

14 May 2025 340-25

Approval Report – Proposal P1064

Australian only Infant Formula Product Standard

Food Standards Australia New Zealand (FSANZ) has approved amendments to the Australia New Zealand Food Standards Code to reflect the New Zealand Government's decision to opt out of Standard 2.9.1 of the Code.

On 27 February 2025, FSANZ called for comment from appropriate government agencies to assist consideration on the draft food regulatory measure. FSANZ received 3 submissions.

After having regard to the submissions received and for the reasons set out in this report, FSANZ approved the draft variation.

FSANZ approved the draft variation on 30 April 2025. The Food Ministers' Meeting.¹ was notified of FSANZ's decision on 14 May 2025.

This report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991*.

¹ Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

Table of contents

EXECUTIVE SUMMARY				
1		ODUCTION		
1		THE PROPOSAL		
1.	-	THE CURRENT STANDARD	. J	
1.	_	REASONS FOR PREPARING THE PROPOSAL		
1.	_	PROCEDURE FOR ASSESSMENT.		
1.	-	DECISION		
	_			
2 SU	MMA	RY OF THE FINDINGS	. 1	
2.	1	SUMMARY OF ISSUES RAISED IN SUBMISSIONS	. 1	
2.	2	RISK ASSESSMENT		
2.	3	RISK MANAGEMENT	. 1	
2.	4	RISK COMMUNICATION		
	2.4.1	Consultation	. 1	
	2.4.2	World Trade Organization (WTO)	. 1	
2.	5	FSANZ ACT ASSESSMENT REQUIREMENTS	. 2	
	2.5.1	Section 59	. 2	
	2.5.2	Subsection 18(1)	. 3	
R	FEREN	CES	. 3	
Α	ГТАСН	MENT A – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	. 4	
Α	ГТАСН	иент B — Draft Explanatory Statement	. 6	

Executive summary

Food Standards Australia New Zealand (FSANZ) prepared Proposal P1064 to amend the Australia New Zealand Food Standards Code (the Code) to reflect that, following Proposal P1028, Standard 2.9.1 of the Code does not apply in New Zealand.

The regulatory changes introduced by Proposal P1028 were endorsed by the Food Ministers' Meeting (FMM) on 25 July 2024 and gazetted on 13 September 2024. These changes, among other things, amended Standard 2.9.1, the Code's infant formula product standard.

On 5 August 2024, the New Zealand Government formally notified the FMM in accordance with paragraph 14 of Annex D of *The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* that New Zealand would opt out of the amended infant formula product standard developed under P1028. As a result, Standard 2.9.1 of the Code applies in Australia only.

The purpose of this proposal was to amend Standards 1.1.1 and 2.9.1 of the Code by inserting notes that state Standard 2.9.1 applies in Australia only. These notes inform readers about where the standard applies but have no legal effect.

Following assessment and the preparation of a draft variation, FSANZ called for comment from appropriate government agencies regarding the draft variation from 27 February 2025 to 27 March 2025. Three submissions were received, all of which FSANZ had regard to (see section 2.1 of this report for details of submissions made).

For the reasons set out in this report, FSANZ has decided to approve the draft variation proposed following assessment.

1 Introduction

1.1 The proposal

Food Standards Australia New Zealand (FSANZ) prepared Proposal P1064 to amend Standards 1.1.1 and 2.9.1 of Australia New Zealand Food Standards Code (the Code) by inserting notes that state Standard 2.9.1 – the infant formula products standard - applies in Australia only. These notes reflect the New Zealand Government's decision to opt out of the amended infant formula product standard developed under Proposal P1028 – Infant Formula.

The regulatory changes were approved by the FSANZ Board on 4 June 2024, endorsed by the Food Ministers' Meeting (FMM) on 25 July 2024 and gazetted on 13 September 2024.

On 5 August 2024, the New Zealand Government formally notified the FMM in accordance with paragraph 14 of Annex D of *The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* (the Treaty).² that New Zealand would opt out of the amended infant formula product standard.

As a result, Standard 2.9.1 now applies only in Australia.

Paragraph 16 of Annex D of the Treaty provides that where New Zealand has opted out of a food standard, the food standard in the Code must be annotated to indicate that the standard does not apply in New Zealand. These annotations also ensure that those who use and rely on the Code are aware of its legal application.

For these reasons, FSANZ prepared Proposal P1064.

1.2 The current Standard

As noted above, and for the reasons explained below, the relevant standards are:

- Standard 1.1.1 Structure of the Code and general provisions
- Standard 2.9.1 Infant formula products.

