FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

06 November 2025
367-25

Call for submissions – Proposal P1065

Code Revision – 2025 Amendments (Compositional requirements for Special Medical Purpose Product for infants and other miscellaneous amendments)

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared to amend the Australia New Zealand Food Standards Code to:

- include compositional fat requirements for Special Medical Purpose Product for infants that were considered and approved in Proposal P1028 but which were inadvertently omitted from the Code amendments made by that Proposal, and
- make other minor amendments such as correction of typographical errors, omissions, inconsistencies, formatting issues and updating references.

FSANZ has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub.

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.
There is no need to send a hard copy of your submission if you have submitted it through the FSANZ Consultation Hub

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 4 December 2025

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

Questions about making a submission or application and proposal processes can be sent to

standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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Supporting document

The following document which informed the assessment of this Proposal is available on the FSANZ website:

SD List of proposed amendments – Proposal P1065

Executive summary

Food Standards Australia New Zealand (FSANZ) has prepared Proposal P1065 to amend the Australia New Zealand Food Standards Code (the Code) to:

- correct an error in the compositional fat requirements for Special Medical Purpose Product for infants (SMPPi). The requirements currently stated in the Code are incorrect. These should be the same as the compositional fat requirements for infant formula set by Proposal P1028 for the reasons set out in the P1028 2nd Call for Submissions and Approval Report. The P1028 Approval Report was based on that Proposal's amendments to the Code setting identical compositional fat requirements for SMPPi and infant formula. However, due to an oversight, the amendments to compositional fat requirements for SMPPi were omitted from the variations approved by that Proposal. As a result, the Code's current compositional fat requirements for SMPPi do not state that medium chain triglycerides in SMPPi must contain predominantly the saturated fatty acids designated by 8:0 and 10:0. This Proposal will amend the compositional fat requirements for SMPPi to include this missing requirement;

- correct other omissions, inconsistencies, formatting issues and typographical errors;

- update references.

FSANZ assessed Proposal P1065 and has prepared a draft variation.

FSANZ invites submissions on the draft variation.

1 Introduction

1.1 The Proposal

Proposal P1065 was prepared to amend the *Australia New Zealand Food Standards Code* (the Code) to:

- correct an error in the compositional fat requirements for Special Medical Purpose Product for infants (SMPPi); and
- make other minor amendments, such as correction of typographical errors, omissions, inconsistencies, formatting issues and updating references.

1.2 The current standards

The relevant standards for this Proposal are:

- Standards 1.1.2, 1.2.8, 2.9.1, 2.10.4, and
- Schedules 3, 4, 17, 18, 20, 22 and 29 of the Code.

1.3 Reasons for preparing the Proposal

Errors and issues are identified in the Code from time-to-time. This Proposal was prepared to resolve them.

1.4 Procedure for assessment

The Proposal is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

No public health and safety concerns have been identified in relation to this Proposal or the draft variation prepared following assessment of the Proposal.

The reasons for the amendments proposed by the draft variation are set out below and are also outlined in the supporting document to this report (SD1).

2.1.1 Proposed amendments to subsection 2.9.1—34(2)

Subsection 2.9.1—34(2) sets compositional fat requirements for SMPPi. These requirements are incorrect. They should be identical to those set by paragraph 2.9.1—7(1)(a) for infant formula.

Proposal P1028 intended to set identical compositional fat requirements for SMPPi and infant formula. The P1028 2nd CFS explained and sought public submissions on this proposed outcome. The P1028 Approval Report explained publicly that this outcome had been approved and why (see, for example, page 60 of SD1 of the P1028 Approval Report). However, the required drafting changes were inadvertently omitted from the P1028 approved draft variation.

The regulatory measures proposed in P1028 were approved by the FSANZ Board on 4 June

2024, endorsed by the Food Ministers' Meeting on 25 July 2024[1] and gazetted on 13 September 2024.

P1028 was an extensive review that updated standards for infant formula products ensuring they continued to be safe and suitable, while taking account the latest scientific evidence, market developments, changes in the international regulatory context and revised Australian and New Zealand policy guidance (FSANZ, 2024[2]). P1028 updated requirements for specialised formula, known as SMPPi. These formulas are used by infants that have special dietary or medical needs, a more vulnerable population group than infants generally. The diet of these infants is usually managed under the supervision of a medical specialist or paediatric dietitian.

Each SMPPi is formulated based on medically determined nutrient requirements to aid the dietary management of the condition, typically where the infant's nutrition cannot be achieved without modification of the normal diet.

The approved regulatory measures prescribed composition for SMPPi that replicated the baseline composition of infant formula (as prescribed in Division 2 of Standard 2.9.1). The review considered the composition of SMPPi should not deviate from infant formula composition, except where necessary to achieve the product's intended medical purpose. This requirement ensured that SMPPi were as closely matched to breast milk composition as possible, protecting the health and safety of sick infants and ensuring SMPPi provided the sole or principal source of nourishment that supported normal growth and development.

