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[01–15]

Call for submissions

FSANZ Consultation Paper on Completing the Review of Microbiological Criteria

FSANZ started reviewing microbiological limits in 2011. The initial work focussed on the review of microbiological limits for *Listeria monocytogenes* in ready-to-eat foods. FSANZ is now starting a broader review of Standard 1.6.1 that will consider the role and purpose of microbiological criteria.

FSANZ is calling for submissions on the attached consultation paper to help us progress the review.

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) 27 February 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.

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Executive summary

The existing microbiological limits in Standard 1.6.1 in the *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.

It is now widely understood that microbiological testing of end products alone cannot assure food safety. Over the past twenty years microbiological food safety management has moved from a reactive approach based on inspection and compliance with end product testing to a preventative approach, in which control measures are implemented throughout the food chain and depends on having "fit for purpose" criteria

FSANZ started a review of the current microbiological criteria by updating microbiological limits for *Listeria monocytogenes* in ready-to-eat foods through Proposal P1017. It is now time to review the remaining microbiological limits to ensure we have appropriate criteria that are consistent with through-chain approaches to food safety that have been implemented over the past decade.

This paper describes FSANZ's strategy for the remaining review of microbiological criteria, including principles for their development and establishment, the pathogen/commodity or commodity groups under consideration and the proposed priority and timeframe for consideration of issues.

FSANZ will apply internationally recognised principles such as those of the Codex Alimentarius in the review of microbiological criteria. These 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 where necessary, taking into account the intended use of the food
- the purpose of establishing and applying a microbiological criterion should be clearly articulated (e.g. food safety or process hygiene)
- the required stringency of a microbiological criterion used should be appropriate to its intended purpose
- a microbiological criterion is established at a specified point in the food chain
- corrective actions when limits are not met will be stated (e.g. rejection of a lot or adjustment of process).

One of the fundamental changes proposed is to clarify the purpose of each criterion, when it should be applied and appropriate corrective actions when limits are not met. FSANZ is proposing that criteria are established as either **food safety criteria** (applied to determine the safety of a lot) or **process hygiene criteria** (applied to verify hygiene measures/control of process).

FSANZ is seeking input on the role of microbiological testing, the use of existing microbiological limits and any difficulties in their application and the proposed development and application of microbiological criteria to support food safety management.

1 Background

The current Standard 1.6.1 – *Microbiological Limits for Food* was incorporated into the joint *Australia New Zealand Food Standards Code* (the Code) in December 2000. The standard established microbiological limits for food at the point of sale. Since the development of this standard, food safety requirements have been included in the Code that support a more preventative approach to ensuring a safe food supply. These include the food safety standards in Chapter 3 and the primary production and processing standards in Chapter 4. Work has also progressed internationally through the Codex Alimentarius Commission Committee on Food Hygiene (CCFH) on the use of risk management metrics in a food safety control system.

To reflect these developments, FSANZ initiated a review of Standard 1.6.1 in 2011. As the first stage, FSANZ prepared a proposal ([P1017 Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods](#)) in 2012 to revise the limits in Standard 1.6.1 for *L. monocytogenes*. This resulted in *L. monocytogenes* limits for nominated foods in Standard 1.6.1 being replaced with limits applicable to RTE foods generally (a horizontal approach) taking into account characteristics of the product that influence risk. Two sets of criteria now apply, based on whether growth of *L. monocytogenes* can or will not occur in the RTE food, providing a more flexible and risk-based approach to the application of microbiological criteria in the code.

The review of the remaining microbiological criteria in Standard 1.6.1 will achieve consistency with the through-chain, preventative approach to food safety that has evolved since 2000 and consistency with current international approaches..

1.1 What are microbiological criteria?

. A microbiological criterion is based on the examination of foods at a specific point in the food chain to determine if the frequency and/or level of a pathogen/indicator in a food exceed a pre-established limit (CAC/GL 63-2007). A microbiological criterion consists of:

- a statement of 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.

The criterion should also state:

- to what foodstuff it applies
- where it applies (what point of the food chain)
- the actions to be taken when the criterion is not met.