1.3 Reasons for preparing the proposal

The New Zealand Government opted out of the amended infant formula products standard (as per Proposal P1028) under Annex D of the Treaty.3.

As a result, Standard 2.9.1 of the Code does not apply in New Zealand.

The Treaty required FSANZ to make editorial amendments to Standard 2.9.1 and Standard 1.1.1 to reflect that fact.

1.4 Procedure for assessment

The proposal was assessed under the Minor Procedure as set out in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

The Minor Procedure is used for proposals involving amendments to the Code that, if made, would not directly or indirectly:

- (a) impose, vary or remove an obligation on any person; or
- (b) create, vary or remove a right of any person; or
- (c) otherwise alter the legal effect of the measure.

² www.foodregulation.gov.au/resources/publications/new-zealand-notice-opt-out-proposal-p1028-infant-formula-standard

³ www.foodregulation.gov.au/resources/publications/agreement-australia-new-zealand-joint-food-standards-system

For the reasons explained above, the proposed amendments meet the criteria.

The Minor Procedure required one statutory round of consultation with 'appropriate government agencies'.

The Act defines 'appropriate government agencies' to mean:

- each Commonwealth, State, Territory and New Zealand Department administered by a Minister who is a member of FMM
- any other body that has an officer on the Food Regulation Standing Committee
- any other Commonwealth, State, Territory and New Zealand body or officer that the FSANZ Board (or delegate) considers has a particular interest in the matter.

The notified government agencies, as per the FSANZ Act, are detailed in Table 1 below.

Table 1: Notified government agencies

(a) each Commonwealth, State, Territory and New Zealand Department administered by a Minister who is a member of FMM						
Australian Government						
New Zealand Government						
ACT Government						
NSW Government						
NT Government						
QLD Government						
SA Government						
TAS Government						
VIC Government						
WA Government						
(b) any other body that has an officer on the Food Regulation Standing Committee						
Department of Health and Aged Care						
Department of Agriculture, Fisheries and Forestry						
New Zealand Ministry for Primary Industries						
ACT Health Directorate						
NSW Food Authority						
NSW Department of Health						
NT Department of Health						
QLD Department of Health						
QLD Department of Agriculture and Fisheries						
SA Department of Health						
SA Department of Primary Industries and Regions						
TAS Department of Health						
TAS Department of Natural Resources and Environment						
VIC Department of Health						
Agriculture Victoria						
WA Department of Health						

Australian Local Government Association

(c) any other Commonwealth, State, Territory and New Zealand body or officer that the FSANZ Board (or delegate) considers has a particular interest in the matter

New Zealand Ministry of Health

New Zealand Ministry of Foreign Affairs and Trade

Department of Foreign Affairs and Trade

1.5 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. The approved draft variation is at Attachment A.

The related 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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Three submissions were received in response to the call for submissions. The New South Wales Food Authority (NSWFA), South Australia Health (SAH) and New Zealand Food Safety (NZFS) supported the draft variation and noted that it achieved the intent of communicating Standard 2.9.1 of the Code does not apply in New Zealand. All 3 submitters also raised broader food regulatory system concerns relating to the impact of the New Zealand Government's decision to opt out of Standard 2.9.1 (as amended by Proposal P1028). These are considered in Table 2 below.

Table 2: Summary of issues

Table 2. Sulfilliary of issues							
Issue	Raised by	FSANZ response					
Supported the draft variation and agreed it achieves the intent that Standard 2.9.1 of the Code does not apply in New Zealand.	NSWFA, SAH, NZFS	Noted.					
Raised multiple concerns regarding the operation of	NSWFA	Noted.					
the other 7 standards and 5 schedules (the consequential amendments) that were amended by Proposal P1028, and whether they apply in New Zealand and the interplay with Standard 2.9.1.		The issues raised are out of scope for this proposal. The New Zealand Government has opted out of Standard 2.9.1 of the Code with the result that Standard of the Code is now an Australian only standard and does not apply in New Zealand. FSANZ is required by the Treaty to annotate the Code to reflect that fact. That is this proposal's purpose.					
		FSANZ understands that Standard 2.9.1 as it was in force immediately prior to the gazettal of the variations made by Proposal P1028 remains in force in New Zealand as part of New Zealand law (the New Zealand standard). That is, as it previously had been adopted by the New Zealand Government under the <i>Food Act 2014</i> (NZ) and no action has been taken to date by that Government to amend or revoke it under section 400 of that Act.					
		The New Zealand standard is not part of the Code for the purposes of the FSANZ Act. Nor is it covered by the 'Australian New Zealand Food Standards System' established by the Treaty and for which FSANZ is authorised to develop draft standards in accordance with the FSANZ Act.					