Current Code requirements

Subsection 2.9.1—34(2) specifies the following fat requirements for SMPPi.

> ***2.9.1—34 Fat requirements***
>
> (2) A special medical purpose product for infants may only contain medium chain triglycerides that are:
>
> (a) a natural constituent of a milk-based ingredient of that product; or
>
> (b) for a fat soluble vitamin that is specified in the table to section S29—5—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the product.

These requirements differ to the medium chain triglyceride requirements for infant formula and follow-on formula prescribed in subsection 2.9.1—7(2). As set out below, these state that infant formula and follow-on formula may only contain medium chain triglycerides that contain predominantly the saturated fatty acids designated by 8:0 and 10:0 and are one of the following: a natural constituent of a milk-based ingredient of that formula; or for a fat soluble vitamin specified in the table to section S29—5, a substance used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula.

These infant formula and follow-on formula requirements were updated under Proposal P1028 and were modelled off the previous definition for medium chain triglycerides, which defined medium chain as triacylglycerols that contain predominantly the saturated fatty acids designated by 8:0 and 10:0. The review moved these compositional requirements from the definition into Division 2, for consistency with how all other compositional requirements were prescribed.

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[1] The New Zealand Government in August 2024 opted out of the amendments made by Proposal P1028.

[2] FSANZ (2024) Approval Report - Proposal P1028. FSANZ, Canberra. Available online at: Approval Report - Proposal P1028 Infant Formula.pdf

2.9.1—7 Fat requirements

(2) Infant formula and follow-on formula may only contain medium chain triglycerides that:

(a) contain predominantly the saturated fatty acids designated by 8 to 0 and 10 to 0; and

(b) are one of the following:

(i) a natural constituent of a milk-based ingredient of that formula; or

(ii) for a fat soluble vitamin that is specified in a following table—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the formula:

(A) for infant formula—the table to section S29—5; and

(B) for follow-on formula—the table to section S29—6.

Drafting issue

As noted above, the regulatory intent in P1028 was for SMPPi and infant formula compositional requirements to be identical, with SMPPi being permitted to deviate from these compositional requirements only where necessary to achieve the product's intended medical purpose or to enable the product's sale for use by those who depend on it.

Proposal P1028 explained, and sought public submissions on, the identical amendments being made to the compositional fat requirements for SMPPi and for infant formula, including the requirement for medium chain triglycerides present in SMPPi to contain predominantly the saturated fatty acids designated by 8:0 and 10:0. The P1028 2nd CFS and Approval Report explained publicly that this change would be made and why (FSANZ, 2023[3], FSANZ 2024).

However, due to an oversight, the requirement that medium chain triglycerides present in SMPPi contain predominantly the saturated fatty acids designated by 8:0 and 10:0 was omitted from the P1028 approved draft variation. As a result, this specific requirement was not included in the Code.

Submissions received during P1028 2nd CFS

The majority of submitters to the 2nd CFS supported the new SMPPi category, including the approach to the proposed composition and the requirement that medium chain triglycerides present in SMPPi contain predominantly the saturated fatty acids designated by 8:0 and 10:0. They supported requirements that ensured the composition of SMPPi comply with the baseline composition of infant formula, except when deviating from specific compositional requirements where required to address the product's special medical purpose (FSANZ, 2024).

No submissions opposing the approach to SMPPi composition were received. All submissions, including responses from FSANZ, are detailed in the Proposal P1028 – Approval Report (FSANZ, 2024).

2.1.2 Other proposed amendments

The proposed amendments to section 1.1.2—2 and to Schedule 3 are required to update references in the Code.

The proposed amendments to the following are required to correct typographical errors,

[3] FSANZ (2023) 2nd Call for Submissions - Proposal P1028. Supporting Document 2 – Nutrient Composition for Infant Formula Products. FSANZ, Canberra. Available online at: 2nd Call for Submissions - Proposal P1028.pdf

omissions, inconsistencies and formatting issues in the Code:

- section 1.1.2—8
- Standard 1.2.8
- sections 2.9.1—7 and 2.9.1—31
- paragraphs 2.9.1—34(1)(d) and 2.9.1—34(1)(f)
- Standard 2.10.4
- Schedules 4, 17, 18, 20, 22 and 29.

These amendments will ensure that the Code remains current, and that typographical errors, omissions, inconsistencies and formatting issues are addressed. The amendments are relatively minor in nature and no potential public health and safety concerns have been identified.

2.2 Risk management

2.2.1 Proposed amendments to subsection 2.9.1—34(2)

Assessment

The composition of SMPPi may differ substantially depending on the specific disease, disorder or medical condition the product is intended for. To ensure SMPPi composition is as closely matched to breast milk as possible, FSANZ considered deviations from the composition of infant formula may only be made where there are medically determined differences in nutrient requirements. Therefore, FSANZ recommended, through Proposal P1028, that each compositional requirement for infant formula be explicitly prescribed for SMPPi.