Microbiological criteria are established to support decision making about a food or process following microbiological testing, namely to:

- determine the acceptance or rejection of a specific lot of food (current purpose of Standard 1.6.1)
- verify the performance of a food safety control system or its elements along the food chain
- monitor or verify that selected control measures are working as intended.

1.2 Current regulatory microbiological limits and guidance

Mandatory microbiological criteria are currently established in Standard 1.6.1 of the Code. There are also microbiological guideline criteria established in guidance documents.

1.2.1 Standard 1.6.1 – Microbiological limits for food

Standard 1.6.1 provides microbiological limits, sampling plans and reference methods of analysis for nominated foods, or classes of foods. These limits were largely derived from microbiological standards that existed in the vertical food standards in the former Australian *Food Standards Code* (before 2000) and were retained based on qualitative risk assessment. Many of the nominated foods link to the definitions and descriptions from those vertical standards (e.g. cooked cured meat and cooked salted meat). Additionally, limits for both hygiene indicators and pathogens were carried over and prescribed equally, though their purpose and best point for application may be different.

1.2.2 FSANZ User guide to Standard 1.6.1

There were a number of microbiological limits for particular foods specified in the former Australian *Food Standards Code* that were not carried across to Standard 1.6.1 in 2000, as they could not be justified as mandatory standards. These limits, along with additional criteria that were developed, are included in the [User guide to Standard 1.6.1 – Microbiological Limits for Food with additional guideline criteria](#) (User Guide) as guideline or advisory criteria. They were intended to provide benchmark levels against which unacceptable microbial contamination of food could be identified and remedial action initiated when limits are exceeded. The User Guide outlines that failure to meet the guideline levels generally indicates a failure in the process or hygiene procedures and may require action to identify the cause and remedy the problem.

1.2.3 FSANZ Guidelines for the microbiological examination of ready-to-eat foods

The [Guidelines for the microbiological examination of ready-to-eat foods](#) (RTE) guidelines were developed in 2002 to provide a consistent approach to interpreting microbiological analyses of food, particularly for monitoring and surveillance purposes. The guidelines provide examples of microbiological testing which could be applied to ready-to-eat foods and outline why testing should be appropriate to the type of food sample being examined and to the processing it has received. The RTE guidelines identify four categories of microbiological quality related to the level of microorganism found, from satisfactory to potentially hazardous. Follow-up actions appropriate to each category of microbiological quality are also recommended.

Guideline levels for determining the microbiological quality of ready-to-eat foods are provided for standard plate count, indicators (*Enterobacteriaceae*, *E. coli*) and pathogens (coagulase positive staphylococci, *Clostridium perfringens*, *Bacillus cereus* and other pathogenic *Bacillus* spp., *Vibrio parahaemolyticus*, *Campylobacter* spp., *Salmonella* spp., *L. monocytogenes*). The RTE guidelines continue to be widely used by enforcement agencies for surveillance and monitoring purposes.

1.2.4 New Zealand Microbiological Reference Criteria for Food

The [New Zealand Microbiological Reference Criteria for Food](#) provides guideline microbiological limits for a number of different food products. The reference criteria continue to be used widely by food business and enforcement agencies to help verify the

microbiological safety of a manufacturing process or the safety of the food.

FSANZ invites submissions to help us elaborate:

- what microbiological testing is currently undertaken by industry and government and why
- how existing microbiological limits are used and any difficulties in their application.

1.3 Why FSANZ is reviewing Standard 1.6.1

Microbiological limits were originally established in the *Food Standards Code* in 1978 and reviewed in 1998 during the development of the joint Code. When developing the joint Code in 2000, the approach was for microbiological standards to be established in a general standard rather than prescribed throughout the commodity standards. FSANZ flagged that the microbiological standards and guidelines were an interim measure and would be reviewed following the implementation of the Chapter 3 standards, with food safety eventually being managed by requirements set by these food safety standards. Over this time there has been a significant change in approaches to food safety management and increasing knowledge on existing and emerging pathogens.

