

17 March 2016
[07–16]

Approval report – Proposal P1039

Microbiological Criteria for Infant Formula

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to amend the Code to include food safety microbiological criteria for infant formula, aligning with international (Codex) standards.

On 9 October 2015, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received nine submissions.

FSANZ approved the draft variation on 3 March 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 16 March 2016.

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

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Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at

<http://www.foodstandards.gov.au/code/proposals/Pages/P1039MicroReviewInfantFormula.aspx>

- SD1 Scientific evidence informing the proposed microbiological criteria for infant formula
- SD2 Process hygiene criteria (at Approval)

Executive summary

The microbiological limits in the current *Australia New Zealand Food Standards Code* (the Code) and associated guidelines were developed before 2000. Since then, a preventative through-chain approach to food safety has evolved and work has progressed internationally to further inform our understanding of pathogen management in the food chain, including the management of 'emerging' pathogens. FSANZ's contemporary risk management approach is to establish microbiological criteria as either **food safety criteria** or **process hygiene criteria**.

In 2008, the Codex Committee on Food Hygiene (CCFH) revised the *Code of Hygienic Practice for Powdered Infant formulae for Infants and Young Children (CAC/RCP 66 - 2008)* in response to the emergence of *Cronobacter* species (referred to as *Enterobacter sakazakii* prior to 2008) as an important pathogen for infants fed with powdered infant formula (PIF).

FSANZ has approved a draft variation to align the food safety microbiological criteria for powdered infant formula products set by Standard 1.1.2 and Schedule 27 with international (Codex) standards.

The approved draft variation:

- separates the microbiological limits for powdered infant formula products in the table into two new food categories: powdered infant formula products and powdered follow-on formula
- removes current limits specified in the table for Coliforms, Coagulase-positive staphylococci, *Bacillus cereus* and SPC in respect of these foods
- amends the sampling plan for *Salmonella* in these foods by replacing 10 with 60 in Column 2(n) in the table
- inserts new limits for *Cronobacter* in powdered infant formula products, where the number of sample units (n) is 30, the acceptable microbiological limit (m) is 'not detected in 10g', and the number of sample units allowed to exceed that acceptable microbiological limit (c) is 0. These limits do not apply to powdered follow-on formula.

The approved draft variation also makes consequential amendments to Standard 1.1.2.

Process hygiene criteria have also been developed for Enterobacteriaceae and Mesophilic Aerobic Bacteria in powdered infant formula that can be used for routine microbiological sampling and testing as part of monitoring and verification of the food safety control system they have in place. These are not food safety criteria and therefore are proposed to be contained in the guidance document *Compendium of Microbiological Criteria for Food* rather than the Code.

1 Introduction

1.1 The Proposal

The existing microbiological limits in the Code and associated guidelines were developed before 2000. Since then, a preventative through-chain approach to food safety has evolved and work has progressed internationally through the Codex Alimentarius (Codex) to further inform our understanding of pathogen management in the food chain, including the management of 'emerging' pathogens.

Proposal P1039 was prepared to review microbiological limits set by Standard 1.6.1 and Schedule 27. FSANZ consulted on the principles underpinning the second stage of the review of microbiological criteria in early 2015¹ and on the proposed draft variation in October 2015². The resulting submissions have informed our work on this Proposal.

1.2 The current Standard

The current infant formula microbiological limits in Schedule 27 do not reflect recent scientific knowledge and approaches to food safety (i.e. they are not fit for purpose) because:

- the limits are out of step with more recent international risk assessment work and microbiological criteria developed by Codex for powdered infant formula for the pathogens *Cronobacter* species and *Salmonella*
- limits are included for indicator tests that are not appropriate as pass/fail criteria for a lot of food
- limits are included for pathogens which do not represent a direct threat to the health of infants.

1.2.1 Other relevant standards

Standard 1.1.2 defines certain terms that are used throughout the Code, including in Standard 1.6.1 and Schedule 27.

Standard 1.1.2 contains the definition of the term 'infant formula product'. Standard 2.9.1 contains definitions for infant formula and follow-on-formula.

Infant formula is defined in the Code as: "an infant formula product represented as a breast milk substitute for infants which satisfies the nutritional requirements of infants aged up to four to six months". Follow-on-formula is defined in the Code as: "an infant formula product that...is suitable to constitute the principle liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months".

Standard 2.9.1 and Schedule 29 specifically regulate the compositional and labelling requirements for infant formula (and other infant formula products), including directions for preparation and use. The Standard applies to all infant formula whether in powder, liquid concentrate or 'ready-to-drink' forms. Standard 2.9.1 is the most prescriptive of all standards in the Code that regulate a food category.

