

9 October 2015
[25–15]

Call for submissions – Proposal P1039

Microbiological Criteria for Infant Formula

FSANZ has assessed a proposal prepared to consider food safety microbiological criteria for infant formula, aligning with international (Codex) standards and 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.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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 [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 20 November 2015

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.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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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

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.

Internationally, the Codex Alimentarius and the International Commission on Microbiological Specifications for Foods (ICMSF) have provided the lead on contemporary food safety management approaches and the application of microbiological criteria. An important principle is that a microbiological criterion is established at a specified point in the food chain for a particular purpose. In general, this is to establish the safety of a food or to verify that the food safety control system or elements of it are working as intended. The terms food safety criteria and process hygiene criteria have been used internationally to differentiate the intended purpose of specific criteria.

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

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

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

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). 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).

Proposal P1039 has been prepared to review microbiological limits in Standard 1.6.1 and the associated Schedule 27 in light of these approaches. The principles underpinning the second stage of the review of microbiological criteria were consulted on in early 2015¹ and the submissions from this consultation informed the work on powdered infant formula under Proposal P1039.

Aligning with the outcomes from the Codex risk assessment, FSANZ has prepared a draft variation to the Code to include only food safety microbiological criteria, with process hygiene criteria (which should not be used for regulatory purposes) being removed. To support this approach a draft guidance document *Compendium of Microbiological Criteria for Food* has been developed and is provided for comment as Supporting Document 2 (SD2).

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)

1 Introduction

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 Codex Alimentarius (Codex) to further inform our understanding of pathogen management in the food chain, including the management of 'emerging' pathogens.

Proposal P1039 has been prepared to review microbiological limits in Standard 1.6.1 and the associated Schedule 27 in light of these approaches. FSANZ consulted on the principles underpinning the second stage of the review of microbiological criteria in early 2015² and the resulting submissions have informed our work on this Proposal.

A revised Code was gazetted in April 2015 and will take effect on 1 March 2016. The microbiological criteria for infant formula are listed in Schedule 27 in the revised Code.

As the expected gazettal date of any approved draft variations arising from this Proposal is after the revised Code takes effect, all references to the Code in this summary are to the revised Code.

1.1 The current Standard

The current infant formula 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 Reasons for preparing the Proposal

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.

1.3 Procedure for assessment

The Proposal is being assessed under the General Procedure.

² [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 Summary of the assessment

2.1 Risk assessment

FSANZ has 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 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). 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).

Codex based these criteria on scientific advice and a risk assessment model undertaken by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) through a series of joint expert meetings. The expert consultations concluded that intrinsic contamination of powdered infant formula with *E. sakazakii* (*Cronobacter* spp.) and *Salmonella* spp. had been a cause of infection and illness in infants, including severe disease which can lead to serious developmental sequelae and death. Although the rate of incidence was low, neonates and immunocompromised infants were at the greatest risk of *Cronobacter* infection.

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.

2.2 Risk management

2.2.1 Consultation paper

In January 2015 FSANZ released a consultation paper, *Consultation Paper on Completing the Review of Microbiological Criteria*, outlining and seeking comment on the approach and guiding principles for completing the review of Standard 1.6.1. FSANZ received 17 submissions from various sectors including from the New Zealand Ministry for Primary Industries (MPI), Australian jurisdictions, industry and industry groups and individuals. Those submissions are available on the FSANZ website³.

The submissions received on the consultation paper supported that the review of microbiological limits for powdered infant formula products progress as a priority. Most submissions also supported the development of food safety criteria and process hygiene criteria (discussed under Section 2.2.2.2), consistent with the Codex general principles. The assessment of P1039 will provide a model for the remaining review of microbiological limits.

³ [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)

2.2.2 Microbiological criteria framework

2.2.2.1 Establishing microbiological criteria

Microbiological criteria are established to support decision making about a food or process following microbiological testing. FSANZ applies the Codex *Principles and Guidelines for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997 [revised and renamed 2013]) in establishing criteria. These principles include:

- A microbiological criterion should be appropriate to protect public health and where appropriate, also ensure fair practices in trade.
- A microbiological criterion should be practical and feasible and established only when necessary.
- The purpose of establishing and applying a microbiological criterion should be clearly articulated.
- The establishment of microbiological criteria should be based on scientific information and analysis and follow a structured and transparent approach.
- Microbiological criteria should be established based on knowledge of the microorganisms and their occurrence and behaviour along the food chain.
- The intended as well as the actual use of the final product by consumers needs to be considered when setting a microbiological criterion.
- The required stringency of a microbiological criterion used should be appropriate to its intended purpose.

