

Keeping our babies safe and well

A multi year review of Infant Formula Requirements for Australia and New Zealand

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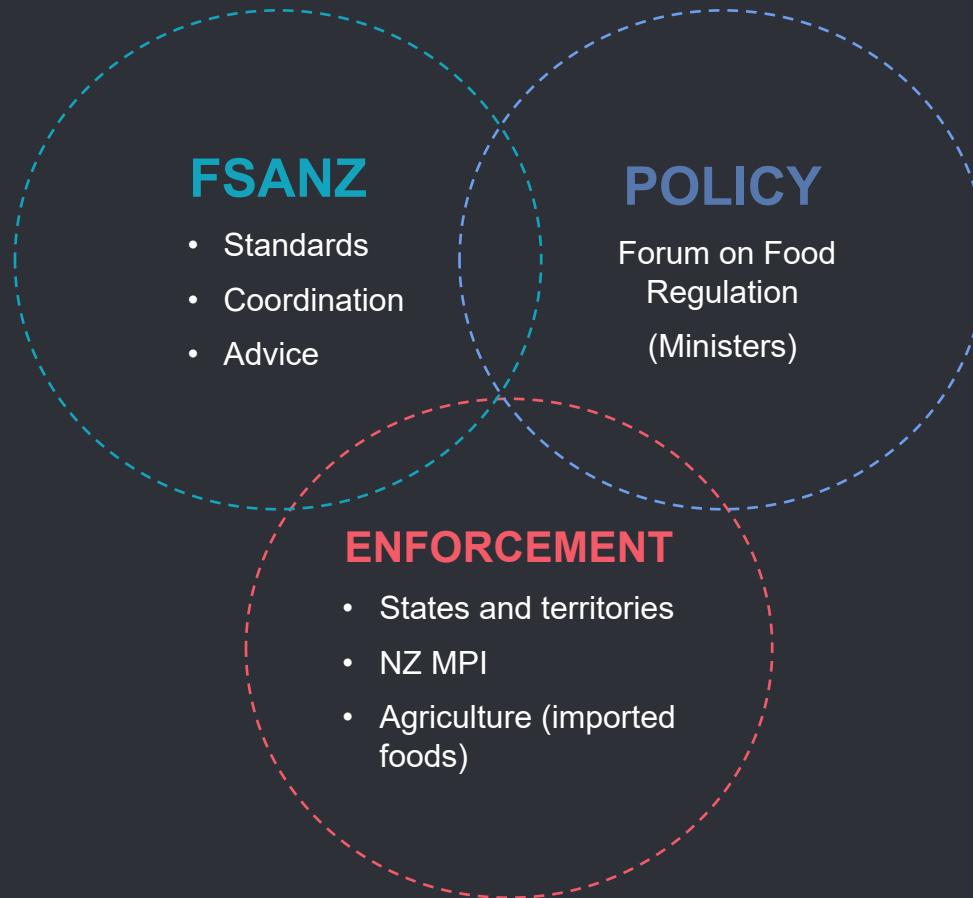


About us

- *We are an Australian statutory agency within the Australian Government Health portfolio*
- *We develop food standards for Australia and New Zealand*
- *Our main function is to develop and administer the Australia New Zealand Food Standards Code (the Code)*
- *The Code is a legislative instrument, that is given effect by state and territory or New Zealand laws*



Food Regulatory Framework





Our vision

Consumers have a high level of confidence
in the safety of food

Corporate Plan 2019–20



Our goals

- A high degree of **consumer confidence** in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand
- An **effective transparent and accountable regulatory framework** within which the food industry can work efficiently
- The provision of **adequate information** relating to food to enable consumers to make informed choices
- The establishment of **common rules for both countries** and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards that apply to public health and consumer protection



Our role

- *Develop and administer the Australia New Zealand Food Standards Code (the Code) including;*
 - *food labelling and composition requirements*
 - *food product standards – for example infant formula*
 - *residue limits*
 - *food hygiene and primary production*
- *Coordination of food recalls and food surveillance*
- *Providing evidence-based advice on food*



When developing measures we consider:

PROTECTION

of public
health and
safety

PROVIDING

adequate
information
to
consumers

PREVENTING

misleading
and
deceptive
conduct

- The need for standards to be based on **risk analysis** using the best available scientific evidence
- The promotion of **consistency between domestic and international** food standards
- The desirability of an **efficient and internationally competitive food industry**
- The **promotion of fair trading** in food
- Written **policy guidelines** formulated by the Forum on Food Regulation



