements for IFPSDU may inadvertently capture products that are not infant formula, including human milk. The departments suggest wording should also be included in the definition to reflect the need for ingredients to be deemed suitable food ingredients, with a history of safe use when added to these products**.

4.2 Definition of infant formula

FSANZ's proposed definition for infant formula is:

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.

Infant means a person under the age of 12 months

FSANZ notes that the definition of infant is applicable in the definition of infant formula. To assist interpretation, it is proposed to insert the definition of *infant* into the note to section 2.9.1—3 to indicate the total period for which infant formula is suitable.

The departments support FSANZ's proposed approach to changing the age from 4 to 6 months to 'under 6 months' in reference to completely meeting nutritional requirements of infants. However, t**he departments are concerned that the definition of infant formula does not clearly reflect its purpose as a breastmilk substitute, that is, suitable for use by infants up until 12 months** of age.

In 2016, FSANZ considered the additional wording for b): *satisfies by itself the nutritional requirements of infants under the age of 6 months and, as part of a progressively diversified diet, of infants from 6 months of age*. The departments supported this addition to clarify that infant formula is appropriate for use as a breastmilk substitute from birth to 12 months of age. This is consistent with the advice in the National Health and Medical Research Council's Infant Feeding Guidelines which states that the use of 'follow-on formula' for infants aged 6–12 months is not considered necessary and no studies have shown advantages over using infant formula'[3].

FSANZ has not discussed this further but has noted that including the definition of infant up until 12 months indicates the total period for which infant formula is suitable. **The departments do not agree that the definition makes it clear that infant formula is an appropriate breastmilk substitute for birth to 12 months** and the proposed definition could be interpreted to mean that infant formula is only appropriate up until 6 months. **This could create a regulatory requirement for follow-on formula, a product not supported by national guidelines and evidence**.

The departments agree that the definition must 'set out the regulatory identity and purpose of infant formula, which then determines the appropriate compositional requirements and labelling to guide safe and intended use' and **that this is best achieved by the addition of the wording '*and, as part of a progressively diversified diet, of infants from 6 months of age*'.**

4.3 Other definitions

FSANZ is considering whether the current definitions for soy-based infant formula, pre-term formula and medium chain triglycerides are required for limits on aluminium (soy and pre-term) and for use in formula using protein substitutes. The departments note the new approach proposed for Division 4 (IFPSDU) will enable relevant conditions of use (taken from EU food additive regulations) for specialised infant formulas such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism or those partially hydrolysed. We also note that the EU does not define most of these terms.

FSANZ QUESTIONS

1) **To manufacturers, please provide information on whether the substances [novel foods] listed in Table 5 are used in infant formula products, food for infants and formulated supplementary food for young children.**
   N/A

2) **Is a definition of soy-based formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.**

It is unclear what purpose the definition for soy-based formula would serve. In its consultation paper on food additives FSANZ has proposed a single aluminium limit for all infant formula (rather than a separate limit for soy formula).

Some of the nutritional compositional requirements do differ for soy-based formula due to the reduction in bioavailability however **it is the departments' view that a definition is not required**. **If the current definition were to be retained (*An IFP in which soy protein is the sole source of protein*), there could be regulatory inconsistencies if a product contained other protein sources in addition**

[3]NHMRC, Infant Feeding Guidelines: information for health workers. 2013.

to soy. The departments note that EU 2016/127 specify different nutritional compositional requirements for 'Infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins' but do not appear to define a soy-based formula itself. If needed, t**he departments support wording similar to the EU**.

3) Is a definition of pre-term formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

There do not seem to be specific food additive requirements proposed for pre-term formula. The departments also note that Codex and EU do not appear to define pre-term formula.

The departments consider that individual classes or conditions being managed (in the dietary context) by special purpose formula should not need to be defined; current medical definitions should be sufficient, provided sufficient risk management strategies are put in place. These include:

- the product clearly stating the purpose or condition it is managing and the modifications made that make it suitable for example, 'not for general use, suitable only for XX condition under medical supervision'.
- A semi-prescribed name for infant formula products for medical purposes to clearly identify these products and their purpose both for consumers and for regulators, allowing for variations for imported products
- the requirement in the definition for these products to be effective in their purpose for the dietary management of the proposed condition (in line with EU regulations)
- semi-prescribed labelling for 'use under medical supervision is required'
- access limits in line with Standard 2.9.5.
- provisions to manage prohibition of nutrition and health claims within the above requirements to declare the intended condition and modifications.

This would address the current labelling requirements for pre-term formula that include a prescribed name and the advisory statement 'suitable only for pre-term infants under specialist medical supervision'.

If specific regulatory provisions were required for certain formula, for example, potentially prohibiting the addition of lactic acid producing microorganisms to pre-term formula or permitting a substance only in pre-term formula, compliance would be determined on the basis of the identified purpose of the product (e.g. labelled as being for pre-term infants).

4) Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1 such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.?

The departments note that FSANZ is considering a number of new food additives approved in the EU for certain IFPSDU, for example for gastro-oesophageal reflux or metabolic disorders and that these are not defined in the EU regulations. **The departments consider regulatory compliance for use of a food additive could be determined via the labelled purpose of the product and the standard medical definition.** Where a product can be used for multiple medical conditions, the dietary condition being managed and the associated modifications need to be made clear e.g. 'suitable for infants requiring a lactose-free diet under medical supervision'.

5 Regulatory framework for IFPSDU

Summary positions:
Categories:

The departments support a single category called Infant Formula Products for Special Medical Purposes (IFPSMP) for any infant formula product that is modified or labelled as being for the dietary management of a condition. There must be sufficient risk management provisions.

Principles:

The departments support the principles with some amendments, including permitting supplementary infant products; ensuring deviation from compositional requirements specifies 'essential' composition and still requires pre-market assessment of new substances; not introducing provisions for use beyond 12 months; and including protections relating to labelling, presentation, and advertising.