Each microbiological criterion should include the following components:

- the purpose of the microbiological criterion
- the food or process to which it applies
- the specified point in the food chain where it applies
- the microorganism of concern or its toxin/metabolite
- the microbiological limits considered appropriate to the food at the specified point(s) of the food chain
- a sampling plan (the number of samples to be taken; the size of the analytical unit; the number of analytical units that should conform to the limits specified)
- the method of analysis and its sensitivity.

Additionally, a criterion should also include a statement of the corrective actions to be taken when limits are not met (e.g. rejection of a lot or adjustment of process).

2.2.2.2 The use of microbiological criteria in food safety management

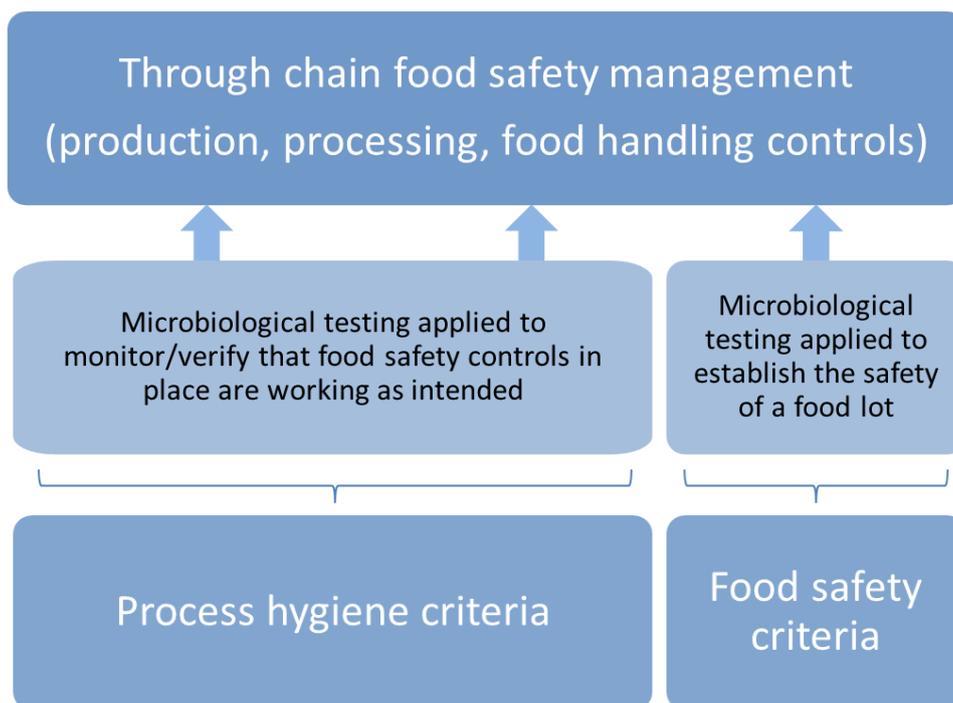
Microbiological food safety management has moved from a reactive approach based on inspection and compliance with end product testing to a preventative approach where control measures are implemented by industry throughout the food chain. The role of microbiological testing in this context may fit different purposes as defined by the microbiological criteria applied.

Internationally, the Codex Alimentarius and the International Commission on Microbiological Specifications for Foods (ICMSF) have provided the lead on contemporary food safety management approaches and the application of microbiological criteria. An important principle is that a microbiological criterion is established at a specified point in the food chain for a particular purpose. In general this is either to establish the safety of a food or to verify that the food safety control system or elements of it are working as intended. The terms food safety criteria and process hygiene criteria have been used internationally to differentiate the intended purpose of specific criteria.

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

- **food safety criteria** (included in the Code and applied to determine the safety of a food lot) or
- **process hygiene criteria** (provided in guidance and applied to verify hygiene measures or control of process).

Together these microbiological criteria should provide a “fit for purpose” suite of decision criteria appropriate to the microbiological testing needed to support the safe production of a food as depicted below.



2.2.2.3 Codex Alimentarius

The Codex Committee on Food Hygiene (CCFH) has a role in recommending microbiological criteria at the international level. National governments may choose to adopt Codex microbiological criteria into their national systems or use them as a starting point for addressing their intended public health goals. The ICMSF has been instrumental in introducing the concepts and principles that Codex has developed.

Internationally agreed microbiological criteria have been established for powdered infant formula by Codex and included in the Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008).