¹ [http://www.foodstandards.gov.au/code/microbiollimits/Pages/Review-of-microbiological-criteria-\(second-stage\).aspx](http://www.foodstandards.gov.au/code/microbiollimits/Pages/Review-of-microbiological-criteria-(second-stage).aspx)

² <http://www.foodstandards.gov.au/code/proposals/Pages/P1039MicroReviewInfantFormula.aspx>

1.3 Reasons for preparing Proposal

P1039 was prepared to amend the Code to include food safety microbiological criteria for powdered infant formula products, aligning with:

- international standards established by Codex Alimentarius (Codex)
- current scientific knowledge
- best practice manufacturing processes
- the transition to outcomes-based risk management processes.

1.4 Procedure for assessment

The Proposal was assessed under the General Procedure.

1.5 Decision

The draft variation as proposed following assessment was approved with amendment. The approved draft variation, as varied after consideration of submissions, is at Attachment A. The variation takes effect on gazettal. 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

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ consulted on the proposed draft variation in October 2015 and nine submissions were received. The majority of the submissions were generally supportive of FSANZ's overall approach in the review and variation to the standard, specifically supporting:

- harmonisation with Codex and international standards
- the creation of two distinct product categories powdered infant formula products and powdered follow-on formula
- differentiation between process hygiene and food safety criteria and the separation of process hygiene criteria into a guidance document
- the development of the *Compendium of Microbiological Criteria for Food* as a food guidance document and the proposed process hygiene criteria and associated sampling plans.

This is consistent with previous consultation on the review of microbiological criteria for food in Standard 1.6.1 and associated guidelines.

Issues raised by submitters are outlined and addressed below in Table 1.