FSANZ, in making this recommendation, had regard to the Ministerial Policy Guideline on the Regulation of Infant Formula Products (MPG, 2011[4]). It stipulates that specialised formulas must be safe, suitable and meet the nutritional requirements to support the growth, development and dietary management of the infants for whom they are intended, and that each product composition should be based on appropriate scientific evidence.

The composition of infant formula products has undergone iterative and rigorous scientific assessment through the progression of Proposal P1028, with each compositional requirement being assessed on its minimum level, maximum level, permitted form, units of expression and calculations. This included the compositional requirement that medium chain triglycerides present in SMPPi contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

The details of these assessments can be found in the 2016 Nutrition Assessment (FSANZ 2016[5]), 2021 Nutrition Assessment (FSANZ 2021[6]) and P1028 Approval Report (FSANZ 2024).

In view of the above, FSANZ considers it appropriate to amend subsection 2.9.1—34(2) of the Code to include a requirement that medium chain triglycerides present in SMPPi contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

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[4] MPG (2011) Ministerial Policy Guideline on Infant Formula Products, Food Regulation Secretariat. Available online at: Policy guideline on infant formula products | Food Regulation

[5] FSANZ (2016) Consultation paper – Proposal P1028. Supporting Document 1 – Definitions and nutrient composition. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

[6] FSANZ (2021) Consultation Paper 2 – Nutrient Composition. Supporting Document 1 – Nutrition Assessment. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx

Cost and benefit

FSANZ considers correcting the error in the SMPPi medium chain triglyceride requirements will pose no cost to the community, government or industry for the following reasons.

- The Code imposed the same requirement prior to the commencement of the P1028 amendments (see the previous definition of *medium chain triglycerides*). As such, the proposed amendment will not implement a new regulatory requirement requiring reformulation or re-labelling.

- The P1028 amendments to the Code remain subject to transition arrangements which cease on 13 September 2029. In this period, a relevant product may comply with the Code as currently in force or with the Code as in force without the P1028 amendments.

- This Proposal's proposed draft variation will include a similar transition arrangement for its proposed requirement that medium chain triglycerides present in SMPPi contain predominantly the saturated fatty acids designated by 8:0 and 10:0 (see below).

- Section 2.9.1—42 permit SMPPi to deviate from the compositional requirements set by the Code for SMPPi to the extent necessary to achieve their intended medical purpose or enable their sale for use by those who depend on these products. This flexibility makes it unlikely that the proposed requirement will impose a cost.

Transitional arrangements

The proposed draft variation will provide a transitional arrangement in relation to the requirement that medium chain triglycerides present in SMPPi contain predominantly the saturated fatty acids designated by 8:0 and 10:0.

The proposed transitional arrangement will align with the transitional arrangements for the P1028 amendments to the Code.

It will commence on gazettal of the proposed draft variation and cease on 13 September 2029 – the date on which the P1028 transitional arrangements cease.

During this transitional period, SMPPi may be sold if they comply with:

- the Code as in force (that is, as amended by P1028 and the above-mentioned amendment made by this Proposal), or
- the Code as in force without the amendments made by P1028 and without the above-mentioned amendment made by this Proposal.

Products must comply fully with one version of the Code or the other. They cannot pick and choose individual permissions from either version of the Code. After the transition period, all infant formula products available in the Australian market[7] would need to comply with the Code as amended.

The above ensures regulatory consistency and provides industry with sufficient time to

[7] See FSANZ (2025) Approval Report – Proposal P1064. Australian only Infant Formula Product Standard. FSANZ, Canberra. Available online at https://www.foodstandards.gov.au/food-standards-code/proposals/p1064-australian-only-infant-formula-product-standard

comply with the proposed requirement.

Conclusion

The proposed amendment will align the fat requirements for SMPPi with those prescribed for infant formula under subsection 2.9.1—7(2). In doing so, it reflects FSANZ's commitment to regulatory consistency and clarity, scientific rigour, and the protection of vulnerable infant populations. By correcting the drafting omission from Proposal P1028 to set identical compositional requirements for SMPPi and for infant formula, while allowing SMPPi composition to deviate from these identical requirements where medically necessary, the amendment upholds the principles of safety, suitability and nutritional adequacy outlined in the Ministerial Policy Guideline. The change imposes no additional cost to stakeholders and will be supported by a transitional arrangement through to 13 September 2029, allowing industry sufficient time to comply while maintaining flexibility for medical necessity.

2.2.2 Other proposed amendments

FSANZ's assessment is that the other proposed amendments of the Code are the appropriate risk management response. These ensure the Code remains correct and current.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of the FSANZ standards development process.