These include food safety criteria for *Salmonella* and *Cronobacter* and process hygiene criteria for Enterobacteriaceae and Mesophilic Aerobic Bacteria (MAB). A change from coliforms to Enterobacteriaceae as a better defined group was recommended based on the outcomes of the FAO/WHO expert meetings.

2.2.3 Powdered infant formula

2.2.3.1 Food safety management

The manufacture of powdered infant formula does not include a processing step that can eliminate all microbiological hazards – it is not a sterile product. This means that the microbiological safety of powdered infant formula must be ensured through good hygienic practices during both manufacture and use.

There are four routes by which the primary pathogens of concern (*Salmonella* and *Cronobacter*) can contaminate powdered formula (Codex, 2008):

- through the ingredients added in dry mixing operations during manufacture
- through contamination from the processing environment in the steps during or following drying
- through contamination after the package is opened
- through contamination during or after reconstitution by the caregiver prior to feeding.

As such, through chain risk management measures are essential to manage microbiological hazards including:

- implementation of good manufacturing and hygienic practices and food safety control systems by ingredient manufacturers
- implementation of good manufacturing and hygienic practices and food safety control systems by infant formula manufacturers
- education and guidance on the safe preparation, storage and use of powdered infant formula.

The *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66 – 2008) was prepared to provide guidance on the hygienic manufacture of powdered infant formula and on the subsequent hygienic preparation, handling and use of reconstituted formula products. Such measures are covered in Australia and New Zealand by food safety and labelling requirements in the Code and, additionally in New Zealand, the *Food Act 2014* and the *Animal Products Act 1999*. Industry food quality assurance systems and food safety management systems such as HACCP, SQF 2000, ISO 9001 and ISO 22000 are also widely implemented.

2.2.3.2 Role of microbiological testing

The ICMSF (2011) provide a good overview on the use of microbiological sampling and testing of powdered infant formula product, including appropriate sampling plans. Sampling and testing may be utilised by infant formula manufacturers from supply of ingredients through to the final product as part of monitoring and verification of the food safety control system:

- Ingredients – microbiological sampling and testing of ingredients may be undertaken as part of supplier assurance to ensure ingredients have been manufactured in accordance with good hygienic practice and that final product criteria can be met. This is particularly important for dry-mix ingredients as there is no kill step during manufacture.

- Processing Environment – sampling and testing of environmental samples can help verify the effectiveness of the control measures in place to prevent entry and establishment of *Salmonella* and *Cronobacter* spp. in the processing environment.
- In process – testing of in-process samples can help verify that the potential for recontamination is being controlled effectively. This may involve taking representative samples at critical steps along the processing line, from the drying step to the filling of the finished product and include testing for *Salmonella*, *Cronobacter* and Enterobacteriaceae.
- Final product – testing of the final product for indicators (e.g. Mesophilic Aerobic Bacteria (MAB) and Enterobacteriaceae) is useful as verification of process control and for trend analysis. Testing of pathogens in the final product should be integrated with in-process sampling and environmental monitoring. For example any positive results for *Salmonella* in the processing environment or in-process sample should result in increased sampling regime of the final product.

2.2.4 Proposed microbiological criteria

2.2.4.1 Food safety criteria

As outlined in Section 2.2, two FAO/WHO meetings of experts on the microbiological safety of powdered infant formula products (FAO/WHO, 2004 and 2006) identified *Salmonella* and *Cronobacter* as the two primary hazards of concern in infant formula products. In relation to *Cronobacter* the FAO/WHO expert meetings identified all infants (<12 months of age) as the population at particular risk for *Cronobacter* infections. Among this group, those at greatest risk are neonates (<28 days), particularly pre-term, low-birthweight (<2500 g), and those less than 2 months of age.

This work supported the development of food safety criteria for *Salmonella* and *Cronobacter* in the Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children. Criteria for *Salmonella* were developed for all powdered infant formula products. A criterion for *Cronobacter* was developed for powdered infant formula only as it does not apply to follow-on formula.

Proposal P1039 proposes replacing the existing microbiological limits for powdered infant formula and follow-on formula with criteria for *Salmonella* and *Cronobacter* as follows:

Powdered Infant formula	(n)	(c)	(m)
<i>Cronobacter</i>	30	0	not detected in 10g
<i>Salmonella</i>	60	0	not detected in 25 g
Powdered follow-on formula	(n)	(c)	(m)
<i>Salmonella</i>	60	0	not detected in 25 g

Where: n = number of sample units
 c = the number of sample units allowed to exceed m
 m = the acceptable microbiological limit

These food safety criteria apply to the finished product (powder form) after packaging and at any stage from that point to the point when the primary package is opened.