The Australia New Zealand Food Standards Code

Chapter 1

General food standards:

- Definitions
- Labelling requirements
- Use of substances added to food
- Use of new foods
- Contaminant MLS & restricted botanicals
- MRLs (Aus)
- Food processing requirements (Aus)

Chapter 2

Food product standards:

- Cereals
- Fruits
- Vegetables
- Dairy products
- Beverages
- Special purpose foods

Chapter 3

Food safety standards *Australia only*

- Food safety programs
- Food premises and equipment

Chapter 4

Primary production standards *Australia only*

- Production and processing of seafood
- Poultry meat
- Meat,
- Other commodities

Schedules

Permissions for use of:

- Substances added to food
- Use of new foods
- Permitted MRLS
- Contaminant MLs
- Identify and purity



APEC Food Safety Cooperation Forum

FSCF

10 MAY 2019, VIÑA DEL MAR, CHILE





**Asia-Pacific
Economic Cooperation**

APEC FOOD SAFETY MODERNISATION FRAMEWORK TO FACILITATE TRADE



**June 2019
Food Safety Cooperation Forum
APEC Sub-Committee on Standards and Conformance**

Advancing Free Trade for Asia-Pacific Prosperity



**Australian Government
Department of Foreign Affairs and Trade**

Food safety modernisation based on internationally accepted principles

Protection of consumers 1

Trade facilitation 2

Whole of food chain approach 3

Transparency 4

Preventive measures 5

6 Evidence and risk-based decision making

7 Shared responsibility: primarily rests with food business operators

8 Equivalence

9 Consistency and impartiality

10 Continuous improvement





Infant formula products

Standard 2.9.1 regulates the following infant formula products:

- infant formula (0-<12 months)
- follow-on formula (6-<12 months)
- infant formula products for special dietary use

Schedule 29 - Special purpose foods



Other relevant Standards and Schedules

- 1.1.1 – Structure & general provisions
- 1.1.2 – Definitions
- 1.3.1 – Food Additives + Schedule 15
- 1.4.1 – Contaminants and Natural Toxicants + Schedule 19
- 1.6.1 – Microbiological Limits for Food + Schedule 27
- 1.5.1 – GM foods + Schedule 26
- 1.5.2 – Novel foods + Schedule 25
- Schedule 1 – RDIs and ESADDIs
- Schedule 3 – Identify & purity
- Schedule 18 – Processing aids

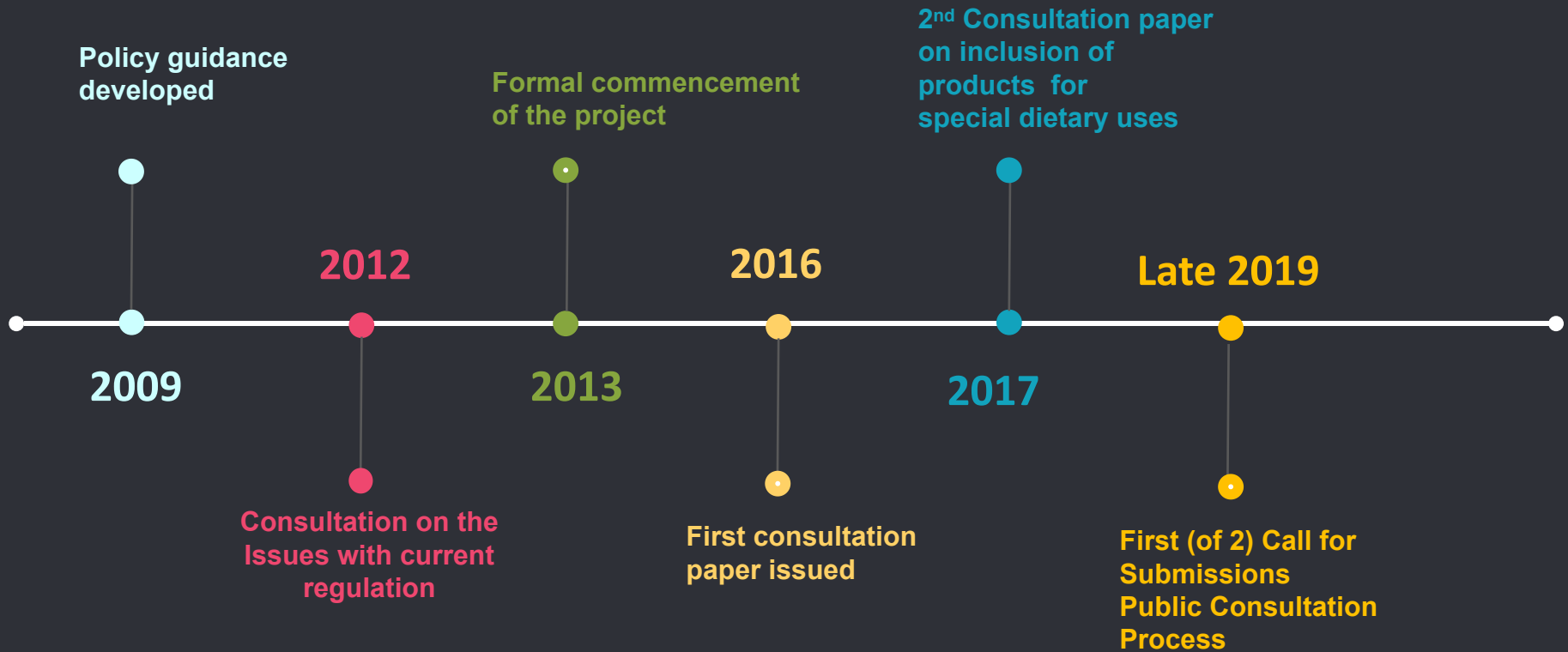
Proposal P1028 Review of the regulation of infant formula