Table 1: Summary of issues

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Stringency of the sampling plans proposed for Salmonella (and Cronobacter)</p> <ul style="list-style-type: none"> - unnecessarily onerous (no evidence of regulatory failure) - Increases the cost of testing (changes, therefore may not be “machinery in nature”). 	<p>Dairy Food Safety Victoria (DFSV) and the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources</p>	<p>The FAO/WHO Expert Consultation (2004) determined <i>Salmonella</i> spp and <i>Cronobacter</i> spp. to be “microorganisms with a clear evidence of causality with illness” (Category A). The establishment of sampling plans by Codex utilised the ICMSF suggested sampling plans based on the degree of health concern and condition for use (ICMSF, 2002). This recommends a stringent sampling plan for <i>Salmonella</i> (case 15, n=60) based on <i>Salmonella</i> being a severe health hazard for infants and that conditions of use may increase the hazard (reconstituted infant formula may support its growth and can be the sole source of nutrition for infants < 6 months). For <i>Cronobacter</i> a case 14 (n=30) sampling plan was proposed as conditions of use cause no change in concern.</p> <p>Food safety criteria for powdered infant formula products in the Code will establish sampling plans for lot acceptance of product for sale in Australia and New Zealand or imported into Australia and New Zealand that can be applied by regulatory authorities. Manufacturers of powdered infant formula products could ensure their product can comply with the sampling plans specified through implementing a food safety system, such as food safety programs or HACCP, and undertaking an appropriate level of testing to verify that the controls in place are working. For example, in relation to n=60 for <i>Salmonella</i> spp, the ICMSF (2011) raises that alternative sampling plans for routine testing are appropriate “for manufacturers applying integrated sampling plans with in-process and environmental samples... end product testing for <i>Salmonella</i> is usually performed as verification only. Positive results of either in-process or environmental samples indicating an increased risk of its presence in the finished product should trigger a change in the sampling regime, i.e., testing of up to 60 x 25 g analytical units for release purposes may be appropriate under such conditions.”</p> <p>Industry should already be operating under food safety systems that include environmental and in-process sampling. Industry submissions are supportive of the stringent sampling plans proposed for <i>Salmonella</i> and <i>Cronobacter</i>. The cost of microbiological testing has not been raised as an issue by industry groups or manufacturers.</p> <p>When testing a large number of samples is required (such as n=30 or 60), it is possible to composite multiple samples thereby increasing efficiency, and reducing the workload and cost of testing.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Removal of limits for <i>Bacillus cereus</i> – mishandling and temperature abuse may cause food poisoning</p> <p>Removal of limits for coagulase positive staphylococcus and coliforms – may be required for testing in overseas countries and so should be retained.</p>	<p>Dairy Food Safety Victoria (DFSV) and the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources</p> <p>Food Technology Association of Australia</p>	<p>The risk assessment work undertaken by the WHO/FAO Expert Consultation (2004) categorised <i>Staphylococcus aureus</i> and <i>Bacillus cereus</i> as “Microorganisms for which causality with illness is less plausible or not yet demonstrated” (Category C). This was based on a lack of evidence that these microorganisms cause illness in infants fed powdered infant formula. It is generally accepted that low levels (<100 cfu/g) of these microorganisms may be present and would be managed through product preparation and handling instructions (ICMSF, 2011). It may be expected that these hazards would be managed under a manufacturer’s food safety program or HACCP plan through controls/specifications on critical ingredients.</p> <p>The majority of submissions support deleting limits for coagulase positive staphylococcus and <i>B. cereus</i> from the Code.</p> <p>Aligning with internationally agreed microbiological criteria established by Codex should also support trade. Additional testing requirements may be imposed by importing countries however this is not a reason for retaining unnecessary microbiological criteria in the Code.</p>
<p>Terminology – Mesophilic Aerobic Bacteria not as well understood as Standard Plate Count or Aerobic Plate Count</p>	<p>Dairy Food Safety Victoria (DFSV) and the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources</p>	<p>Mesophilic aerobic bacteria are the group of microorganisms that are being tested for. The test method used generally has been referred to as a Standard Plate Count or Aerobic Plate Count. The applicable Australian Standard and ISO methods (AS 5013.5 – 2004 and ISO 4833 – 1:2013) are described as “horizontal methods for enumeration of microorganisms that are able to grow and form colonies in a solid medium after aerobic incubation at 30 °C”.</p> <p>Process hygiene criteria have been proposed for Mesophilic Aerobic Bacteria, not a test method.</p>
<p>Both the names “<i>Cronobacter</i>” and “<i>Enterobacter sakazakii</i>” should be included for reference for a nominated period (12 months)</p>	<p>Food Technology Association of Australia</p>	<p>As a result of reclassification and increased understanding of the taxonomy, the correct nomenclature is now <i>Cronobacter</i> (see section 3.1.1 in SD1) and this will be the name included in the Code.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
Qualification regarding SPC and added lactic acid bacteria should be made in the process hygiene criteria for PIFs.	Dairy Food Safety Victoria (DFSV) and the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources	Now included.
It is premature to change the name of the Standard 1.6.1 from “Microbiological limits in food” to “Food safety microbiological criteria” as there are indicators that are still included for other commodities.	Dairy Food Safety Victoria (DFSV) and the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources	Agreed. To avoid any confusion the title of Standard 1.6.1 will not be changed until the review of microbiological criteria has been completed.
Process hygiene criteria for Enterobacteriaceae are not consistent with Codex guidelines. Explanatory notes from the Codex guidelines as to why this is not a true 2-class sampling plan could also be included.	NZ Ministry for Primary Industries	<p>Agree. The “n” value proposed in the sampling plan for Enterobacteriaceae in powdered infant formula products was incorrectly transcribed in the Call for Submissions Report and has now been amended to n=10.</p> <p>Information included in the explanatory notes will be included in the final version of the Compendium guidance document.</p>
Additional definitions in Schedule 27 for powdered infant formula and powdered follow on formula to assist with avoiding uncertainty in the application of microbiological criteria	Dairy Goat Cooperative	<p>Definitions in Standard 1.1.2 apply across the Code and the current definitions cover age applicability. FSANZ considers that no additional definitions are required in Schedule 27.</p> <p>However, it is noted that the term used, ‘powdered infant formula’, should actually be ‘powdered infant formula products’ and this has been amended in the revised drafting.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>New Zealand data be accurately represented in the Supporting Document (SD) 1, including:</p> <ul style="list-style-type: none"> o Table 2 – 2004 reference to a premature baby dying of meningitis caused by <i>C. sakazakii</i> infection with four other infants being colonized but not becoming ill. The additional four infants to not be referred to as cases. o Results of 2009 NZ survey to be included in table 4 	<p>NZ Ministry for Primary Industries</p>	<p>Agree. Table 2 has been updated to reflect this clarification on reported cases of illness from <i>Cronobacter</i> spp in NZ. Results of the 2009 NZ survey have also been added to Table 4</p>
<p>WHO recommendations on PIF reconstitution in SD1 be excluded from the final version, or if it remains, a footnote noting that NZ guidance for PIF reconstitution is different</p>	<p>NZ Ministry for Primary Industries</p>	<p>The reference to reconstitution temperatures in SD1 is in relation to the outcomes of the JEMRA reports, recognising that <i>Cronobacter</i> spp are rapidly inactivated at temperatures >70°C. Section 4.1 has been refined to make this clearer. Guidance on reconstitution temperatures will be considered in detail under a separate Proposal P1028 – Infant formula.</p>

2.2 Risk assessment

FSANZ prepared a summary of the risk assessment work undertaken to inform the Codex risk management approach; in particular, the information supporting establishment of microbiological criteria (refer to SD1).