The stringency of these sampling plans (n=30 and n=60) assumes the history of the lot is not known. This is discussed further under section 2.3.3.3.

Schedule 27 currently contains microbiological limits for *B. cereus* and *S. aureus*. The FAO/WHO expert consultations found that, while *S. aureus* and *B. cereus* may be occasionally present at low levels, they do not represent a direct threat to the health of infants. It is generally accepted that low levels are acceptable (<100 cfu/g) and will not lead to illness as long as the product is prepared and handled according to the recommendations. As such, food safety criteria for *B. cereus* and *S. aureus* are not necessary and limits for these microorganisms will be removed from the Code.

2.2.4.2 Process hygiene criteria

Safe production of powdered infant formula depends on maintaining a high level of hygiene control to prevent entry and establishment of *Salmonella* and *Cronobacter* in processing areas. Testing of infant formula products, both end product and during processing, for Enterobacteriaceae and MAB is useful to verify that the hygiene measures in place within a manufacturing facility are working as intended. This provides assurance that the potential for pathogens such as *Salmonella* and *Cronobacter* to be in the processing environment and to cross-contaminate infant formula products is being controlled. Failure to meet criteria for Enterobacteriaceae and MAB may be a trigger to examine environmental and process hygiene controls and to increase sampling for the pathogens of concern.

Powdered infant formula	(n)	(c)	(m)	(M)
Mesophilic Aerobic Bacteria	5	2	500/g	5000/g
Enterobacteriaceae	5	2	0/10g	N/A

Where: n = number of sample units
 c = the number of sample units allowed to exceed m
 m = the acceptable microbiological limit
 M = the limit which must not be exceeded

These process hygiene criteria apply to the finished product or at any other point in manufacture that provides the information necessary to verify process control.

Process hygiene criteria for Mesophilic Aerobic Bacteria and Enterobacteriaceae in powdered infant formulae will be incorporated into a guidance document that will be available on the FSANZ website and is presented in Supporting Document 2.

2.2.4.3 Sampling plans

There are a number of factors to take into account when choosing a sampling plan including (ICMSF, 2002):

- the risk posed by the hazard (severity and likelihood of occurrence)
- the susceptibility of the target group
- the desired statistical probability of accepting/rejecting a contaminated lot.

The ICMSF recommend sampling plans based on the degree of concern (e.g. severity of the hazard) and the conditions in which food is expected to be handled and consumed (e.g. if it will be eaten cooked so that the risk is reduced or whether there is potential for growth prior to consumption and therefore an increase in risk). These are described as “cases” with the highest, case 15, being the most stringent sampling plan and applicable to severe hazards and foods for susceptible populations.

Salmonella and *Cronobacter* are severe hazards for infants. As such, very stringent sampling plans were proposed for these pathogens in powdered infant formula to provide an appropriate level of assurance that, if tested, a contaminated batch of powdered infant formula would be detected. For example a case 15 sampling plan (where $n=60$ and $c=0$) provides a 95% probability that a contaminated lot will be detected if the mean concentration of the pathogen is at least 1.9 cfu per 1000g (1 cfu in 526g). Conversely, if the pathogen is present at a lower concentration than this, then there is a greater than 5% probability that it would not be detected and the lot would be accepted (ICMSF, 2002).

For *Salmonella*, which may grow in prepared formula if not handled correctly, a case 15 sampling plan is recommended, where $n=60$ and $c=0$. For *Cronobacter* a case 14 sampling plan has been recommended, where $n=30$ and $c=0$. Case 14 provides a 95% probability that a mean concentration of *Cronobacter* of 1 cfu in 340g will be detected.

These sampling plans are based on the premise that the history of the lot is unknown. Alternate sampling criteria would be appropriate where the history of the product is known e.g. it is produced under a validated and verified food safety system such as HACCP where manufacturers apply integrated sampling plans with in-process and environmental samples.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by this Proposal and the effects of regulatory options. Every submission is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments may be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

FSANZ develops communication plans to ensure stakeholders are aware of proposed changes to the Code. All calls for submissions are notified through the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News. A dedicated web page on the review of microbiological limits is available on the FSANZ website. For this proposal, FSANZ will also carry out targeted consultation with the Infant Nutrition Council (INC).