P1028 date

Timeline of activities to





Proposal P1028

SCOPE: Provisions applicable to infant formula (0-<12 months) and IFPSDU. Excludes Follow-on formula

Considering issues relating to the essential composition and safety of infant formula, including a review of:

- safety related labelling
- labelling for information
- macro and micro nutrient levels & permitted forms of added nutrients
- food additive & processing aid permissions, contaminant MLs
- pre-market assessment requirements
- IFPSDU framework

Series of reports = many opportunities to provide comments and feedback as the Proposal progresses



Key issues

Pre-market approval for new ingredients:

- We wish to improve the clarity of regulation around composition
- Interpretations by enforcement agencies and industry can differ as to whether new ingredients for infant formula are novel or nutritive substances that require pre-market approval by FSANZ
- Industry support reducing the need for FSANZ to carry out pre-market assessment
- Enforcement agencies support the continued premarket assessment of all new ingredients added to infant formula



Key issues

Labelling elements - Prohibition on claims

- Nutrition content and health claims are prohibited on all infant formula products
- The policy environment (domestic and increasingly global) for infant formula does not support any change to permit health, nutrition content or ingredient claims on the label
- Industry suggest that nutrition content claims on labels will enable informed choice and assist caregivers to choose between products



Key issues

Labelling elements – changes to current labels

- We are considering whether some mandatory labelling such as preparation and use instructions and the nutrition information statement are working as intended or could require further prescription in the Code
- These options are being informed by literature and social research as well as international policy context and potential impacts on trade
- Industry are not supportive of further prescription for labelling requirements



Proposal P1028 timing

- Aim to release 1st CFS before the end of the 2019
- Builds on all the information from 2012, 2016 and 2017 papers
- Propose drafting intent for some issues and seeking responses on options and questions about a number of issues, including labelling issues
- Website has all papers to date and submissions