Issue	Raised by	FSANZ response
		To date, FSANZ also understands that the consequential amendments made by Proposal P1028 to Standards 1.1.2, 1.2.3, 1.3.1, 1.5.1, 2.9.2, 2.9.3, 2.9.5, and Schedules 8, 15, 19, 25 and 29 of the Code have not been adopted in New Zealand under the <i>Food Act 2014</i> (NZ).
		The application, interpretation and amendment of the New Zealand standard is a matter for the New Zealand Government.
		The application or otherwise to New Zealand of infant formula product related amendments to Code provisions other than the Australia only Standard 2.9.1 is also a matter for the New Zealand Government.
Raised concerns regarding the potential for	NSWFA	Noted.
desirable consequences and ambiguity to arise if a amendments made by P1028 aren't considered ad adopted in their entirety in New Zealand.		These issues are out of scope for this proposal. As explained above, the purpose of this proposal is to ensure the Code reflects the existing law as it relates to the application of Standard 2.9.1 of the Code in New Zealand, and for the Australian Government to meet its obligations under the Treaty.
		As explained above, the concerns raised are matters for the New Zealand Government.
Requests clarity as to whether future applications to		Noted.
add new substances to infant formula products apply in Australia only.		Standard 2.9.1 of the Code is an Australian only standard. FSANZ's approach for assessing and developing food regulatory measures concerning infant formula products will be applicable to Australia only.
		The New Zealand standard is not part of the Code for the purposes of the FSANZ Act. Nor is it covered by the 'Australian New Zealand Food Standards System' established by the Treaty and for which FSANZ is authorised to develop draft standards in accordance with the FSANZ Act. See also responses below.
		The application, interpretation and amendment of the New Zealand standard is a matter for the New Zealand Government.
		The application or otherwise to New Zealand of infant formula product related amendments to Code provisions other than the Australia only Standard 2.9.1 also remains a matter for the New Zealand Government.

Issue	Raised by	FSANZ response
Raised concern regarding the portrayal of Standard 2.9.1 in New Zealand, as described in section 2.5.1.3 of the CFS, and requested the following text be removed from the section: Standard 2.9.1 as it is in force in New Zealand is not part of the Code for the purposes of the FSANZ Act. Nor is it covered by the 'Australian New Zealand Food Standards System' established by the Treaty.	NZFS	 Noted. However, FSANZ considers the statement in question accurately reflects the current situation for New Zealand and Australia. That is: The Treaty establishes the 'Australian New Zealand Food Standards System' for the purpose of developing and maintaining a joint food standards code. New Zealand formally opted out of Standard 2.9.1 of the joint Code on 5 August 2024 in accordance with the Treaty. As stated above, the result is that Standard 2.9.1 as it was in force immediately prior to the gazettal of Proposal P1028 variations (the New Zealand standard) remains in force in New Zealand as a part of New Zealand law. This New Zealand standard is not part of the joint Code for the purposes of the Treaty. Given the above, New Zealand did not adopt the Food Standards (Proposal P1028 - Infant Formula) Variation. Therefore, Standard 2.9.1 of the joint Code no longer applies to and operates in New Zealand. What remains in New Zealand, as FSANZ understand the provisions of the Food Act 2014 (NZ), is an adopted food standard that will remain in force as a standard made under that Act, but not a standard that is made under or can be varied under the FSANZ Act. It is not a joint standard or part of the (joint) Code for the purposes of the Treaty or the FSANZ Act.
Raised concerns regarding the inconsistencies between the regulation of infant formula products in Australia and New Zealand and the effects on the operation of the Trans-Tasman Mutual Recognition Arrangement (TTMRA), regulatory clarity and economic and compliance implications.	SAH	Noted. The issues raised are out of scope for this proposal. As explained above, the purpose of this proposal is to ensure the Code reflects the existing law as it relates to the application of Standard 2.9.1 of the Code in New Zealand, and for the Australian Government to meet its obligations under the Treaty. The operation of the TTRMA is a matter for the Australian and New Zealand governments and out of scope of this proposal. The Imported Food Control Act 1992 applies to food imported into Australia. The Department of Agriculture, Fisheries and Forestry is responsible for the administration of that Act.

2.2 Risk assessment

All of the issues considered are editorial in nature and merely reflect the existing law. Please see section 2.1 in the Call for Submissions for further details (FSANZ, 2025).

No potential public health and safety concerns have been identified.

2.3 Risk management

Having regard to all submissions received, and for the reasons set out in this report, FSANZ has approved the draft variation proposed in the call for submissions.