In 2008, the CCFH revised the *Code of Hygienic Practice for Powdered Infant formulae for Infants and Young Children (CAC/RCP 66 - 2008)* in response to the emergence of *Cronobacter* species (referred to as *Enterobacter sakazakii* prior to 2008) as an important pathogen for infants fed with powdered infant formula (PIF). The revised code introduced a set of microbiological criteria for *Cronobacter* spp. in PIF, and reconfirmed the application of a set of microbiological criteria for *Salmonella* spp. in both PIF and follow-up formula (FUF).

The FAO/WHO expert consultations identified the organisms of concern in infant formula and the relevant control measures throughout the food chain to reduce the risks for infants associated with consumption of infant formula. Guidance on how a microbiological criterion could be used to reduce relative risk was also considered in the expert consultations. This was achieved by providing examples of how effectively different sampling plans are able to reject lots through detecting elevated levels of contamination and the corresponding predicted reduction in relative risk.

2.3 Risk management

FSANZ's risk management approach was to establish microbiological criteria as either:

- **food safety criteria** or
- **process hygiene criteria**

Together, these microbiological criteria provide a "fit for purpose" suite of decision criteria appropriate to the microbiological testing needed to support the safe production of a food.

Following consideration of the assessment findings, a basic cost-benefit analysis and the issues raised during consultation, FSANZ approved the draft variations to Standards 1.1.2 and Schedule 27.

The approved draft variation will amend the Code to include food safety microbiological criteria for infant formula that is supported by the available science and harmonises with Codex by:

- removing limits for indicator tests (standard plate count and coliforms) as these are not appropriate as food safety criteria
- removing limits for the microorganisms *Bacillus cereus* and coagulase positive staphylococci as the FAO/WHO expert consultations found that these do not represent a direct threat to the health of infants
- introducing limits for *Cronobacter* species in powdered infant formula products
- amending the sampling plan for *Salmonella* to increase case stringency to that endorsed by Codex.

Process hygiene criteria have also been developed for Enterobacteriaceae and Mesophilic Aerobic Bacteria in powdered infant formula that can be used for routine microbiological sampling and testing as part of monitoring and verification of the food safety control system they have in place (SD2). These will be available in a guidance document that FSANZ is compiling titled *Compendium of Microbiological Criteria for Food* (the Compendium) to provide guidance on appropriate process hygiene criteria for specific commodities or food types.

The draft variations also include consequential amendments to the related Standard 1.1.2 to address other elements which were no longer required as a result of amendments to 1.6.1, such as definitions.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. Every submission was considered and reviewed by FSANZ, (see Table 1). All comments are valued and contribute to the rigour of our assessment.

FSANZ also undertook targeted consultation with the Infant Nutrition Council (INC) on the proposed variation and the associated Compendium. The INC advised that the approved draft variation's approach reflects current international developments and scientific principles. Specific feedback included:

- support for the proposed process hygiene criteria to be incorporated into the Compendium
- that the food safety criteria which remain in the Code as a result of the approved draft variation align with international standards
- the sampling plan, while stringent, reflects that the target audience is a vulnerable population.
- support for testing for broader pathogen categories

The Compendium will be published on the FSANZ website to coincide with the commencement of the approved draft variation and related arrangements for implementation of its requirements.

The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News. Every submission was considered by the FSANZ Board.

The FSANZ Board's decision has been notified to the Forum. If the decision is not subject to a request for a review, the public will be notified of the gazettal of the variation to the Code in national press and on the FSANZ website.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations 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.

FSANZ made a notification to the WTO for this Proposal in accordance with the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. No WTO member nation provided comment on this Proposal.