All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's digital channels and Food Standard News. Subscribers and interested parties are also notified about the availability of reports for public comment.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with existing or imminent international standards and the proposed measure may have a significant effect on trade.

Amending the Code to make minor corrections and updates is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Proposal and in the subsequent development of the draft variation, FSANZ had regard to the following matters in section 59 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

2.4.1 Section 59

2.4.1.1 Consideration of costs and benefits

Section 59 requires FSANZ to have regard to whether the direct and indirect benefits that would arise from a food regulatory measure developed as a result of this proposal will outweigh the costs to the community, government or industry that would arise from the proposal.

FSANZ does not expect the amendments will impose any additional costs on the community, government or industry, compared to the status quo. This is because all amendments within this proposal are relatively minor in nature and are designed to maintain the Code.

All sectors (the community, government and industry) are likely to benefit from the Code being maintained, as it will be easier to interpret and enforce and therefore more likely to result in the outcomes intended.

Therefore, FSANZ expects that the likely benefit identified above outweighs any potential costs that may arise from this proposal.

FSANZ has not prepared a regulation impact statement (RIS) for this proposal. This is due to the minor impact of the proposal (as described above). This is in line with previous advice from the Office of Impact Analysis (OIA) on similar Code maintenance proposals (for example, P1061 – Code Maintenance Proposal 2023, OIA reference 22-03854). Under changes to impact analysis requirements, FSANZ is not required to seek confirmation from the OIA that a RIS is not required.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than the amendments proposed by the draft variation.

2.4.1.3 Any relevant New Zealand standards

The standards affected by the proposed amendments apply either in Australia only, or in both Australia and New Zealand. The proposed amendments do not amend any New Zealand only standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

FSANZ had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this proposal, that is:

- the protection of public health and safety
- the provision of adequate information relating to food to enable consumers to make informed choices
- the prevention of misleading or deceptive conduct.

FSANZ's assessment is that the proposed variations will have little or no direct impact in terms of these objectives. As mentioned above, no potential public health and safety concerns have been identified.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food

- any written policy guidelines formulated by the Food Ministers' Meeting (FMM).

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Proposal P1065 – Code Revision – 2025 Amendments (Compositional requirements for Special Medical Purpose Product for infants and other miscellaneous amendments)) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1065 – Code Revision – 2025 Amendments (Compositional requirements for Special Medical Purpose Product for infants and other miscellaneous amendments)) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

4. Transitional arrangements for the variation made by Item [11] of the Schedule

(1) Section 1.1.1—9 of Standard 1.1.1 does not apply to the variation made by Item [11] of the Schedule.

(2) During the transition period, a food product may be sold if the product complies with one of the following:

(a) the Code as in force without the variations made by the instruments; or

(b) the Code as amended by the variations made by the instruments.

(3) For the purposes of this clause:

(a) the ***instruments*** mean:

(ii) Item [11] of the Schedule; and
(iii) the *Food Standards (Proposal P1028 – Infant Formula) Variation; and*
(iv) the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*; and

(b) the ***transition period*** means the period commencing on the date of commencement of this instrument and ending on 13 September 2029.

Schedule

Standard 1.1.2 Definitions used throughout the Code

[1] Subsection 1.1.2—2(3) (subparagraph (a)(i) of the definition of *permitted flavouring substance*)

Repeal the subparagraph, substitute:

(i) Generally Recognised as Safe (GRAS) lists of flavouring substances published by the Flavour and Extract Manufacturers' Association of the United States from 1960 to 2024 (edition 31);

[2] Paragraph 1.1.2—8(2)(d)

Repeal the paragraph, substitute:

(d) the use of a food as a special medical purpose product for infants;

does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section.

Standard 1.2.8 Nutrition information requirements

[3] Subsection 1.2.8—6(1)

Omit:

(1) A nutrition information panel must contain the following information:

Substitute:

(1) A nutrition information panel must contain the following information:

[4] Paragraph 1.2.8—6(4)(d)

Repeal the paragraph, substitute:

(d) *trans fatty acids.

Standard 2.9.1 Infant formula products

[5] Paragraph 2.9.1—7(1)(d)

Repeal the paragraph, substitute:

(d) have an arachidonic acid (20:4 n-6) content of equal to or more than docosahexaenoic acid (22:6 n-3) content; and

[6] Paragraph 2.9.1—7(1)(f)

Repeal the paragraph, substitute:

(f) for any long chain *polyunsaturated fatty acids that are present—have an eicosapentaenoic acid (20:5 n-3) content of no more than the docosahexaenoic acid (22:6 n-3) content; and

[7] Paragraph 2.9.1—7(2)(a)

Repeal the paragraph, substitute:

(a) contain predominantly the saturated fatty acids designated by 8:0 and 10:0; and

[8] Section 2.9.1—31 (heading)