The departments note and support the concerns raised about the preliminary proposal in 2017 to change from three subcategories of IFPSDU to four with the creation of a transient gastrointestinal category. We agree that the current regulatory framework with subcategories in Division 4 for IFPSDU (products for premature or low birthweight infants, products for metabolic, immunological, renal, hepatic and malabsorptive conditions and products for specific dietary use based on a protein substitute) creates inconsistencies in definitions and labelling.

The departments strongly support FSANZ's proposed approach to create a single category, called Infant Formula Products for Special Medical Purposes (IFPSMP), provided there are sufficient risk management strategies put in place (as outlined above) to manage the broadening of regulations to allow products for potentially any condition. FSANZ proposes that subcategories should only be established if specific regulation beyond that set for all of Division 4 is needed. **The departments agree to this in principle.**

5.3 Principles for purpose, composition, use and sale of IFPSDU

FSANZ has outlined its proposed principles to guide the framework for the regulation of composition, use and access of IFPSDU. The departments support most of these principles, with specific comments provided in the table below:

FSANZ principles **that IFPSDU:**	**Departments' Comments**
1. serve as a sole or principal source of nourishment for infants (IFP definition) 2. serve as a substitute for human milk, and replacement for infant formula and follow on formula	The departments consider that its role in nourishment and replacement of breastmilk or formula should only be in the context of a medical need and this needs to be reflected in these principles. It is also the departments' preference that all infant formula products be regulated under 2.9.1 for reasons outlined above. Therefore, the departments recommend the first two principles be combined and reworded along the lines of: 1. serve as a partial or sole source of nourishment for infants when a diagnosed medical condition requires dietary management that is unable to achieved with breastmilk or infant formula alone.
3. are formulated for infants with a specific disease, disorder or medical condition	Support

4. are intended to meet an infant's nutritional requirements to support growth and development	Support
5. are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose	As the purpose of these products are also to provide nourishment, the need for these products to be effective needs to be clearly linked to the proposed condition. E.g. 'are formulated in accordance with scientific evidence that demonstrates the efficacy of the product *for the dietary management of the intended condition/ in accordance with the intended purpose of the IFPSMP*
6. have a nutrient composition that reflects that of IF or FOF except where necessary to meet the intended purpose of the IFPSMP	Support Important risk management clarifications should include: – permission to deviate from the *essential* composition of infant formula (optional ingredients should not be given unless specifically for dietary management of condition). This is due to even greater vulnerability of infants requiring IFPSMP and being susceptible to burden of unnecessary ingredients. – Pre-market assessment is still required for all new substances not currently permitted in infant formula.
7. are intended for use under medical supervision to manage risk to unhealthy infants	Not only to manage the risk to 'unhealthy infants' but to manage the risk to all infants: formula fed and breastfed[4][5][6].
8. used in infancy and beyond should be accommodated in regulation	Do not support. The Code does not currently prohibit the use beyond infancy and it is beyond the scope of the Code to prescribe the medical use of these products. The use of IFPSDU beyond infancy is done on a case by case basis based on the child's weight and size, activity level, status of the medical condition and specific nutrition requirements. Broadening the age range in regulations risks inappropriate use and creates

[4] Belamarich, P. F. et al. *A critical review of the marketing claims of infant formula products in the United States***.** Clinical Pediatrics*,* 2016 55(5), 437-442

[5]Douglas, P. S. *Diagnosing gastro-oesophageal reflux disease or lactose intolerance in babies who cry alot in the first few months overlooks feeding problems*. J Paediatr Child Health, 2013 49: E252–E256.

[6] Douglas, P. S. *Diagnosing gastro-oesophageal reflux disease or lactose intolerance in babies who cry a lot in the first few months overlooks feeding problems*. J Paediatr Child Health, 2013 49: E252–E256.

	potential uncertainty for regulators in these products for compliance and enforcement purposes. These products should continue to indicate suitable age range, e.g. from birth to 12 months, with medical decisions about use beyond this time left to the discretion of the treating medical team.
9. are subject to a restriction on sale.	Support
10. **The departments believe there is an additional, important principle** (in line with the EU regulations): should incorporate protections relating to infant formula regarding labelling, presentation, advertising, and promotional and commercial practices, with adjustments for necessary labelling relating to the intended purpose of the product	

5.4 Name and definition of IFPSDU

Summary position:

The departments support the proposed name and definition with minor amendments to the definition to make it clear that the IFPSMP must be safe, beneficial and effective for the partial or full dietary management of the specified condition.

Name

The departments support FSANZ's proposed approach to change the name of IFPSDU to Infant Formula Products for Special Medical Purposes (IFPSMP). This better reflects the unique nature and audience of infant formula and the associated regulatory framework which needs to ensure specialised products are only created where there is a valid medical need and the dietary management cannot be met through breastmilk or standard formula alone. This is also more consistent with the EU naming of 'food for special medical purposes for infants'.

Definition of IFPSMP

The departments support FSANZ's approach to create a definition based around the elements of a 'food for special medical purpose' as defined in Standard 2.9.5, with adjustments for infant products to reflect the vulnerable nature of this population and the need for a regulatory framework that reflects this greater risk.

The proposed definition is a good start to capture the elements needed for these very specialised products. Minor improvements should be made to ensure adequate risk management strategies are in place given the increasingly broad category and the lack of compositional requirements for specific conditions, to ensure certainty in product identity for compliance and enforcement purposes and to improve alignment with EU as the majority of products are imported from the EU. The departments suggest the definition is amended to incorporate these elements as follows (amendments in bold):

- serves as a substitute for human milk, and replacement of infant formula and follow on formula
- is specially formulated ***to be safe, beneficial and effective*** for the ***partial or full*** dietary management of ***the specified condition*** in infants based on appropriate scientific evidence.
    - *[the words 'safe, beneficial and effective' are taken from EU regulations and ensure products captured by IFPSMP are legitimate medical purpose products.*

  - *'Partial or full' dietary management also aligns with the EU provisions and allows supplementary formula to be included in 2.9.1 which minimises the complexities of managing these products under a separate Standard.*
  - *It is important that it is specified that these products are 'formulated…for the dietary management of the specified condition' rather than just of infants. This ensures the products must be formulated for their specific purpose rather than just to meet infant nutritional requirements]*

- is for infants:
  - who have special medically determined nutrient requirements, **and** *[if 'or' to remain, must insert 'medically determined' into point below ie medically determined impaired capacity.]*
  - who have limited or impaired capacity to take, digest, absorb, metabolise other IFPs or excrete the metabolites of other IFPs, and
  - whose dietary management cannot be completely achieved without the use of IFPSMP
- is a food that must be used under medical supervision.