The food safety standards in Chapter 3 of the Code were developed by FSANZ in 2000 and are based on a preventative approach to food-borne illness. These standards specify process control requirements to be satisfied at each step of the food handling process. Some requirements relate to the receipt, storage, processing, display, packaging, distribution disposal and recall of food. Other requirements relate to the skills and knowledge of food handlers and their supervisors, the health and hygiene of food handlers, and the cleaning, sanitising, and maintenance of premises and equipment.

Since that time FSANZ has also developed through-chain requirements in Chapter 4 primary production and processing standards for the seafood, dairy, poultry, egg, seed sprout and meat sectors. However, the existing microbiological limits, which were derived from the previous vertical product-based approach to food standards development, were not reviewed when food safety and primary production standards were established and, as a consequence, the adequacy of existing microbiological limits in supporting through-chain food safety measures has not been assessed.

The food safety standards and primary production and processing standards in the Code do not apply in New Zealand. In New Zealand, the manufacture and sale of food produced in New Zealand is covered by the *Food Act 1981* (which will be replaced by the *Food Act 2014* on 1 March 2016) and the primary production and processing [and export] of animal products is covered by the *Animal Products Act 1999*.

1.3.1 Contemporary food safety management approaches

. Over the past 20 years 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.

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

Codex Alimentarius

Codex Alimentarius 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 CCFH's *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* provide a framework for national governments and food business operators on establishing and applying microbiological criteria that can be applied for food safety and other aspects of food hygiene. Most recently, CCFH have developed practical examples for establishing and implementing microbiological criteria and these will be published in early 2015 in the journal *Food Control*. These include:

- the development of microbiological criteria to assess the acceptability of a food lot (milk powder as an example)
- using a microbiological criterion to verify the performance of a food safety system (using *Campylobacter* as a performance target at the end of processing of broiler chickens)
- operationalising a performance objective with a microbiological criterion using a risk-based approach
- establishment of good hygiene practice-based microbiological criteria in food industries using an example for meat preparations.

The examples will also be made available via the Food and Agricultural Organization (FAO) and World Health Organization (WHO) websites to ensure accessibility by all member countries. Publication is scheduled for early 2015.

International Commission on Microbiological Specifications for Foods (ICMSF)

The ICMSF has been instrumental in introducing the concepts and principles that Codex has developed. Their most recent publications, *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management* (ICMSF, 2006) and *Microorganisms in Foods 8: Use of Data for Assessing Process Control* (ICMSF, 2011) provide detailed guidance on appropriate sampling plans and the use of microbiological testing in contemporary food safety management.

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 and will be the terms this review will use.

1.3.2 The changing knowledge base

Since Standard 1.6.1 was established new pathogens have emerged and knowledge of the factors that affect the risk of acquiring or contributing to foodborne illness has increased. For example, the emergence of *Cronobacter sakazakii* as an opportunistic pathogen resulted in joint FAO/WHO microbiological risk assessment work on powdered infant formula in 2004. This informed the development of microbiological criteria by the CCFH, including limits for *C. sakazakii* in powdered infant formula, formula for special medical purposes and human milk fortifiers¹.

¹ [Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children CAC/RCP 66-2008](#)

In relation to *L. monocytogenes*, international risk assessments were undertaken in the past 10 years that demonstrated that the risk of illness is strongly influenced by the ability of the food to support the growth of *L. monocytogenes* to high levels. This informed the development of microbiological criteria by the CCFH to accompany the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods* (CAC/GL 61 – 2007).

FSANZ also has produced an extensive body of scientific information over the past decade to support development of the primary production and processing standards. This includes risk assessments for the seafood, poultry meat, dairy, egg and egg products, meat, and seed sprout industries². The assessments have differed in complexity and approach (e.g. qualitative and quantitative assessments) depending on available data and were aimed to reflect Australia's situation at that point in time. While microbiological criteria were not explicitly considered in many of these risk assessments, the assessments provide a contemporary identification of microbiological hazards of concern and their association with human illness and risk factors.

Foodborne illness data

The recently released report *Foodborne illness in Australia: Annual incidence circa 2010* (Department of Health, 2014) provides the latest estimates of the incidence of foodborne illness in Australia. It found that there are about 4.1 million cases of foodborne gastroenteritis in Australia each year. Of the known causes, most are due to four organisms – norovirus, pathogenic *E. coli*, *Campylobacter* spp. and *Salmonella* spp.