<http://www.foodstandards.gov.au/code/infant/Pages/default.aspx>

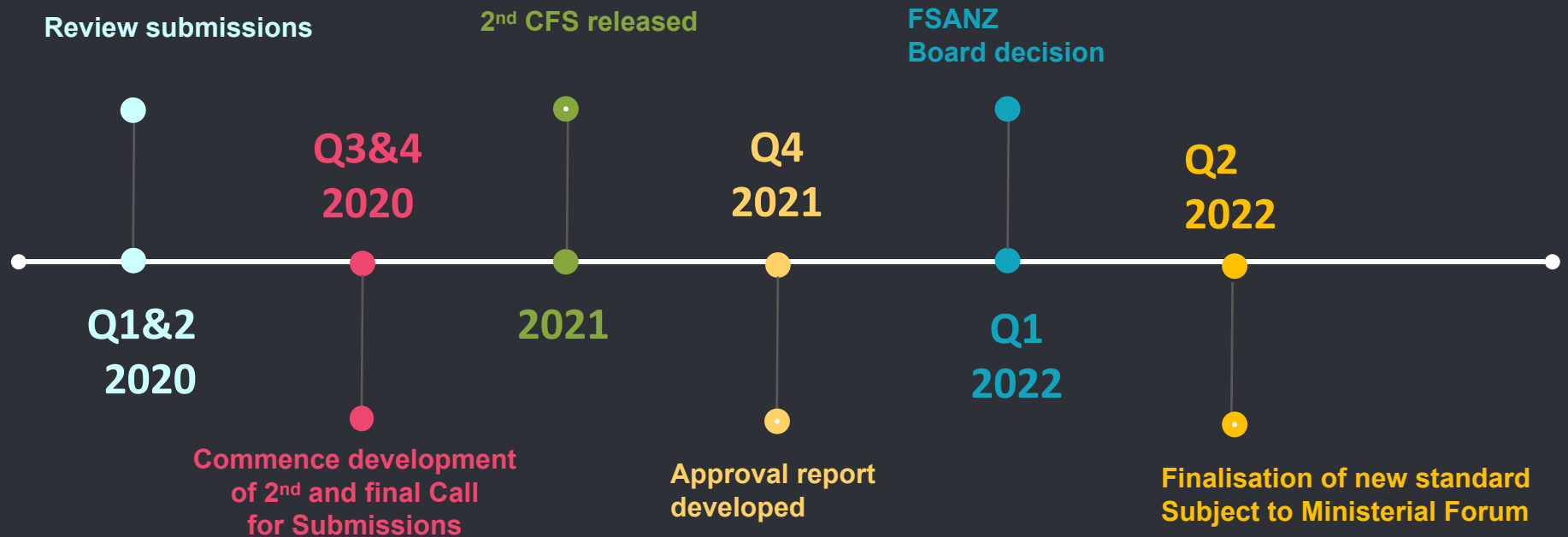
- Can get yourself added to the FSANZ interested parties list and/or subscription service

<http://www.foodstandards.gov.au/media/pages/subscription-service.aspx>



P1028

Next steps



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P1028 Social science focus

Two main threads:

- Preparation instructions, warning
- Nutrition information, ingredient list

Ingredients: Milk solids, vegetable oils (contains **soy**, antioxidant (ascorbyl palmitate, citric acid)), galacto-oligosaccharides (contains **milk**), dried omega LCPUFAs (contain **fish, milk, soy**, antioxidant (mixed tocopherols, dl-alpha tocopherol, ascorbyl palmitate, sodium ascorbate, citric acid)), long chain polyfructose, emulsifier (**soy** lecithin), taurine, choline chloride, Bifidobacterium breve M-16V (750 million cfu/100mL), L-carnitine, inositol.
Mineral: Potassium, calcium, chloride, phosphorus, sodium, magnesium, iron, zinc, copper, iodine, manganese, selenium.
Vitamin: Vitamins (A, B₁, B₂, B₃, B₅, B₆, B₁₂, C, D₃, E, K₁), folic acid, biotin. **Nucleotides:** Cytidine-5'-monophosphate, uridine-5'-monophosphate, adenosine-5'-monophosphate, inosine-5'-monophosphate, guanosine-5'-monophosphate. If correctly stored & made up in accordance with the directions contained on the label, no further vitamin or mineral preparations are necessary.

Aptamil® Profutura® Infant Formula is based on cows' milk protein.

IMPORTANT NOTICE: BREAST MILK IS BEST FOR BABIES. BEFORE YOU DECIDE TO USE THIS PRODUCT, CONSULT YOUR DOCTOR OR HEALTH WORKER FOR ADVICE.

Meets the nutritional needs of formula fed infants.

PREPARATION OF APTAMIL® PROFUTURA® INFANT FORMULA

-  Wash hands before preparing the feed. Clean and then sterilise all the utensils by submerging bottles and teats in water and boiling for 5 minutes, or using an approved steriliser.
-  Boil safe drinking water and allow to cool. Measure the required volume of water into a sterilised feeding bottle.
-  Use only the enclosed scoop. Fill the scoop lightly & level off using the built-in leveller. Avoid compacting powder.
-  Always add one level scoop of powder for each 50mL of water. Cap the bottle & shake briskly to dissolve the powder.
-  Test temperature on wrist before feeding. Feed immediately (do not store). Discard unfinished feeds.

Prepare each bottle separately. For all brands of formula, it is safer to use immediately after they are prepared. Product is packed by weight, not volume. Some settling of the powder may occur during transportation and distribution.