5.5 Provisions for IFPSMP — composition

Summary position:

The departments support a provision to allow for compositional deviation for all IFSMP but that this should specify: this is only permitted for the purposes of the condition based on scientific evidence; deviation should only be permitted from the *essential* composition unless an optional ingredient is specifically required for the dietary management of the condition; and that substances not currently permitted in infant formula still need to undergo pre-market assessment.

In relation to specific compositional elements, the departments consider:

- further risk assessment is required to establish maximum manganese levels for both standard infant formula and IFPSMP.
- lactose-free should mean no detectable lactose.
- the need for a low lactose definition is unclear and its inclusion and level should be based on a medical need for these infant products
- compositional nutritional requirements for products for specific dietary use based on a protein substitute are not necessary
- for molybdenum and chromium, an amended Option 1 is supported, which is to require the presence of molybdenum only (not chromium) in infant formula pending as assessment of the essentiality of chromium.
- For medium chain triglycerides (MCT), Option 1 is supported: to apply the permission to the entire IFPSMP category with limits specifying addition is only permitted where necessary to manage the specified condition

Deviation from infant formula compositional requirements

The departments note and support in principle FSANZ's proposed approach to continue to allow compositional deviation from infant formula for IFPSMP (and extend to all IFPSMP). FSANZ has not proposed draft wording at this stage. **The departments support drafting that clarifies that deviation from essential IF composition is only permitted for the specified condition of the IFPSMP based on scientific evidence** (to prevent creating a nonspecific permission to deviate from infant formula composition).

The departments remain concerned about barriers to trade for these products given that FSANZ's proposed approach in Consultation Paper 2 continued to align the composition of standard infant formula to the Codex levels for many nutrients, rather than the recently updated EU levels (which no

longer align with Codex). With the majority of special purpose formula being imported from the EU, and the requirement that these formulas only deviate from the mandatory compositional requirements of standard infant formula where required by the condition, this could lead to many of these formulas being non-compliant with the Code.

Optional Ingredients

The departments support drafting that specifically excludes optional ingredients from permissions for IFPSMP, unless specifically needed to manage the intended condition. The inclusion of unnecessary components, or unnecessary amounts of components, has been recognised to place a burden on the metabolic and other physiologic functions of the infant, particularly under conditions of stress and illness, which would be expected for many medical conditions[7]. Studies used to inform safety assessments to support permissions for optional ingredients are routinely conducted in healthy infants and the findings cannot be extrapolated to infants with medical conditions.

If optional ingredients are not to be excluded from IFPSMP, then a regulatory framework for optional ingredients that involves regular reviews and removal of permissions for unnecessary substances becomes more imperative.

Pre-market assessment

It is important that the drafting also clearly specifies that the requirement for pre-market approval remains for nutritional modifications that would involve the addition of a substance not approved in infant formula generally. This should include all new substances (including nutritive substances, bioactive substances, food additives and processing aids). The Policy Guideline acknowledges the vulnerability of infants and the need for the regulatory framework to require new substances to undergo premarket safety and suitability assessments. From a risk point of view this is even more important for products for infants with medical conditions, who are more vulnerable than healthy infants. If this is not specified, it may also create a perverse incentive for companies to trial new substances in IFPSMP in order to establish a history of safe use and potentially enable them to be used in standard formula without pre-market assessment.

Retention of subcategories

The departments view is that subcategories are not required. All IFPSMP should be permitted to deviate from compositional requirements for infant formula to manage the specified condition, provided that the other risk management strategies discussed in our comments on the principles and definition are included. Similarly, specific permissions to add substances to IFPSMP (such as food additives) should be applied to the whole category, provided drafting specifies these additions are to meet the intended purpose.

QUESTIONS

5) To health professionals: Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk? If you consider that there is a health concern or risk, please provide relevant details and data, where available.

6) To industry submitters: How many and what types of low lactose IFPSDU are on the market? What is their maximum level of lactose? Please provide supporting detail and data, where available.

Manganese

The departments note that products for metabolic, immunological, renal, hepatic and malabsorptive conditions have a significantly lower guideline maximum amount for manganese than for standard

[7] Koletzko, B., et al., Global standard for the composition of infant formula: recommendations of an ESPGHAN coordinated international expert group. Journal of Pediatric Gastroenterology and Nutrition, 2005. 41(5): p. 584-599.

infant formula (7.2 µg/100 kJ compared to 24 µg/100 kJ). FSANZ proposes to increase the maximum level to align with standard formula. FSANZ has not indicated why a lower level was originally set. **The departments consider it is important to understand why a lower limit was set and the risks of increasing the level.** Manganese is a trace element but there is growing recognition that it is also a toxicant, with excess levels resulting in neurotoxicity[8]. A number of studies have assessed this, with one finding that children consuming water containing >400 µg/L showed significant reductions in academic achievement (noting a maximum of 24 µg/100 kJ is equivalent to 654 µg/L and provides levels above this)[9]. Recent literature calls for a review of manganese regulations in infant formula and formulas for young children[10]. In infants requiring IFPSMP impaired hepatic or renal function may result in a higher risk of manganese accumulation[11], noting higher manganese levels were measured in adults with chronic renal failure[12]. **The departments request further risk assessment is conducted to determine a guideline maximum amount for both standard and IFPSMP that is not associated with increased risk of neurotoxicity**.