A number of strategies and initiatives have been introduced to reduce foodborne illness including, for example, primary production and processing standards. Assessment work undertaken in developing food safety requirements has highlighted the risk factors and control measures needed for reducing microbiological pathogens in the food supply. Leverage of this work can inform the development of appropriate microbiological criteria as part of the risk management toolkit.

In New Zealand, the Institute of Environmental Science and Research Limited produces an annual report: *Foodborne Disease in New Zealand* that includes information about the reported cases of notifiable disease and reported outbreaks. A number of the notifiable illnesses may be caused by the transmission of pathogens in food and for some illnesses the proportion of cases caused by foodborne transmission has been estimated. In 2013, notified foodborne illness was mainly due to four organisms – *Campylobacter*, *Yersinia*, *Salmonella* and pathogenic *E. coli*. The number of notified foodborne cases of norovirus is unknown due to the number of different transmission pathways.

The New Zealand Ministry for Primary Industries has established three foodborne pathogen strategies aiming to minimise the incidence of foodborne illness. For example, using *Campylobacter* as a performance target at the end of processing of broiler chickens was introduced in 2008.

Food and Agricultural Organization/World Health Organisation (FAO/WHO)

The FAO/WHO Joint Expert Meeting on Microbiological Risk Assessments (JEMRA) provides independent scientific expert advice to the Codex Alimentarius Commission and its specialist Committees (e.g. Codex Committee on Food Hygiene; CCFH). Since 2000, it has provided advice on a range of microbiological hazards in foods including: *Vibrio* spp. in

² Available on the FSANZ website at <http://www.foodstandards.gov.au/code/primaryproduction/Pages/default.aspx>

seafood; *Campylobacter* in poultry meat; *Salmonella* spp. in poultry meat and eggs; enterohaemorrhagic *E. coli* (EHEC) in meat; microbiological hazards associated with fresh produce; viruses in food; foodborne parasites; *L. monocytogenes* in RTE foods; *C. sakazakii* and other microorganisms in powdered infant formula³.

FAO/ WHO have more recently undertaken a structured review and analysis of information in the public domain on microbiological hazards associated with low moisture foods. The report will be published by FAO/ WHO in the first quarter of 2015. Their objective was to review, evaluate and summarise the existing knowledge as well as gaps in the knowledge related to human illness associated with low moisture foods, prevalence and/or concentration of selected microbial hazards in low-moisture foods, and identifying interventions that are associated with minimising the food safety risks of low moisture foods.

Low moisture foods were defined as any food product with a water activity of less than 0.85 and were categorized into eight commodity groups: cereals and grains; confections and snacks; dried fruits and vegetables; dried protein products; honey and preserves; nuts and nut products; seeds for consumption; spices, dried herbs and tea. The scope of microbiological hazards was limited to the following nine pathogens: *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens*, *Cronobacter* spp., *Escherichia coli* (including generic *E. coli* and pathogenic strains), *Salmonella* spp., *Staphylococcus aureus*, *Listeria monocytogenes*, and Enterobacteriaceae.

The final report of this work will be published by FAO/ WHO in the first quarter of 2015.

The FAO/WHO have recently developed an annex on the statistical and mathematical considerations for elaboration of microbiological criteria to the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods for publication on the FAO⁴ and WHO⁵ websites as an electronic resource.

2 The issue

2.1 What is the current problem?

Existing microbiological criteria, particularly the limits in Standard 1.6.1, were originally established before the development of the current food safety management framework. Both indicator and pathogen limits are applied equally although their intended purpose, which is not clearly stated, may differ (e.g. food safety or process hygiene criteria). For some foods there are a number of limits listed. This may result in onerous or unnecessary testing requirements being applied to the final product.

In addition to being out of step with contemporary food safety management approaches, the microbiological limits in Standard 1.6.1 have not kept pace with our changing knowledge base. New pathogens have emerged and knowledge of the factors that affect the risk of acquiring or contributing to foodborne illness has increased. Consequently it is important to ensure microbiological criteria exist that effectively protect public health and safety based on this contemporary knowledge.