The proposed amendments do not have any legal effect in and of themselves, nor do they amend any provisions of Standard 2.9.1. The Code requirements remain unchanged. As such, no potential public health and safety concerns have been identified.

The approved draft variation inserts notes into subsections 1.1.1—2(2) and 1.1.1—3, and under the title of Standard 2.9.1, to inform readers that Standard 2.9.1 of the Code applies in Australia only.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ called for submissions regarding the draft variation from 27 February 2025 to 27 March 2025. As this proposal was assessed under the Minor Procedure, consultation on the proposed draft variations was undertaken with notified government agencies as required by the FSANZ Act.

Three submissions were received. All submissions were considered by the FSANZ Board as part of its assessment. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal. All comments are valued and contribute to the rigour of our assessment.

2.4.2 World Trade Organization (WTO)

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

The approved draft variation does not change the legal effect of the Code. It merely reflects what is the existing law in terms of the Code's application and informs readers of that fact. Proposal P1064 was considered unlikely to have significant effect on international trade as it would not impose any new regulatory requirements for Australia. Therefore, a notification to the WTO under Australia's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 FSANZ Act assessment requirements

2.5.1 Section 59

2.5.1.1 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 development of that measure.

Proposal P1064 will not change the law or impose any new requirements. Its purpose is to reflect the existing law, which is that Standard 2.9.1 of the Code does not apply in New Zealand. None of the proposed amendments will have any legal effect in or of themselves, or impose any obligations on, or vary the rights, of any person. As such, all amendments in the approved draft variation are minor in nature and are not expected to impose costs on the community, industry or government additional to those already generated by compliance with or enforcement of the existing Code.

If the amendments are not made, regulatory uncertainty (e.g. stakeholder misunderstandings) will continue to exist because the Code will not reflect existing law.

For those reasons, FSANZ considers the benefits to the community, government or industry that will arise from the approved draft variation would outweigh the costs that would arise from the development of that measure.

FSANZ did not prepare a regulation impact statement (RIS) for this proposal. This is due to the minor impact of the proposal (as described above) and is in line with previous advice from the Office of Impact Analysis (OIA) (e.g. 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.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal.

2.5.1.3 Any relevant New Zealand standards

FSANZ understands that:

- Standard 2.9.1, as it was in force immediately prior to the gazettal of the variations made by Proposal P1028, remains in force in New Zealand as a part of New Zealand law. That is, it had previously been adopted under the *Food Act 2014* (NZ) and no action has been taken by the New Zealand Government to amend or revoke it under section 400 of the *Food Act 2014* (NZ).
- Standard 2.9.1, as it is in force in New Zealand, is not part of the Code for the purposes of the FSANZ Act, nor is it covered by the 'Australian New Zealand Food Standards System' established by the Treaty.

The approved draft variation will not amend any New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ had regard to the 3 objectives in subsection 18(1) of the FSANZ Act during the assessment of the proposal:

- 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 concluded that the approved draft variation will have little or no direct impact in terms of these objectives. As mentioned above, no potential public health and safety concerns were identified.

The purpose of Proposal P1064 was to reflect the existing law as it relates to the application of Standard 2.9.1 of the Code in New Zealand, and for the Australian Government to meet its obligations under the Treaty. The amendments required are editorial and machinery in nature and do not have any legal effect. Consequently, the approved draft variation does not raise public health and safety issues for consideration.

2.5.3 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 FMM.

References

FSANZ (2025) Call for Submissions - 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

Attachments

- Approved draft variation to the Australia New Zealand Food Standards Code
- B. Explanatory Statement

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



Food Standards (Proposal P1064 – Australian only Infant Formula Product Standard) Variation

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 the Delegate]

[Insert Delegate's name and position title]

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 P1064 – Australian only Infant Formula Product Standard) 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.

Schedule

Standard 1.1.1 - Structure of the Code and general provisions

[1] Subsection 1.1.1—2(2)

Omit:

Standard 2.9.1 Infant formula products

Substitute:

Standard 2.9.1 Infant formula products

Note Applies in Australia only

[2] Note 1 to Subsection 1.1.1—3(1)

Omit:

(vii) Chapter 3 (food safety standards) and Chapter 4 (primary production and processing standards).

Substitute:

(vii) Standard 2.9.1 (infant formula products);

(viii) Chapter 3 (food safety standards);

(vix) Chapter 4 (primary production and processing standards).

Standard 2.9.1 - Infant Formula Products

[3] Note 2 to the title of the Standard

Repeal the Note, substitute:

Note 2 This Standard applies in Australia only. New Zealand has under Annex D of the Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System opted out of this Standard. See also section 1.1.1—3.