Low lactose/ Lactose-free formula

The departments support 'lactose-free' formula as being 'no detectable lactose' (in line with Australian Competition and Consumer Commission (ACCC) advice and the definitions in the Code more generally) and that this criterion would apply across all IFPSMP. **The departments are less clear on the need for a definition, and associated criterion of 0.3g lactose/100mL for a 'low lactose formula'. A decision on this should be based on determining whether a low lactose formula is a valid dietary treatment for a condition and then the level of lactose required for it to be considered 'low-lactose'.** The departments note the EU permits only lactose-free claims.

Products for specific dietary use based on a protein substitute

QUESTIONS

7) To industry and government submitters: What types of partially hydrolysed IFP are on the market? And what is their maximum level of protein denaturation? Are any on the pharmaceutical benefits schemes in Australia or New Zealand? Please provide supporting detail and data, where available.

8) To health professionals: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy? Please provide supporting detail and data, where available

The departments are not aware of any partially hydrolysed infant formula on the Pharmaceutical Benefits Scheme in Australia (only extensively hydrolysed and amino acid formulas).

[8] Roels HA, Bowler RM, Kim Y, Claus Henn B, Mergler D, Hoet P, Gocheva VV, Bellinger DC, Wright RO, Harris MG, Chang Y, Bouchard MF, Riojas-Rodriguez H, Menezes-Filho JA, Téllez-Rojo MM. Manganese exposure and cognitive deficits: a growing concern for manganese neurotoxicity. Neurotoxicology. 2012 Aug;33(4):872-80. doi: 10.1016/j.neuro.2012.03.009. Epub 2012 Apr 3. PMID: 22498092; PMCID: PMC3839941.

[9] Khan K, Wasserman GA, Liu X, et al. Manganese exposure from drinking water and children's academic achievement. Neurotoxicology. 2012;33(1):91-97. doi:10.1016/j.neuro.2011.12.002

[10] Mitchell EJ, Frisbie SH, Roudeau S, Carmona A, Ortega R. How much manganese is safe for infants? A review of the scientific basis of intake guidelines and regulations relevant to the manganese content of infant formulas. J Trace Elem Med Biol. 2021 May;65:126710. doi: 10.1016/j.jtemb.2020.126710. Epub 2020 Dec 25. PMID: 33450552.

[11] Erikson KM, Thompson K, Aschner J, Aschner M. Manganese neurotoxicity: a focus on the neonate. Pharmacol Ther. 2007 Feb;113(2):369-77. doi: 10.1016/j.pharmthera.2006.09.002. Epub 2006 Sep 22. PMID: 17084903; PMCID: PMC1852452.

[12] Sánchez-González C, López-Chaves C, Gómez-Aracena J, Galindo P, Aranda P, Llopis J. Association of plasma manganese levels with chronic renal failure. J Trace Elem Med Biol. 2015;31:78-84. doi: 10.1016/j.jtemb.2015.04.001. Epub 2015 Apr 16. PMID: 26004896.

The departments have been advised that clinically, hydrolysed formula is used for allergy management, not prevention. Systematic reviews, including a recent Cochrane review, have concluded the evidence does not support the use of partially or extensively hydrolysed formula in reducing risk of or preventing allergic disease[13,14]. This led to the recent guidance from the Australasian Society of Clinical Immunology and Allergy (ASCIA) which does not recommend hydrolysed formula for the prevention of allergic disease[15]. In relation to dietary management, ASCIA also states that 'Partially hydrolysed formula is not a suitable formula for babies with cow's milk allergy as enough allergenic protein is usually present to trigger an allergic reaction.' This is consistent with advice we have had from paediatric dietitians.

The departments consider that specific compositional nutrient requirements for products for specific dietary use based on a protein substitute are not necessary and that, similar to other IFPSMP, composition should be able to deviate from infant formula where it is necessary for the specific condition, based on scientific evidence (noting that modified fats and carbohydrates can also be required with extensively hydrolysed protein). **Specific permissions, for example for medium chain triglyceride (MCT) oil, should be for all IFPSMP, with drafting that indicates addition is only permitted for the purpose of managing the specified condition.**

Molybdenum and chromium in protein substitutes

The departments note that molybdenum and chromium contents are not, and are not proposed to be, regulated in standard infant formula because sufficient amounts are provided naturally by base ingredients. For amino acid formulas, these trace elements are not naturally present and are currently required to be added (2.9.1 – 15(2)(e) currently prescribes minimum and maximum levels of molybdenum and chromium to be achieved naturally and/or by addition to protein substitutes).

QUESTION

9) Regarding options for the regulation of molybdenum and chromium, which option do you prefer and why? Please provide supporting detail and data, where available.

If Division 4 were to become one category, FSANZ has proposed the following options for the regulation of molybdenum and chromium:

1. Retain current mandatory requirement to be met naturally and/or through addition for protein substitutes – status quo
2. Permit voluntary addition within compositional limits to be met naturally and/or through addition for all IFPSMP
3. Permit voluntary addition without any compositional limits for all IFPSMP
4. Delete the requirement altogether which then serves to prohibit addition since molybdenum and chromium are classified as nutritive substances, and their permitted forms in section S29–7 become redundant.

The departments note that chromium is no longer considered an essential trace mineral by the European Food Safety Authority (EFSA) but it proposed a minimum molybdenum content for infant formula of 0.4ug/100kcal[16]. The regulations for infant formula and special medical purpose formula

[13] Boyle, R. J. *et al.* (2016) 'Hydrolysed formula and risk of allergic or autoimmune disease: Systematic review and meta-analysis', *BMJ (Online)*, 352. doi: 10.1136/bmj.i974.

[14] Osborn, D., Sinn, J. and Jones, L. (2018) 'Infant formulas containing hydrolysed protein for prevention of allergic disease (Review)', *Cochrane Database of Systematic Reviews*, (10). doi: 10.1002/14651858.CD003664.pub6. Copyright.

[15] ASCIA (2020) *ASCIA Guidelines- infant feeding and allergy prevention*. Available at: https://www.allergy.org.au/hp/papers/infant-feeding-and-allergy-prevention (Accessed: 11 October 2021)

[16] EFSA (2014) 'Scientific Opinion on the essential composition of infant and follow-on formulae',

do not seem to have a minimum requirement for molybdenum however. The departments consider that if molybdenum is considered essential for infants, then it must be present in a breastmilk substitute (standard or medical purpose formula) unless the specific condition requires its exclusion. Pending further advice from FSANZ on the essentiality of molybdenum, **the departments support an amended Option 1, which is to require the presence of molybdenum only (not chromium) in infant formula**.