The food safety requirements provided in Chapters 3 and 4 and their implementation and enforcement under state and territory regulation establishes the food safety management framework for Australia. A similar regulatory approach is provided in New Zealand under the

³ <http://www.fao.org/food/food-safety-quality/scientific-advice/jemra/risk-assessments/en/>

⁴ <http://www.fao.org/food/food-safety-quality/en/>

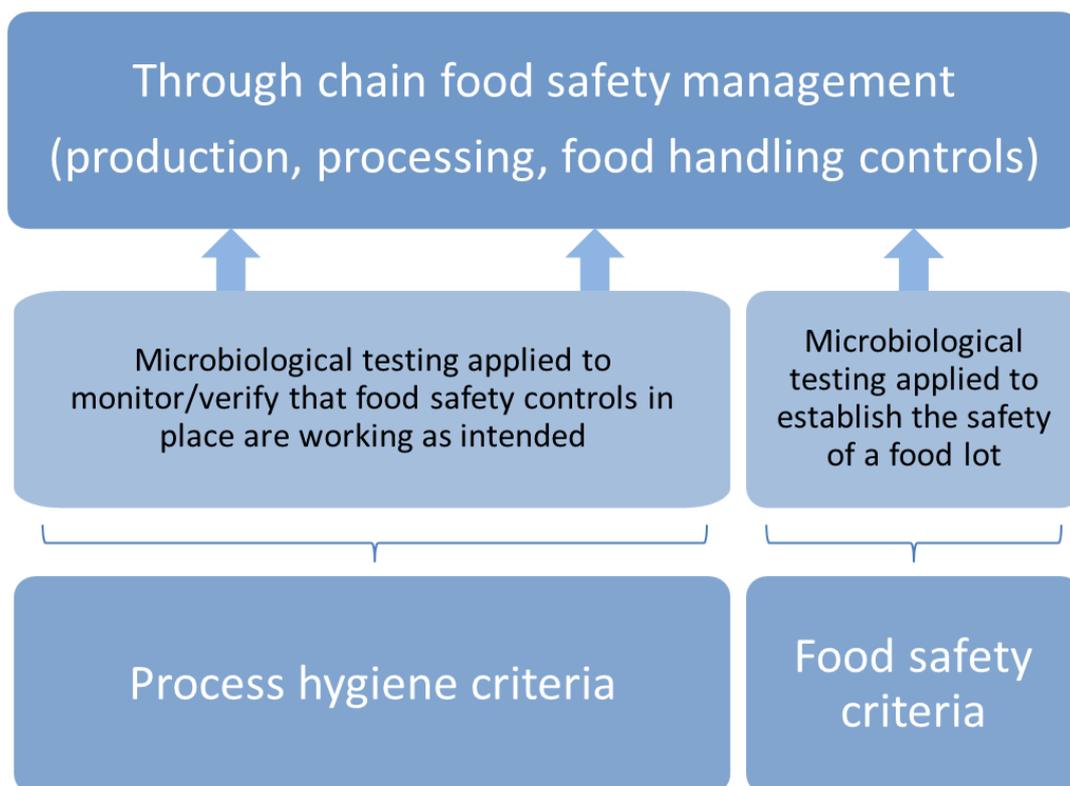
⁵ <http://www.who.int/foodsafety/en/>

Food Act 1981 and the *Animal Products Act 1999*. It is in this framework that appropriate microbiological testing by both industry and government can be an important tool.

Appropriate microbiological testing means the microbiological criteria applied should be “fit for purpose”. This requires the reason for testing and action to be taken as a consequence to be clearly established before use as this will determine the type of test to be used (e.g. pathogen or indicator), where the sample should be taken (e.g. end product or further down the processing chain) and the sampling plan to be used.