WARNING: FOLLOW INSTRUCTIONS EXACTLY. PREPARE BOTTLES & TEATS AS DIRECTED. DO NOT CHANGE PROPORTIONS OF POWDER EXCEPT ON MEDICAL ADVICE. INCORRECT PREPARATION CAN MAKE YOUR BABY VERY ILL. INFANTS OVER 6 MONTHS SHOULD BE OFFERED FOODS IN ADDITION TO INFANT FORMULA PRODUCT.

Dental Hygiene: Putting your baby to bed with a bottle can cause tooth decay.
Storage: Store in a cool dry place. Use by the date on container bottom. After opening, keep container airtight & use contents within four weeks.

NUTRITION INFORMATION

Average Quantity Per 100mL of Prepared Feed

Energy	67kcal
	280kJ
Protein	1.4g
	Whey 60%
	Casein 40%
Carbohydrate	6.8g
Fat	3.6g
OMEGA LCPUFAs¹	
Arachidonic Acid (AA)	15.8mg
Docosahexaenoic Acid (DHA)	14.0mg

MINERAL

Calcium	61mg
Phosphorus	41mg
Sodium	22mg
Potassium	90mg
Chloride	57mg
Magnesium	7.0mg
Iron	0.96mg
Zinc	0.56mg
Manganese	7.2µg
Copper	66µg
Iodine	12.6µg
Selenium	2.0µg

VITAMIN

Vitamin A	68µg-RE
Vitamin D	0.89µg
Vitamin E	0.87mg
Vitamin K	5.3µg
Vitamin B ₁	67µg
Vitamin B ₂	117µg
Vitamin B ₅	52µg
Vitamin B ₁₂	0.40µg
Niacin (B ₃)	0.56mg
Pantothenic Acid (B ₅)	0.52mg
Biotin	2.0µg
Folate	11.4µg
Vitamin C	12.7mg

OTHERS

Choline	11.0mg
Taurine	5.4mg
Inositol	5.6mg
L-Carnitine	1.6mg

NUCLEOTIDES

Cytidine 5'-monophosphate	1.2mg
Uridine 5'-monophosphate	0.78mg
Adenosine 5'-monophosphate	0.78mg
Inosine 5'-monophosphate	0.44mg
Guanosine 5'-monophosphate	0.23mg

PREBIOTICS

GOS ²	0.72g
lc Polyfructose ³	0.08g

¹ LCPUFAs – Long Chain Polyunsaturated fatty acids

² GOS – Galacto-oligosaccharides

³ lc Polyfructose – long chain Polyfructose



2016 Eye-tracking

- Infant formula preparation task with eye-tracking
- Individual in-depth interviews
- Sample of 30, based in Adelaide
- Caregivers of infants ≤ 12 months (16 out of 30 had an infant < 6 months)
- 13 out of 30 were first-time parents





Statement of ingredients



- Consumers' use & understanding
 - can be scary or off-putting if long
 - don't recognise many of the ingredients; jargon
 - used for product comparison
- Desktop survey (2018 labels) found vitamins & minerals commonly grouped with/without subheadings
- INC mocked up label proposes grouping vitamins & minerals
- FSANZ considering whether deviating from general ingredient labelling requirements is justified





Nutrition, health and related claims

IFP – claims are prohibited 1.2.7-4

FSFYC – claims permitted but conditions for certain claims in 2.9.3-8

Standard 1.2.7 sets out:

- claims that may be made on labels or in advertisements about the nutritional content of food (described as ‘nutrition content claims’); and
- claims that may be made on labels or in advertisements about the relationship between a food or a property of a food, and a *health effect (described as ‘health claims’); and
- describes conditions under which such claims may be made



Safety related labelling issues

Issues raised include:

- date marking
- directions for use, preparation and storage instructions
- warning statements and other statements
- prescribed name & protein source statements
- legibility requirements
- IFPSDU required statements and warnings

Options being informed by submitter evidence, FSANZ literature reviews & social research

Considering regulatory and non-regulatory options



Provision of information labelling issues

- Nutrition information statement
 - guidelines, format
 - macronutrient subgroups
 - base units of expression
 - ‘average amount’ versus ‘average quantity’
- Declaration of permitted nutritive substances
- Claims – ingredient and nutrition content
- Notification of product reformulation
- Options being informed by submitter evidence, FSANZ literature reviews & social research
- Considering regulatory and non-regulatory options