Medium Chain Triglycerides (MCT)

The departments note that MCT oil is not permitted to be added to standard infant formula for a range of reasons (such as risks of deficiency of essential unsaturated fatty acids and some fat-soluble vitamins) but is currently permitted in certain IFPSDU. FSANZ proposes that if Division 4 were to become one category, the options in relation to the use of MCT are that permission is:

1. Applied to the entire IFPSMP category, with or without limits
2. Removed from protein substitutes with the effect that Division 4 is silent and possibly unclear with respect to its use but noting the restriction proposed for IF in Consultation paper 2 (FSANZ 2021).

QUESTIONS

10) To industry submitters: What type of products contain MCT oil? For what purpose and at what levels? Please provide supporting detail and data, where available.

11) To health submitters: Are there any health concerns from current practice using products that contain MCT oil? Please provide supporting detail and data, where available.

The departments support Option 1, to apply the permission to the entire IFPSMP category **with limits specifying addition is only permitted where necessary to manage the specified condition,** rather than a broad permission (given the concerns raised in Consultation Paper 2 about its general addition to standard formula, the proposal to not permit unless naturally present and the possibility that industry may use it more broadly if this is not specified, noting from CP2 that industry sought MCT permissions in all infant formula to enable flexibility in the type of fat used).

5.6 Provisions for IFPSMP — purpose, use and sale

5.6.1 Scientific evidence of purpose

Summary position:

The departments consider scientific evidence of effectiveness for the specified condition is an essential risk management strategy for IFPSMP and that this should be a provision in Division 4 rather than a principle. The departments do not yet have a position on whether evidence requirements should be set out as for health claims in schedule 6.

FSANZ has proposed to enshrine in regulation the principle that IFPSMP are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose. This is consistent with Codex and the EU regulations for medical purpose formula. **The departments strongly support this approach.** Given the particularly vulnerable nature of this population of infants and the relatively broad permission to deviate from standard infant formula composition, a requirement for scientifically valid and effective products is essential to discourage the development of unnecessary products. It is particularly important that the intended purpose **be specified as the medical purpose**, rather than leaving an open statement, which may be taken to mean the intended purpose as a breastmilk substitute to provide nourishment.

EFSA Journal, 12(7), pp. 1–106. doi: 10.2903/j.efsa.2014.3760.

The departments support FSANZ's proposed approach to insert this as a provision in Division 4 (in line with international regulations) rather than include it as a 'principle' to be followed. FSANZ has indicated such a provision could be a simple statement of requirement without further detail on how the requirement should be met (similar to Codex and EU). Under this arrangement, industry would be expected to hold the evidence for a product's efficacy in line with its represented purpose, and determination of a product as IF or IFPSMP would become the responsibility of enforcement agencies. Alternatively, the requirement could be accompanied by guidance either in the Code, similar to Schedule 6 for health claims, or elsewhere such as a code of practice, on how the requirement should be met. **The departments do not have a position yet as to which approach would be preferable, however considers that an enforcement agency should not have to determine whether a product is an IFPSMP or a standard formula and that the prescribed names (infant formula or IFPSMP) are important for regulatory certainty. The questioning of compliance with efficacy requirements for IFPSMP is then secondary.**

Questions related to scientific evidence of purpose for IFPSMP

12) To industry submitters: Do infant formula manufacturers hold scientific evidence that supports the purpose of Division 4 products, including for reflux, colic, diarrhoea, and similar products (i.e. for less serious conditions)?

N/A

13) If so, what type of scientific evidence is held by companies and what is its strength of evidence?

N/A

5.6.2 Extension of use beyond infancy

Summary position: The departments do not support including provisions for labelling a product for use beyond infancy.

FSANZ indicates it is 'open to permitting the use of IFPSMP beyond infancy in the regulation of IFP' and its preliminary view is that extension of use beyond infancy may be appropriate in some circumstances.

14) What is the maximum labelled age on products suitable for use beyond infancy? What are the parameters that indicate when the product is no longer appropriate?

The departments do not support regulatory changes to label IFPSMP as suitable beyond infancy.

The Code currently indicates an age range for infant formula products (e.g. 0-12 months) but does not actually prohibit use of any formula beyond a certain age. **The departments are of the view that it is beyond the scope of the Code to regulate medical usage or practice**. Discussions with clinical paediatric dietitians indicate use of paediatric formula beyond infancy is determined on a case by case basis guided by a combination of factors and individual requirements (i.e. the individual size, weight, activity, medical condition of the child). No single parameter would make a formula broadly suitable after 12 months and specifying an extended age could encourage inappropriate use. **The departments consider that use of an IFPSMP beyond infancy should continue to be at the discretion and under supervision of the health professional and not specified by food regulations or labelling**. This ensures sufficient support is provided to avoid nutritional imbalances and other health risks.

5.6.3 Lactose-free and low-lactose formulas

Summary position: The departments do not support formulas that are modified to be and/or presented as being lactose-free being classified as standard formula and exempt from the risk management provisions of IFPSMP.

FSANZ indicates that in the original proposal for infant formula (P93) in 1999, then ANZFA indicated that 'with the exception of formulas targeted to lactose intolerant infants, special purpose formulas are not suitable for general use and are to be labelled as such'. Standard 2.9.1 currently includes provisions for lactose-free and low lactose claims. Codex does not include provisions for lactose claims while the EU permits lactose-free statements (but not low-lactose statements) for infant formula and follow-on formula if specific compositional criteria are met. Article 9 of Regulation EU 2016/127 also requires the statement 'not suitable for infants with galactosaemia' for infant formula and follow-on formula manufactured from protein sources other than soy protein isolates.