2.2 The proposed response

The existing microbiological criteria will be tested against advances in our scientific understanding of pathogens and their management in the food supply, as was undertaken through P1017 for *L. monocytogenes*. It is anticipated that only necessary and suitable microbiological criteria are retained or developed and that their purpose and point of application is clear and these will complement the through chain food safety management controls. It is proposed that **food safety criteria** (applied to determine the safety of a lot) and **process hygiene criteria** (applied to verify hygiene measures/control of process) will be developed as applicable:



An important part of this approach is to clarify the purpose of each microbiological criterion. The reason for carrying out any microbiological testing should be established before use as it will determine:

- the type of test used (e.g. for a pathogen or an indicator organism)
- the sample taken (e.g. end product or in-line sample)
- the interpretation of the result and action taken (e.g. rejection of a lot or readjustment of the process).

The food safety and process hygiene criteria that result should provide a “fit for purpose” suite of decision criteria appropriate to the microbiological testing needed to support food safety management.

3 The approach

3.1 The principles underpinning the review

During the CCFH review of *Principles and Guidelines for the Establishment and Application of Microbiological Criteria for Foods*, a number of principles were agreed to provide a framework for national governments to use for establishing and applying microbiological criteria for foods at any point in the food chain (Codex, 2013). FSANZ is adopting these principles in reviewing microbiological criteria:

- 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 where necessary, taking into account the intended use of the food
- The purpose of establishing and applying a microbiological criterion should be clearly articulated (e.g. food safety or process hygiene).
- The required stringency of a microbiological criterion used should be appropriate to its intended purpose
- A microbiological criterion is established at a specified point in the food chain
- Corrective actions when limits are not met will be stated (e.g. rejection of a lot or adjustment of process)

3.2 The review process

Both microbiological criteria specified in Standard 1.6.1 and associated guideline criteria for foods in each group will be reviewed. The review of these will use:

- work carried out by CCFH including:
 - Codex Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)
 - The current consideration of developing examples of microbiological criteria for different categories of low-moisture foods
- guidance provided on microbiological testing and sampling plans in *Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance* (ICMSF, 2011)
- work undertaken for identifying through-chain control measures during development of primary production and processing standards in Chapter 4 of the Code
- any relevant industry and/or government data including international risk assessments.

It is proposed that, where appropriate, internationally recognised criteria developed under CCFH will provide the preferred approach.

An outcome of the review process may be the establishment of microbiological criteria, as either food safety criteria (for pathogens or an index organism⁶ if appropriate) or process hygiene criteria (primarily indicator tests). Each type of criterion might be included in the Code, but the purpose will need to be clearly described, and distinguished to reflect the different purpose and consequences if the limits are not met e.g. for food safety criteria, withdrawal/recall if on the market, or for process hygiene criteria, a review of the process and associated controls.

FSANZ has previously consulted on the criteria developed by CCFH for powdered infant formula⁷. Submissions supported international alignment and developing criteria for either safety or hygiene (process control) purposes. As such, proposed microbiological criteria for powdered infant formula are provided below as an example as to how FSANZ will consider and differentiate between food safety and process hygiene criteria. The main elements to be described will include:

- purpose
- sampling plan
- where it applies
- actions when limits are not met.

Microbiological criteria for powdered infant formula (Example)

Food: Powdered infant formula

Pathogens of concern:

Two FAO/WHO meetings of experts on the microbiological safety of powdered infant formula have identified two primary hazards of concern, *Salmonella* and *Cronobacter sakazakii* (FAO/WHO, 2004 and 2006)

Microbiological criteria proposed:

Two sets of criteria are proposed.

A. Food safety criteria

- Purpose: to assess the safety of a specific lot or consignment of infant formula product
- Sampling plans:

Microorganism	n	c	m
<i>Enterobacter sakazakii</i>	30	0	0/10g
<i>Salmonella</i>	60	0	0/25g

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

⁶ A group/or species indicative of pathogen presence and behaviour respectively.

⁷ Consultation paper "Regulation of Infant Formula Products in the *Australia New Zealand Food Standards Code*" – September 2012. <http://www.foodstandards.gov.au/code/infant/Pages/default.aspx>

m = the acceptable microbiological limit

The stringency of this sampling plan assumes the history of the lot is not known. Where the history of production is known (e.g. it has been produced under a documented HACCP based food safety management system), alternative sampling criteria would be appropriate (e.g. n = 10).

- Where it applies: 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.