Repeal the heading, substitute:

2.9.1—31 Restriction on the sale of special medical purpose product for infants

[9] Paragraph 2.9.1—34(1)(d)

Repeal the paragraph, substitute:

(d) have an arachidonic acid (20:4 n-6) content of equal to or more than docosahexaenoic acid (22:6 n-3) content; and

[10] Paragraph 2.9.1—34(1)(f)

Repeal the paragraph, substitute:

(f) for any long chain *polyunsaturated fatty acids that are present in the product—have an eicosapentaenoic acid (20:5 n-3) content of no more than the docosahexaenoic acid (22:6 n-3) content; and

[11] Subsection 2.9.1—34(2)

Repeal the subsection, substitute:

(2) A special medical purpose product for infants may only contain medium chain triglycerides that:

(a) contain predominantly the saturated fatty acids designated by 8:0 and 10:0; and

(b) are one of the following:

(i) a natural constituent of a milk-based ingredient of that product; or

(ii) for a fat soluble vitamin that is specified in the table to section S29—5—a substance that was *used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the product.

Standard 2.10.4 Miscellaneous standards for other foods

[12] Section 2.10.4—2 (Note)

Repeal the Note, substitute:

Note In this Code (see section 1.1.2—3):

chocolate means a confectionery product that is characterised by:

(a) the presence of

(i) cocoa bean derivatives; and

(ii) no more than 50 g/kg of edible oils, other than cocoa butter or dairy fats; and

(b) preparation from a minimum of 200 g/kg of cocoa bean derivatives.

cocoa means the powdered product prepared from cocoa beans from which a portion of the fat may have been removed, with or without salt or spices added.

coffee means the product prepared by roasting, grinding, or both roasting and grinding, coffee beans.

decaffeinated coffee means coffee from which most of the caffeine has been removed.

decaffeinated tea means tea from which most of the caffeine has been removed.

gelatine means a protein product prepared from animal skin, bone or other collagenous material, or any combination of those things.

instant coffee means the dried soluble solids prepared from the water extraction of coffee.

instant tea means dried soluble solids prepared from the water extraction of tea.

peanut butter means a peanut based spread.

tea means the product made from the leaves and leaf buds of one or more of varieties and cultivars of *Camellia sinensis* (L.) O. Kuntz.

Schedule 3 Identity and purity

[13] Subparagraph S3—2(1)(b)(xvi)

Repeal the subparagraph, substitute:

(xvi) FAO JECFA Monographs 26 (2021);

(xvii) FAO JECFA Monographs 27 (2022);

(xviii) FAO JECFA Monographs 30 (2022);

(xix) FAO JECFA Monographs 31 (2023);

(xx) FAO JECFA Monographs 32 (2024);

(xxi) FAO JECFA Monographs 34 (2025); or

[14] Paragraph S3—2(1)(c)

Repeal the paragraph, substitute:

(c) United States Pharmacopeial Convention (2024) Food chemicals codex, 14th ed, United States Pharmacopeial Convention, Rockville, MD; or

[15] Paragraph S3—3(j)

Repeal the paragraph, substitute:

(j) the International Oenological Codex (2025), Organisation Internationale de la Vigne et du Vin (OIV).

Schedule 4 Nutrition, health and related claims

[16] Section S4—2 (Note stating *Sugars** is relevant for claims about no added sugar)

Repeal the Note.

[17] Section S4—3 (table item related to 'Sugar or sugars', descriptor of 'No added' in column 3, paragraph (f) column 4, subparagraphs (xi)-(xiii)))

Repeal the subparagraphs, substitute:

(xi) native bee honey;

(xii) malt;

(xiii) malt extracts;

(xiv) any of the following unless the food for sale is a prescribed beverage:

(A) concentrated fruit juice;

(B) concentrated vegetable juice;

(C) deionised fruit juice;

(D) deionised vegetable juice.

Schedule 17 Vitamins and minerals

[18] Section S17—2

Omit "minerals", substitute "vitamins".

Schedule 18 Processing aids

[19] Subsection S18—3 (table entry for Dimethyldialkylammonium chloride)

Omit:

Dimethyldialkylammonium chloride	GMP

substitute:

Dimethyldialkylammonium chloride	GMP

[20] Subsection S18—9(3) (cell at table item dealing with Uridine diphosphate (UDP)-glucosyltransferase sourced from *Escherichia coli* K-12 containing the UDP-glucosyltransferase gene from *Oryza sativa*, column headed "*Substance*")

Repeal the cell, substitute:

Uridine diphosphate (UDP) glucosyltransferase sourced from *Escherichia coli* K-12 containing the UDP glucosyltransferase gene from *Oryza sativa*

Schedule 20 Maximum residue limits

[21] Section S20—3 (table entry for Agvet chemical: Abamectin)

Omit:

Chive, dry

substitute:

Chives, dried

[22] Section S20—3 (table entry for Agvet chemical: Acetamiprid)

Omit:

Fruiting vegetables other than cucurbits [except tomato]	0.2
Fungi, edible (except mushrooms)	0.2
Goji berries	2

substitute:

Fruiting vegetables, other than cucurbits [except goji berry; tomato]	0.2
Fungi, edible (except mushrooms)	0.2
Goji berry	2

[23] Section S20—3 (table entries for Agvet chemicals: Benzyladenine and Buprofezin)

Omit:

Walnut

substitute:

Walnuts

[24] Section S20—3 (table entry for Agvet chemical: Chlorantraniliprole)

Omit:

Cotton seed	0.3
Coriander (leaves, roots, stems)	T20

substitute:

Coriander (leaves, roots, stems)	T20
Cotton seed	0.3

[25] Section S20—3 (table entry for Agvet chemical: Chlorpyrifos-methyl)

Omit:

Cereal grains [except rice; sweet corns]	10

substitute:

Cereal grains [except rice; sweet corns]	10

[26] Section S20—3 (table entry for Agvet chemical: Cyclaniliprole)

[26.1] Omit:

Fruiting vegetables other than curcubits

substitute:

Fruiting vegetables, other than cucurbits

[26.2] Omit:

Pome fruit [except persimmon, Japanese]

substitute:

Pome fruits [except Persimmon, Japanese]

[27] Section S20—3 (table entry for Agvet chemical: Dieldrin)

Repeal the table entry.

[28] Section S20—3 (table entry for Agvet chemical: Fenhexamid)

Omit:

Currant, black, red, white

substitute:

Currants, black, red, white

[29] Section S20—3 (table entry for Agvet chemical: Fipronil)

Omit:

Citrus fruit

substitute:

Citrus fruits

[30] Section S20—3 (table entry for Agvet chemical: Fluopicolide)

Omit:

Brassica vegetables (except Brassica leaft vegetables)

substitute:

Brassica vegetables (except Brassica leafy vegetables)

[31] Section S20—3 (table entry for Agvet chemical: Isofetamid)

Omit:

Podded peas (young pods) (snow and sugar snap)

substitute:

Podded pea (young pods) (snow and sugar snap)

[32] Section S20—3 (table entry for Agvet chemical: Isopyrazam)

Omit:

Pome fruit

substitute:

Pome fruits

[33] Section S20—3 (table entry for Agvet chemical: Kresoxim-methyl)

[33.1] Omit:

Barley, similar grains, and pseudocereals with husks (barley; buckwheat; oats)

substitute:

Barley, similar grains, and pseudocereals with husks

[33.2] Omit:

Chard (beet leaves)

substitute:

Chard (silver beet)

[34] Section S20—3 (table entry for Agvet chemical: Mandestrobin)

Omit:

Fruiting vegetables, curcubits

substitute:

Fruiting vegetables, cucurbits

[35] Section S20—3 (table entry for Agvet chemical: Penconazole)

Omit:

Strawberries

substitute:

Strawberry

[36] Section S20—3 (table entry for Agvet chemical: Pendimethalin)

Omit:

Brassica leafy vegetables (except Broccoli, Chinese (Gai lan)

substitute:

Brassica leafy vegetables [except Broccoli, Chinese (Gai lan)]

[37] Section S20—3 (table entry for Agvet chemical: Penthiopyrad)

Omit:

Brassica leafy vegetables (except broccoli, Chinese (Gai lan)

substitute:

Brassica leafy vegetables [except Broccoli, Chinese (Gai lan)]

[38] Section S20—3 (table entry for Agvet chemical: Propamocarb)

Omit:

Brassica vegetables (except Brassica leafty vegetables)

substitute:

Brassica vegetables (except Brassica leafy vegetables)

[39] Section S20—3 (table entry for Agvet chemical: Pyriofenone)

Omit:

Berries and other small fruit [except Cane berries; cloudberry; cranberry; strawberry]

substitute:

Berries and other small fruits [except Cane berries; cloudberry; cranberry; strawberry]

[40] Section S20—3 (table entry for Agvet chemical: Pyriproxyfen)

Omit:

Peppers, chili, dried)

substitute:

Peppers, chili, dried

[41] Section S20—3 (table entry for Agvet chemical: Sethoxydim)

Omit:

Leaft vegetables [except lettuce, head; lettuce, leaf]

substitute:

Leafy vegetables [except lettuce, head; lettuce, leaf]

[42] Section S20—3 (table entry for Agvet chemical: Spirotetramat)

Omit:

Brassica vegetables (except Brassica leafy vegetables) [except Brussels sprouts; Chinese cabbage (Pe-tsai)]]

substitute:

Brassica vegetables (except Brassica leafy vegetables) [except Brussels sprouts; Chinese cabbage (Pe-tsai)]

Schedule 22 Food and classes of food

[43] Subsection S22—5(7) (table item 1, column 2)

Omit “Fruit”, substitute “Fruits”.