FSANZ's preliminary view is that lactose-free formula should be considered general purpose formula, the current lactose labelling provisions should continue, a galactosemia statement is not required because galactose content is declared and performs the same function, and that the Standard should clarify that IFPSMP labelling provisions would not apply (use under medical supervision).

The departments do not support classifying 'lactose-free formula' as standard formulas (exempting them from identifying as a medical purpose formula or requiring medical supervision) on the basis of them being of low acute risk to healthy infants. Understanding of the role of lactose for infant growth and development and the effects of marketing of modified formulas have grown over the past 20 years. The predominant source of carbohydrate in breastfed infants is lactose, providing 40% of energy. The acute nutritional risk of lactose-free formula to healthy infants may be low, but these products are not necessarily benign nor without consequences. For example, lactose is important for calcium absorption and the development of an optimal gut microbiome and lactose-free formulas have been found to elicit different insulin, glycaemic and neurological effects which could have long term implications for health[17,18,19,20,21]. Consumption of a lactose-free formula may impair the development of a healthy gut microbiome, and there is some evidence for this in infants with allergic disease[22]. Other concerns raised in the literature include increased dental caries (from replacement sugars) and unnecessary longer term dietary restrictions which may increase the risk of inadequate nutrients required for growth[23,24]. Research from the United States indicates excessive and increasing use of lactose-free formulas despite little or no evidence that lactose-reduced formulas are beneficial, with the suggestion that use should be limited to true lactose intolerance[25]. Other literature describes claims such as lactose-free as representing 'indication creep' to widen the use of modified formulas by exploiting a mistaken health belief regarding the prevalence of lactose intolerance in infants and

[17] Romero-Velarde E, Delgado-Franco D, García-Gutiérrez M, Gurrola-Díaz C, Larrosa-Haro A, Montijo-Barrios E, Muskiet FAJ, Vargas-Guerrero B, Geurts J. The Importance of Lactose in the Human Diet: Outcomes of a Mexican Consensus Meeting. Nutrients. 2019 Nov 12;11(11):2737. doi: 10.3390/nu11112737. PMID: 31718111; PMCID: PMC6893676.

[18] Steven A Abrams, Ian J Griffin, Penni M Davila, Calcium and zinc absorption from lactose-containing and lactose-free infant formulas, The American Journal of Clinical Nutrition, Volume 76, Issue 2, August 2002, Pages 442–446, https://doi.org/10.1093/ajcn/76.2.442

[19] Rossen et al. Types of Infant Formulas Consumed in the United States Clin Pediatr (Phila). 2016 March ; 55(3): 278–285

[20] Crawley, H. and Westland, S. (2018) *Infant Milks in the UK: A Practical Guide for Health Professionals*, *First Steps Nutrition*. England.

[21] lupsky, C.M., He, X., Hernell, O. et al. Postprandial metabolic response of breast-fed infants and infants fed lactose-free vs regular infant formula: A randomized controlled trial. Sci Rep 7, 3640 (2017). https://doi.org/10.1038/s41598-017-03975-4

[22] Francavilla, R. et al. Effect of lactose on gut microbiota and metabolome of infants with cow's milk allergy. Pediatric Allergy and Immunology, 2012, 23: 420–427.

[23] Crawley, H. and Westland, S. (2018) *Infant Milks in the UK: A Practical Guide for Health Professionals*, *First Steps Nutrition*. England.

[24] Douglas P & Hiscock H. The unsettled baby: crying out for an integrated, multi-disciplinary primary care approach. MJA 2010; 193 (09): 533-536.

[25] Di Costanzo M, Berni Canani R: Lactose Intolerance: Common Misunderstandings. Ann Nutr Metab 2018;73(suppl 4):30-37. doi: 10.1159/000493669

potentially impacting on breastfeeding[26]. Limiting access to pharmacies and clear labelling about the need for medical supervision could help address concerns about overuse of these products.

Infants that are unable to be breastfed should consume a breastmilk substitute which uses breastmilk composition as its primary reference**. A formula which has been modified to be a lactose-free formula is no longer standard and should be considered an IFPSMP and subject to the same risk management provisions including the need to be effective for the proposed condition, used under medical supervision and subject to access limitations to ensure there are checks for appropriate use where possible**.

The departments note that soy-based formula is considered a standard formula and is lactose-free. The departments consider an argument could be made to classify soy formula as an IFPSMP given it diverges further from the reference composition of breastmilk than cow's milk based products. Alternatively, soy-based formula could remain as standard formula unless it represents itself as being appropriate for the dietary management of a condition (such as for infants requiring lactose-free); in this instance it should be regulated as an IFPSMP. Lactose-free claims, like other nutrition and health claims, should be prohibited on general formula. Carers seeking to use soy formula for the management of a medical condition under medical supervision can source information about relevant ingredients such as lactose or cow's milk protein from the ingredients list. This is similar to the situation where health professionals advise patients on the use of general foods to help manage a medical condition, without needing to classify these foods as FSMPs.

5.6.4 Distribution and access

Summary position: The departments access restrictions for IFPSMP in line with Standard 2.9.5.

FSANZ indicates that to be consistent with risk management approaches within Standard 2.9.5, a restriction on sale is appropriate for the sale of IFPSMP. FSANZ's preliminary view is that supermarket sales of infant formula products will be restricted to general infant formula and that access to IFPSMP will be restricted to those medical practitioners, responsible institutions, or permitted sellers (to be defined in the Code, similarly to Standard 2.9.5). **In line with our comments in 2017, the departments support this approach. The departments also support including formulas modified to be, or represented as being, for the management of a medical condition in this access restriction.**

5.7 Labelling of IFPSMP

Summary positions:

The departments support (with some conditions) FSANZ's preliminary views:

• to replace the labelling provisions for pre-term formula and IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions (except for lactose-free and low lactose formulas) with FSMP provisions in paragraphs 2.9.5—10(1)(a) to (f) **BUT this needs to be extended to all IFPSMP, not just formula for the conditions listed above.**

• that replicating allergen declaration requirements and advisory and warning statements in subsections 2.9.5 —10(2) and (3) in Standard 2.9.1 for all infant formula products is unwarranted