Attachment B - Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Proposal P1064 – Australian only Infant Formula Product Standard) 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.

FSANZ prepared Proposal P1064 to add or amend Notes in Standards 1.1.1 and 2.9.1 of the Code in order to advise readers that Standard 2.9.1 applies in Australia only.

The Authority considered the proposal in accordance with Division 2 of Part 3 and has approved a draft variation - the *Food Standards (Proposal P1064 – Australian only Infant Formula Product Standard) Variation* (the approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

2. Variation will be a legislative instrument

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

This instrument is 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 purpose of the approved draft variation is to add or amend Notes in Standard 1.1.1 and 2.9.1 of the Code to reflect that Standard 2.9.1 applies in Australia only and to inform readers of that fact.

Standard 2.9.1, the Code's infant formula products standard, was amended in 2024 as result of Proposal P1028. That Proposal's regulatory changes were endorsed by the FMM on 25 July 2024 and gazetted on 13 September 2024. On 5 August 2024, the New Zealand Government formally notified the FMM in accordance with paragraph 14 of Annex D of *The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System* that New Zealand would opt out of the amended infant formula products standard developed under P1028. As a result, Standard 2.9.1 of the Code now applies in Australia only.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1064 included one round of consultation with government agencies in accordance with the FSANZ Act. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

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

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 of the approved draft variation provides that the name of the variation is the *Food Standards (P1064 – Australian only Infant Formula Product Standard) Variation.*

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

Clause 3 of the approved draft variation provides that the variation will commence on the date of gazettal of the instrument.

Schedule to the approved draft variation

Item [1] of the Schedule would amend subsection 1.1.1—2(2) of the Code.

Subsection 1.1.1—2(2) of the Code sets out the structure of the Code and lists each standard. It provides, in effect, a table of contents for the Code. The list of standards in that subsection identifies for readers which standards of the Code apply in Australia only by the use of a Note after the entry for each relevant Chapter or standard.

Item [1] amends subsection 1.1.1—2(2) by inserting a Note stating 'Applies in Australia only' after the reference in that subsection to Standard 2.9.1. The Note would inform readers of the fact that Standard 2.9.1 of the Code applies in Australia only

Item [2] of the Schedule amends Note 1 to subsection 1.1.1—3(1).

Section 1.1.1—3 sets out to what food the Code applies. Subsection 1.1.1—3(1) provides that, unless stated otherwise, the Code applies to food that is sold, processed or handled for sale or imported into Australia or New Zealand. Note 1 to that subsection lists those standards or provisions in the Code which the New Zealand Government has not incorporated or adopted under the *Food Act 2014* (NZ).

The approved draft variation amends the above-mentioned list in Note 1 of subsection 1.1.1—3(1) by replacing the existing paragraph (vii) – which refers to 'Chapter 3 (food safety standards) and Chapter 4 (primary production and processing standards)' - with three new paragraphs as follows:

- (vii) Standard 2.9.1 (infant formula products);
- (viii) Chapter 3 (food safety standards);
- (vix) Chapter 4 (primary production and processing standards).

The effect of this amendment is to add Standard 2.9.1 to the list in Note 1 of Code provisions that have not been incorporated or adopted under the *Food Act 2014* (NZ). It also separates the references to Chapter 3 (food safety standards) and Chapter 4 (primary production and processing standards), currently combined in one paragraph (vii), into their own paragraphs: (viii) and (vix).

The amendment will inform readers of the fact that Standard 2.9.1 of the Code applies in Australia only.

Item [3] of the Schedule repeals and replaces Note 2 to the title of Standard 2.9.1.

The Code identifies standards that do not apply in New Zealand by use of a note under the title of the relevant standard and that states the standard applies in Australia only.

At present, the following note is included under the title of Standard 2.9.1:

Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the *Food Act 2014* (NZ). See also section 1.1.1—3.

This note is now incorrect as Standard 2.9.1 of the Code (as amended by Proposal P1028) has not been incorporated in or adopted under the New Zealand Food Act and does not apply in New Zealand

Item [3] amends the text of Note 2 to state as follows:

Note 2 This Standard applies in Australia only. New Zealand has under Annex D of the Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System opted out of this Standard. See also section 1.1.1—3.

The amended Note would inform readers of the fact that Standard 2.9.1 of the Code applies in Australia only. The above is the same approach as taken for other standards of the Code that do not apply in New Zealand, such as Standard 1.4.2 – *Agvet chemicals* and Standard 1.6.2 – *Processing requirements for meat*.