[44] Subsection S22—5(7) (table item 1, column 3)

[44.1] Omit “Citrus Fruit”, substitute “Citrus Fruits”.
[44.2] Omit “Berries and other small fruit”, substitute “Berries and other small fruits”.
[44.3] Omit “Assorted Tropical and sub-tropical fruit—edible peel”, substitute “Assorted tropical and sub-tropical fruits—edible peel”.

[45] Subsection S22—5(8) (table item dealing with Fruit, column 1)

Omit “Fruit”, substitute “Fruits”.

[46] Subsection S22—5(8) (table item dealing with Fruit, column 2)

[46.1] Omit “Citrus Fruit”, substitute “Citrus Fruits”.
[46.2] Omit “Pome Fruit”, substitute “Pome Fruits”.
[46.3] Omit “Stone Fruit”, substitute “Stone Fruits”.
[46.4] Omit “Assorted Tropical and sub-tropical fruit—edible peel”, substitute “Assorted tropical and sub-tropical fruits—edible peel”.

Schedule 29 Special purpose foods

[47] Section S29—19 (table item dealing with L-carnitine, column 2)

Omit “2g”, substitute “2 g”

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1065 – Code Revision – 2025 amendments (Compositional requirements for Special Medical Purpose Product for infants and other miscellaneous amendments)) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1065 to correct the compositional fat requirements for Special Medical Purpose Product for infants and make minor amendments to the Code. The Authority considered the Proposal in accordance with Division 2 of Part 3 of the FSANZ Act and has prepared a draft variation – the *Food Standards (Proposal P1065 – Code Revision – 2025 amendments (Compositional requirements for Special Medical Purpose Product for infants and other miscellaneous amendments)) Variation* (the draft variation).

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as

part of those food laws.

3. Purpose

The Authority prepared the draft variation to amend the Code to correct typographical errors, omissions, inconsistencies and formatting issues; update references; and to correct the compositional fat requirements for Special Medical Purpose Product for infants. The Code's current compositional fat requirements for Special Medical Purpose Product for infants are incorrect due to a drafting error in the *Food Standards (Proposal P1028 – Infant Formula) Variation*. They should be identical to those set by Proposal P1028 (P1028) for infant formula and for follow-on formula for the reasons stated in the 2nd Call for Submissions and in the Approval Report published for P1028. The proposed amendments are relatively minor in nature.

4. Documents incorporated by reference

Section 14 of the *Legislation Act 2003* provides that a legislative instrument (for example, the draft variation) may (among other things):

> incorporate any other matter contained in any other instrument or document in writing, which in force or exists at the time the legislative instrument commences, or a time before its commencement irrespective of whether the document still exists at the time the legislative instrument commences.

The following Code provisions incorporate by reference written documents in accordance with the above section. The draft variation would amend these provisions to update reference to an incorporated document. This reference by incorporation is consistent with the current practice in the Code.

Standard 1.1.2

The definition of 'permitted flavouring substance' in subsection 1.1.2—2(3) of the Code incorporates certain publications by reference. These include Edition 30 (1960 to 2022) of the Generally Recognised as Safe (GRAS) lists of flavouring substances published by the Flavour and Extract Manufacturers' Association of the United States (FEMA). This reference is now outdated as FEMA has published Edition 31 (1960 to 2024) of its GRAS lists of flavouring substances. The draft variation would amend the definition of 'permitted flavouring substance' to refer instead to the 31st Edition.

A copy of Edition 31 (2022) of FEMA's GRAS lists of flavouring substances is freely and publicly available online at https://www.femaflavor.org/publications/gras-publications/gras-31

Schedule 3

Section 1.1.1—15 of the Code requires certain substances to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code when added to food in accordance with the Code or sold for use in food.

Schedule 3 of the Code incorporates certain publications by reference to set specifications for various substances in the circumstances specified in that Schedule. The publications listed include the following:

- the Combined Compendium of Food Additive Specifications published by the Food and Agriculture Organisation of the United Nations/World Health Organisation Expert Committee on Food Additives (JECFA) in the Monographs listed in Schedule 3;

- the 13th edition (2022) of the Food chemicals codex published by the United States Pharmacopeial Convention; and
- the edition of the International Oenological Codex published by the Organisation Internationale de la Vigne et du Vin (OIV) in 2022.

The draft variation would amend relevant provisions in Schedule 3 to update these references to refer to the following.

- JECFA has added new Monographs 27 (2022), 30 (2022), 31 (2023), 32 (2024) and 34 (2025) to its Compendium of Food Additive Specifications. Copies are freely and publicly available online at https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/

- The OIV has published a new edition (2025) of the International Oenological Codex. A copy is freely and publicly available online at https://www.oiv.int/standards/international-oenological-codex.