• to adopt an approach consistent with section 2.9.5—11 for information relating to ingredients to be made in accordance with Standard 1.2.4 or information that complies with European or United States regulations **provided this does not permit nutrition or health claims, even if these are present on imported products.**

[26] Belamarich, P. F. et al. A critical review of the marketing claims of infant formula products in the United States. Clinical Pediatrics, 2016 55(5), 437-442

• to adopt an approach consistent with section 2.9.5—12 for date marking information to be made either in accordance with Standard 1.2.5 or for the words 'Expiry date' or similar words to be used on the label

• to extend the exemption from the 'breast milk is best' warning statement to all IFPSMP, **provided IFPSMP are clearly labelled with a prescribed name**
• extend the exemption from the statement about offering other foods in addition to IFPs to all IFPSMP **provided all formulas presented as, or modified, for conditions are subject to access provisions and are labelled with a prescribed name.**
• exempt IFPSMP from the requirement for a statement that the infant formula product may be used from birth
• the general directions for preparation and use requirements are appropriate for IFPSMP, and there are no additional, specific directions that should be mandated. **Drafting for preparation and use should include provisions that allow for deviation where required for IFPSMP.**

The departments also support a clear prohibition on **nutrition and health claims**, semi prescribed labelling for '**use under medical supervision'** and provisions that state the **Potential Renal Solute Load** should be included on labels where possible.

The departments **do not** support FSANZ's preliminary views:

• for lactose-free and low lactose formulas, maintain existing labelling requirements and clarify that IFPSMP labelling provisions would not apply

• the prescribed name 'Infant formula' does not apply to IFPSMP, and that no overarching name should be prescribed for this category. Generic provisions in paragraph 1.2.2—2(1)(b) would apply to IFPSMP

QUESTION

15) Do you support FSANZ's preliminary views for IFPSMP labelling? Why or why not? Please provide supporting detail and data for your position, where available.

FSMP statements

The Code currently requires:

- for IFPSDU formulated for premature or low birthweight infants, a warning statement 'Suitable only for pre-term infants under specialist medical supervision' (paragraph 2.9.1—13(2)(a))
- for IFPSDU suitable for infants with metabolic, immunological, renal, hepatic or malabsorptive conditions, statements in paragraphs 2.9.1—14(2)(c)-(e) indicating the:
- product is not suitable for general use and should be used under medical supervision
- condition, disease or disorder for which the product has been specially formulated, and
- nutritional modifications, if any, which have been made to the product

Subsection 2.9.5—10(1) requires FSMP to be labelled with the following advisory or warning statements:
a) a statement to the effect that the food must be used under medical supervision
b) a statement indicating, if applicable, any precautions and contraindications associated with consumption of the food
c) a statement indicating the medical purpose of the food, which may include a disease, disorder or medical condition for which the food has been formulated
d) a statement describing the properties or characteristics which make the food appropriate for the medical purpose
e) 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

f) a statement indicating whether or not the food is suitable for use as a sole source of nutrition
g) a statement to the effect that the food is not for parenteral use and any additional statements describing any nutritional modifications made
FSANZ's preliminary view is to replace the labelling provisions for pre-term formula and IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions (except for lactose-free and low lactose formulas) with FSMP provisions in paragraphs 2.9.5—10(1)(a) to (f).

The departments support in principle FSANZ's preliminary view to align the labelling provisions with those in standard 2.9.5, including the exclusion of the statement about parenteral use, **but do not support exempting formula that identifies as lactose-free from these labelling provisions.**

The departments would like it clarified that all special purpose formulas should be classified as IFPSMP and be subject to the labelling provisions. FSANZ's preliminary wording refers only to replacing labelling provisions for pre-term formula and IFPSDU for metabolic, immunological, renal, hepatic and malabsorptive conditions. **Assigning these labelling provisions to only certain IFPSMP represents inadequate risk management of the broader category of IFPSMP and is not consistent with the EU or the move to remove subcategories.**

In drafting these provisions, it is important to recognise that infants and infant products have a unique inherent risk that goes beyond that associated with Foods for Special Medical Purposes for older populations. Presentation and labelling of products, even if restricted to chemist shops, have the potential to influence carers' feeding decisions, which can include decisions around breastfeeding as well as choice of first foods. The presence of non-evidence based infant formula products aimed at managing colic, 'hungry babies', constipation, 'improving sleep' indicates some manufacturers are willing to use marketing to influence purchasing decisions. The health claims standard and prohibition on claims on infant formula products has gone some way to reduce this practice, however care is needed when drafting the new provisions for IFPSMP to prevent this practice. The requirement for products that are effective for the dietary management of the specific condition will help manage this, but further risk management labelling strategies, that still allow flexibility to ensure access to essential imported products, are required and include:

- a prescribed name for IFPSMP (discussed further below)
- for a) a statement to the effect that the food must be used under medical supervision. If the entire statement is not to be prescribed, the elements 'medical supervision' should be to ensure there is a greater level of medical supervision than the statement required for general formula, which must state, 'before you decide to use this product, consult your doctor or health worker for advice'.
- A clear prohibition on nutrient content or health claims in line with current restrictions and the EU regulations. Statements about medical purpose should be set out as under EU regulations: the statement *'For the dietary management of …' where the blank shall be filled in with the disease, disorder or medical condition for which the product is intended*'. Statements must be limited to the medical purpose of the food and modifications which make it suitable for this purpose

5.7.2 Other advisory and warning statements in Standard 2.9.5

The departments agree with FSANZ's preliminary view that replicating other advisory statements from Standard 2.9.5 is not required in Standard 2.9.1, noting that mandatory allergen information will still apply. These include advisory statements about bee pollen, aspartame or aspartame-acesulphame salt, guarana or guarana extracts, propolis and certain polyols or polydextrose above specified limits and a warning statement about royal jelly.