The draft variations will be considered for approval by the FSANZ Board taking into account comments received following this call for submissions. Anyone who is an interested party or who makes a submission will be notified at each stage of the assessment. Subscribers and interested parties are also notified by email about the availability of reports for public comment.

If the draft variations to the Code are approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review, stakeholders will be notified of the gazettal of the variations to the Code in the national press and on the FSANZ website.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are 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 draft variations to Schedule 27 are consistent with the principles underpinning the Codex *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66 – 2008) and will potentially be a trade facilitating measure. Notification under the WTO Sanitary and Phytosanitary Measures Agreement has been made to facilitate transparency and enable other WTO member countries to comment on the draft variations.

2.4 FSANZ Act assessment requirements

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.4.1 Section 59

2.4.1.1 Cost benefit analysis

The proposed changes that would arise from a food regulatory measure developed or varied as a result of the proposal are unlikely to have material impacts on businesses, governments or community and are largely minor and machinery in nature.

Primarily, these changes involve moving the process hygiene criteria from Schedule 27 to the associated guidance document which will prevent food recalls being undertaken unnecessarily and also remove the need for redundant testing, reducing the number of expensive microbiological tests required by the businesses. This will potentially lead to less destruction of food, and recalls which are not related to community safety. The additional testing for *Cronobacter* and Enterobacteriaceae is already undertaken by the industry as it is required for international trade, and to meet customer expectations of food safety.

Consultation to date has found industry supports the proposed amendments. It also identified that infant formula manufacturers currently undertake a range of microbiological testing, both in-process and end-product testing, in order to meet internal food safety controls, regulatory (domestic and international) and customer requirements. All feedback received from the industry has indicated that they are already undertaking testing as per the criteria outlined in the proposed changes in order to meet international standards.

The OBPR assessment is that a Regulation Impact Statement is not required (OBPR reference 19531).

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

Standard 1.6.1 and the associated Schedule 27, establishes microbiological limits for food for sale in Australia and New Zealand.

2.4.1.4 Any other relevant matters

There are no other relevant matters.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ considers that preparing the draft variation is consistent with this objective. 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 draft variation addresses this.

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

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

The provision of adequate information relating to food is not directly relevant to the draft variation to Standard 1.6.1.

2.4.2.3 The prevention of misleading or deceptive conduct

No issues were 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**

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 this 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 preparation of a draft variation to Schedule 27 that establishes appropriate food safety microbiological criteria for two pathogens of concern is in line 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 is supportive of an efficient and internationally competitive food industry. Australian producers are already meeting criteria as presented in the proposed changes to meet the international regulatory requirements.

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

No issues were identified.

- **any written policy guidelines formulated by the Ministerial Council**⁴

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

3 Draft variation

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

The 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 Legislative Instruments (FRLI).

4 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.

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

⁴ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

Attachment A – 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 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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Attachment B – Draft 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 has considered the Proposal P1039 in accordance with Division 2 of Part 3 and prepared a draft variation.

2. Purpose

The purpose of this variation is to amend the Code (Standard 1.6.1 and Schedule 27) to align the food safety microbiological criteria for powdered infant formula products with international (Codex) standards.

The amendments made by P1039 are not subject to the stock in trade exemption provided by section 1.1.1—9 of Standard 1.1.1.

3. Documents incorporated by reference

The variation does 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 will include one round of public consultation following an assessment and the preparation of a draft variation to the Code and an associated report.

A Regulation Impact Statement was not required because the proposed variations to Standards 1.1.1, 1.1.2 and 1.6.1 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 1.1.1—2(2) of Standard 1.1.1 to change the reference to Standard 1.6.1 in that subsection to reflect the variation made by item [3] below. Item [3] changes the name of Standard 1.6.1.

Item [2] 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 [4.2] below, which removes the limit for SPC in powdered infant formula from the Code.

Item [3] varies Standard 1.6.1 to change its title from “Microbiological limits in food” to “Food safety microbiological criteria”.

Item [4] varies Schedule 27.

Item [4.1] replaces the Note to section 27—2 to reflect the variation made by item [2] above. The new Note refers to the amended definition of **SPC** in subsection 1.1.2—2(3) of Standard 1.1.2.

Item [4.2] 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 [4.3] removes the limits for SPC in powdered infant formula from the Code.

Item [4.3] varies the table to section S27—4. The variation:

- separates the microbiological limits for powdered infant formula products in the table into two new food categories: powdered infant formula 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; and
- inserts new limits for *Cronobacter* in powdered infant formula, 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.