2.5 FSANZ Act assessment requirements

2.5.1 Section 59

2.5.1.1 Cost benefit analysis

The regulatory impact on Government, industry and consumers was considered to be minor given:

- Current testing requirements have been found to be out of date in terms of current scientific thinking, best practice manufacturing processes, and international standards as outlined in the World Health Organization's Codex Alimentarius³ (Codex). Removing the redundant testing regime may reduce industry testing costs and government compliance costs.
- The segregation of food safety and process hygiene criteria will avoid the unnecessary destruction of products and unnecessary food recalls. Failure to meet process hygiene criteria should lead to a review of the effectiveness of the businesses' process hygiene rather than destruction of the product, as is required in the current standard. The separation of criteria for safety and those indicating process hygiene is the approach adopted in Codex.

New testing requirements are being introduced as part of this Proposal. FSANZ's extensive consultation with industry has indicated that these will not materially increase costs as these tests are already undertaken to meet international trade requirements, and customer expectations of food safety.

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 14 August 2015 (reference 19531) confirmed that a Regulation Impact Statement (RIS) was not required for this Proposal.

2.5.1.2 Other measures

FSANZ is not aware of any other measures (whether available to FSANZ or not) that would be more cost-effective than the approved draft variation.

2.5.1.3 Any relevant New Zealand standards

Standard 1.6.1 and Schedule 27 establish microbiological limits for food for sale in Australia and New Zealand.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

³ Codex Alimentarius Commission – a joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) body responsible for developing internationally recognised standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety.

2.5.2.1 Protection of public health and safety

The emergence of *Cronobacter* as an opportunistic pathogen with potential severe consequences, including permanent disability or fatality, led to its inclusion in the criteria for pathogenic microorganisms for powdered infant formula in the Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CoHP). As Schedule 27 (currently Standard 1.6.1) predates the development of the CoHP, it does not currently provide a microbiological limit for *Cronobacter*. This is out of step with international approaches which could potentially be putting infants at greater risk of contracting foodborne illness. The approved draft variation addresses this risk.

Establishing appropriate microbiological limits for foods is an important element in a risk management framework for a safe food supply.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

No issues were identified.

2.5.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

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**

Several risk assessments have been undertaken internationally by the FAO/WHO which led to the development of the current Codex standards. FSANZ has had regard to that risk assessment work in assessing P1039 and is satisfied that it reflects the best available scientific evidence.

- **the promotion of consistency between domestic and international food standards**

The approved draft variation establishes appropriate food safety microbiological criteria for two pathogens of concern which are consistent with the approach agreed internationally (through Codex) for the food safety management of infant formula.

- **the desirability of an efficient and internationally competitive food industry**

Aligning microbiological criteria with an internationally agreed approach supports an efficient and internationally competitive food industry. Australian producers are already meeting the criteria which are consistent with international regulatory requirements.

- **the promotion of fair trading in food**

No issues were identified.

- **any written policy guidelines formulated by the Forum on Food Regulation**

There are no written policy guidelines relevant to the assessment of this Proposal.

3 References

Codex (2008) *Code of hygienic practice for powdered infant formulae for infants and young children* (CAC/RCP 66 – 2008), http://www.codexalimentarius.org/standards/list-standards/en/?no_cache=1 accessed 28 July 2015.

Codex (2013) *Principles and Guidelines for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997 [revised and renamed 2013]). Codex Alimentarius Commission, Geneva, Switzerland.

FAO/WHO (2004) *Enterobacter sakazakii* and microorganisms in powdered infant formula: Meeting Report

International Commission on Microbiological Specifications for Foods (2002) *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*. Springer, New York.

International Commission on Microbiological Specifications for Foods (2011) *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance*. Springer, New York.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Proposal P1039 – Microbiological Criteria for Infant Formula) 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 Standards Management Officer]

Standards Management Officer
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 P1039 – Microbiological Criteria for Infant Formula) 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 Effect of the variation to the Code

Section 1.1.1—9 of the Code does not apply to the variation made by this instrument.

Schedule

[1] **Standard 1.1.2** is varied by omitting the definition of **SPC** from subsection 1.1.2—2(3), substituting

SPC means a standard plate count at 30°C with an incubation time of 72 hours.

[2] **Schedule 27** is varied by

[2.1] omitting the note to section S27—2, substituting

Note In this Code (see section 1.1.2—2):

SPC means a standard plate count at 30°C with an incubation time of 72 hours.