5.7.3 Information relating to ingredients

FSANZ proposes to adopt an approach consistent with section 2.9.5—12 for information relating to ingredients to be made in accordance with Standard 1.2.4 or information that complies with European or United States regulations to allow flexibility for imported IFPSMP. **The departments support this approach, provided it only relates to ingredient list information and does not enable nutrient and health claims, even if present on imported products.**

5.7.4 Date marking information

The departments support FSANZ's preliminary view to adopt an approach consistent with subsection 2.9.5—12(2) for date marking information to be made either in accordance with Standard 1.2.5 (where products require either a best-before or use-by date on infant formula products) or for the words 'Expiry date' or similar words to be used on the label. This ensures labelling about the appropriate shelf life (which takes into account nutritional adequacy with degradation of nutrients) is present while providing flexibility for imported products that use the term Expiry date.

5.7.5 Prescribed name

The departments do not support FSANZ's preliminary view that IFPSMP will no longer require a prescribed name.

The departments do support not prescribing names for individual conditions (such as pre-term products). The departments support removing the subcategories and introducing one overarching category of IFPSMP provided that products in this category can be clearly identified by both carers and regulators, which includes provisions for a prescribed name.

FSANZ suggests it is unnecessary to have any prescribed name relating to infant formula or infant formula for special medical purpose because the application of certain FSMP statements would ensure IFPSMP are distinguishable from general purpose formula and provide sufficient information about their medical purpose and characteristics to health professionals and caregivers. Further, the suggested approach in section 5.6.3 to restrict their sale would address submitter concerns that caregivers of healthy infants may be confused by these products. Given large discount chemists can stock a range of general formula and medical purpose products, **the departments consider carers may still be confused between general and medical purpose formula (and potentially other FSMP) unless there is wording on the front of pack that clearly labels the formula as a formula for special medical purpose.** While restrictions on sale from pharmacies provide some safeguards, they are not sufficient on their own, particularly in light of the rise in online purchasing without access to pharmacist advice.

The departments also support a prescribed name for IFPSMP for regulatory clarity and enforcement purposes. Given the broadening of the regulations with respect to the types of IFPSMP permitted, a lack of prescription in compositional requirements for the intended condition, the lack of prescribed name could introduce sufficient uncertainty to make it difficult to enforce labelling and compositional provisions for a product that is not labelled as either an infant formula or an IFPSMP and may not be packaged in a traditional infant formula type tin. For example if the following product appeared on chemist shelves: infant milk for hungrier babies, suitable from birth, it would be unclear whether this would be considered a general infant formula or an IFPSMP:

The departments note that the recently updated EU regulations for foods for special medical purpose specifically raises the issue of increasing FSMPs aimed at infants and the need for greater protections for IFPSMP to 'avoid possible abuses linked to the misclassification of products, reduce confusion for consumers on the nature of the different products being offered to them and guarantee conditions of fair competition'. Given the growing innovation in this area, and the greater flexibility introduced for the category of IFPSMP, **it is important there is sufficient clarity to ensure the regulatory provisions put in place to protect infants and carers can be enforced**.

In order to clearly distinguish IFPSMP from both standard formula and from other FSMP to ensure infant-specific provisions are applied, **the departments support a prescribed name for all special purpose products that:**

- Includes prescribed elements of 'special medical purpose' for infants, such as infant formula for special medical purpose or food for special medical purpose for infants
- Must be placed on the front of the label, consistent with the approach in the EU.
- Similar to ingredients labelling, drafting of the standard that permits imported products that comply with certain international prescribed naming requirements, provided the labelling clearly includes prescribed elements such as food or formula for medical purpose and clearly distinguishes them from standard formula and other FSMP.

This is consistent with the prescribed naming of these products in the EU and with Codex provisions, which indicate FSMP products should be labelled in such a way to avoid the risk of confusion between infant formula, follow-up formula and formula for special medical purposes.

5.7.6 Exemption from 'breast milk is best for babies' warning statement

The departments support FSANZ's proposed approach to exempt IFPSMP only from the 'breast milk is best' warning statement **provided IFPSMP are clearly labelled with a prescribed name** to ensure these can be clearly distinguished from general infant formula by carers and regulators.

5.7.7 Exemption from statement about offering foods in addition to IFPs

FSANZ proposes to extend the exemption from the statement about offering other foods in addition to IFPs from just pre-term formula to all IFPSMP. The departments note concerns raised that not all IFPSMP require altered introduction of solids after 6 months, however inclusion of this statement might cause trade issues when it is not required overseas. In this instance, **the departments support FSANZ's proposed approach provided the risk management strategies discussed in this paper are included (including a prescribed name for IFPSMP**) to ensure carers to reduce the risk of carers of healthy babies mistakenly using these in place of general formulas and not having information about offering foods.

5.7.8 Statement that the infant formula product may be used from birth

The departments note that the Code currently requires both infant formula and IFPSMP to include a statement indicating that the infant formula product may be used from birth. FSANZ previously proposed to maintain this requirement for all infant formula products to enable caregivers to correctly identify the appropriate formula for their infants aged from birth and all submitters to the 2016 and 2021 (CP1) consultation papers supported this approach. FSANZ now proposes exempting IFPSMP from the requirement for a statement that the infant formula product may be used from birth because the EU FSMP regulations do not require a similar statement, indicating this requirement would be trade restrictive.

The departments support the exemption provided IFPSMP will be required to include a statement specifying the appropriate age the product is formulated for, as indicated.

5.7.9 Labelling information on safe preparation and use

The departments partly support FSANZ's preliminary view that the general directions for preparation and use requirements are appropriate for IFPSMP and there are no additional, specific, directions that should be mandated. However, the departments consider that all IFPSMP, including those used to supplement breastmilk or formula (such as bovine human milk fortifiers and formula for PKU) should be regulated under Standard 2.9.1. **Drafting for preparation and use should include provisions that allow for deviation where required for IFPSMP.**

Additional labelling consideration

The departments have been informed by clinical paediatric dietitians that infants with medical conditions often have different fluid tolerances and information about the potential renal solute load (PRSL) of IFPSMP is essential. While a mandatory requirement for this information may create a trade barrier, the departments support provisions that state the PRSL should be included on labels where possible.