- The United States Pharmacopeial Convention has published a new 2024 (14th edition) of the Food chemicals codex (FCC). A copy is available online at https://www.foodchemicalscodex.org/

  The FCC is not available for free. However, it is anticipated that the persons most affected by its adoption in the Code (food manufacturers), would be in possession of the document in order to manufacture food products. As important international benchmark for the safety and quality of food ingredients, it would be infeasible from a regulatory perspective to not adopt such benchmarks on the basis that the publications are not available for free.

  However, by prior written arrangement with the Authority, members of the public may arrange to view the FCC without charge at the Authority's Wellington and Canberra Offices.

  The National Library's Trove online system (www.trove.nla.gov.au/) allows users to identify libraries in Australia that are open to the public where editions (in most cases, earlier editions) of the FCC may be viewed. Members of the public may also approach any library that participates in inter-library loans with those university libraries to request an inter-library loan, or to obtain a photocopy of a particular part or monograph for personal study or research (but not for commercial purposes). Fees apply in relation to the making of such a request. Enquiries can be made through local libraries, State libraries and the National Library. For example, Trove indicates that access to the 1996 edition of the FCC is available at the University of Melbourne Library and the Hawksbury Campus Library of the Western Sydney University, which are both open to the public.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1065 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a 4-week period.

A regulation impact statement (RIS) has not been prepared for this proposal. This is because the amendments proposed in the draft variation are considered unlikely to have more than a minor regulatory impact. This is in line with previous advice from the Office of Impact Analysis on similar proposals (for example Proposal P1061 – Code Maintenance Proposal 2023, OIA reference 22-03854).

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

References to 'the variation' in this section are taken to be references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Proposal P1065 – Code Revision – 2025 Amendments (Compositional requirements for Special Medical Purpose Product for infants and other miscellaneous amendments)) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation commences on the date of gazettal of the instrument.

Clause 4 provides a transitional arrangement for the amendment made by Item [11] of the Schedule.

Subclause 4(1) provides that the stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 does not apply to the amendment made by Item [11] of the Schedule.

Instead, subclauses 4(2) and (3) provide a transitional arrangement where, during a transitional period commencing on the date of gazettal of the variation, a food product may be sold if the product complies with one of the following:

(a) the Code as in force at the time of sale, including as amended by each of the following:

- Item [11] of the Schedule; and
- the *Food Standards (Proposal P1028 – Infant Formula) Variation; and*
- the *Food Standards (Proposal P1028 – Infant Formula – Consequential Amendments) Variation*; or

(b) the Code as in force at the time of sale, but without the amendments made by the each of the above.

Subclause 4(3) also provides that this transition period ends on 13 September 2029. This is the end date for the transitional period for the amendments made by *Food Standards (Proposal P1028 – Infant Formula) Variation* and which should have included the amendment now being made by Item [11] of the Schedule.

8. Schedule to the variation

As explained above, each Item of the Schedule amends the Code.

7.1 Reflecting the amendments made to the compositional fat requirements for Special Medical Purpose Product for infants

Item [11] of the Schedule will amend subsection 2.9.1—34(2) by repealing the subsection and replacing it with a new subsection.

Current subsection 2.9.1—34(2) provides that a Special Medical Purpose Product for infants may only contain medium chain triglycerides that are either: a natural constituent of a milk-based ingredient of that product; or for a fat soluble vitamin that is specified in the table to section S29—5, a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the Special Medical Purpose Product for infants.

The phrase 'used as a processing aid' in relation to a food is defined in section 1.1.2—13 of the Code

New subsection 2.9.1—34(2) will provide that a Special Medical Purpose Product for infants may only contain medium chain triglycerides that: (a) contain predominantly the saturated fatty acids designated by 8:0 and 10:0; and (b) are one of the following:

(i) a natural constituent of a milk-based ingredient of that product; or

(ii) for a fat soluble vitamin that is specified in the table to section S29—5—a substance that was used as a processing aid in the preparation of that permitted fat soluble vitamin for use in the product.

The new subsection's compositional fat requirements for Special Medical Purpose Product for infants are identical to those currently set by paragraph 2.9.1—7(2)(a) of the Code for infant formula.

The requirement in the new subsection that permitted medium chain triglycerides must contain predominantly the saturated fatty acids designated by 8 to 0 and 10 to 0 should have been included by and with the amendments made by the *Food Standards (Proposal P1028 – Infant Formula) Variation.*

The amendment made by Item [11] of the Schedule will correct that drafting error.

7.2 Correcting typographical errors, omissions, inconsistencies and formatting

Items [2] – [10], and [12], [16] – [47] of the draft variation include amendments to correct typographical errors, omissions, and formatting issues; and to improve consistency across the Code.

7.3 Updating references

Items [1], and [13] – [15] of the draft variation include amendments to update references in the Code.