[2.2] omitting section S27—3

[2.3] omitting the following from the table to section S27—4

Powdered infant formula products

<i>Bacillus cereus</i>	5	0	10 ² /g	
Coagulase-positive staphylococci	5	1	not detected in 1 g	10/g
Coliforms	5	2	less than 3/g	10/g
<i>Salmonella</i>	10	0	not detected in 25 g	
SPC	5	2	10 ³ /g	10 ⁴ /g

substituting

Powdered infant formula products*

<i>Cronobacter</i>	30	0	not detected in 10g	
<i>Salmonella</i>	60	0	not detected in 25 g	

Powdered follow-on formula*

<i>Salmonella</i>	60	0	not detected in 25 g	
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Attachment B – Explanatory Statement

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 P1039 to include food safety microbiological criteria for infant formula in Schedule 27- Microbiological limits in food. These criteria align with international (Codex) standards. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved the variation to Standard 1.1.2 and Schedule 27 to align the Code's food safety microbiological criteria for powdered infant formula products with international (Codex) standards.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1039 included one round of public consultation following an assessment and the preparation of a draft variation to the Code and an associated report. Submissions were called for on 9 October 2015 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.1.2 and Schedule 27 are likely to have a minor impact on business and individuals.

5. 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 94 of the FSANZ Act.

6. Variation

Item [1] varies subsection 1.1.2—2(3) of Standard 1.1.2 by replacing the definition for **SPC**. The new definition reflects the variation made by item [2.2] below, which removes the limit for SPC in powdered infant formula from the Code.

Item [2] varies Schedule 27.

Item [2.1] replaces the Note to section 27—2 to reflect the variation made by item [1] above. The new Note refers to the amended definition of **SPC** in subsection 1.1.2—2(3) of Standard 1.1.2.

Item [2.2] omits section S27—3. Section S27—3 provides that the limit for SPC in section S27—4 does not apply to powdered infant formula products that contain lactic acid producing microorganisms. This exemption is no longer required as item [2.3] removes the limits for SPC in powdered infant formula products from the Code.

Item [2.3] replaces the table to section S27—4. The new table:

- separates the microbiological limits for powdered infant formula products into two new food categories: powdered infant formula products and powdered follow-on formula
- removes the current limits specified in the table for Coliforms, Coagulase-positive staphylococci, *Bacillus cereus* and SPC in respect of these foods
- amends the sampling plan for *Salmonella* in these foods by replacing 10 with 60 in Column 2(n) in the table
- inserts new limits for *Cronobacter* in powdered infant formula products, where the number of sample units (n) is 30, the acceptable microbiological limit (m) is 'not detected in 10g', and the number of sample units allowed to exceed that acceptable microbiological limit (c) is 0. These limits do not apply to powdered follow-on formula.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 does not apply to any of the above variations. See clause 3 of the instrument.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)



Food Standards (Proposal P1039 – Microbiological Criteria for Infant Formula) 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 Standards Management Officer]

Standards Management Officer
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 P1039 – Microbiological Criteria for Infant Formula) Variation*.

2 Variation to a Standard 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 Effect of the variations to the Code

Section 1.1.1—9 of the Code does not apply to the variations made by this instrument.

Schedule

[1] **Standard 1.1.1** is varied by omitting from subsection 1.1.1—2(2) the words “Standard 1.6.1 Microbiological limits in food”, substituting “Standard 1.6.1 Food safety microbiological criteria”.

[2] **Standard 1.1.2** is varied by omitting the definition of **SPC** from subsection 1.1.2—2(3), substituting

“**SPC** means a standard plate count at 30°C with an incubation time of 72 hours.”

[3] **Standard 1.6.1** is varied by omitting the words “Microbiological limits in food” from the title of the Standard, substituting “Food safety microbiological criteria”.

[4] **Schedule 27** is varied by

[4.1] omitting the note to section S27—2, substituting

“**Note** In this Code (see section 1.1.2—2):

SPC means a standard plate count at 30°C with an incubation time of 72 hours.”

[4.2] omitting section S27—3, substituting

“**S27—3 Omitted**”

[4.3] omitting the following from the table to section S27—4

“

Powdered infant formula products

<i>Bacillus cereus</i>	5	0	10 ² /g	
Coagulase-positive staphylococci	5	1	not detected in 1 g	10/g
Coliforms	5	2	less than 3/g	10/g
<i>Salmonella</i>	10	0	not detected in 25 g	
SPC	5	2	10 ³ /g	10 ⁴ /g

”

substituting

“

Powdered infant formula*

<i>Cronobacter</i>	30	0	not detected in 10g	
<i>Salmonella</i>	60	0	not detected in 25 g	

Powdered follow-on formula*

<i>Salmonella</i>	60	0	not detected in 25 g	
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