Actions when limits are not met: failure to meet limits should result in the affected lot not being released for human consumption. If it is already in the market place the product should be recalled.

B. Process hygiene criteria

Safe production of powdered infant formula is dependent on maintaining a high level of hygiene control to prevent entry and establishment of *Salmonella* and *E. sakazakii* in processing areas.

- Purpose: to verify the performance of hygiene control measures

Sampling plans:

Microorganism	n	c	m	M
Mesophilic Aerobic bacteria	5	2	500/g	5000/g
Enterobacteriaceae	10	2	0/10g	-

Where: n = number of sample units
c = the number of sample units allowed to exceed m
m = the acceptable (2 class sampling plan) or marginally acceptable (3 class sampling plan) microbiological limit
M = the limit which must not be exceeded

- Where it applies: these process hygiene criteria apply to the finished product (powder form) or at any other previous point that provides the information necessary for the purpose of verification.
- Actions when limits are not met: failure to meet the above criteria should result in investigation to determine and correct the root cause of the failure. Continued failures should be accompanied by increased sampling of the product for *E. sakazakii* and *Salmonella*.

FSANZ seeks comment on:

- the proposed approach to include food safety criteria and process hygiene criteria in the Code noting that each will have different corrective actions (i.e. response to not conforming to the criteria)

3.3 How the review will progress

FSANZ proposes to complete the review of existing microbiological criteria (limits in Standard 1.6.1 and associated guidelines criteria) by the end of 2016. Broadly, the groups identified for review include:

- infant formula products
- seafood
- dairy foods
- meat and poultry products
- low moisture foods
- packaged water
- other⁸.

The existing *Salmonella* criteria for pasteurised and processed egg products and cultured seeds and grains in Standard 1.6.1 have more recently been considered during development of primary production and processing standards for eggs and seed sprouts. FSANZ is not intending to review these limits however their purpose (e.g. food safety criteria) will be clarified during the review.

Under Proposal 1022, FSANZ is proposing criteria in Standard 1.6.1 for *Salmonella* and staphylococcal enterotoxin for raw milk cheese. These are supported by monitoring criteria during milk production for animal health (e.g. somatic cell count and pathogen monitoring) and milking hygiene (e.g. *E. coli*) and process hygiene indicators (e.g. *E. coli*) and pathogen testing (*Salmonella*, *L. monocytogenes*, coagulase positive staphylococci) in the guidance documents.

The limits for *L. monocytogenes* also apply to raw milk cheese (as a ready-to-eat food) following gazettal of amendments to Standard 1.6.1 in July 2014.

3.3.1 Infant formula products

FSANZ will initially progress work on infant formula products in early 2015 as previous stakeholder consultation under W1063 (Regulation of Infant Formula Products in the Food Standards Code) identified support for a review of current criteria in line with Codex. Through this initial proposal the foundation for how food safety criteria and process hygiene criteria are developed and documented in the Code can be established. It is expected that this will be completed by the end of 2015.

3.3.2 Commodity based foods

Work will also begin during 2015 to prioritise and assess microbiological criteria for commodity based foods (seafood, dairy, meat and poultry). The risk assessment and other work undertaken during development of primary production and processing standards, as well as any implementation requirements for these sectors, will help inform this process. This

⁸ Submissions may identify additional foods to be considered.

will take into account, for example, commodity specific hazards, primary production and processing factors as well as end product characteristics. Targeted consultation will be undertaken as required.

3.3.3 Low moisture foods

The review of limits for specific dried foods currently listed in Standard 1.6.1 (paprika, cinnamon, cocoa powder, desiccated coconut, and cereal based foods for infants) will be progressed as a broader approach to low moisture foods. This will be informed by the work CCFH has been undertaking in relation to a Hygienic Code of Practice for Low Moisture Foods including an Annex for microbiological criteria. CCFH will consider adopting the Hygienic Code of Practice for Low Moisture Foods and progress the annex for microbiological criteria in November 2015. As such, FSANZ will not address microbiological criteria for low moisture foods until after this time.

3.3.4 Packaged water

Existing microbiological criteria for packaged water and ice will be considered later in the review process.

As part of this process, FSANZ will also review the criteria to ensure that there is consistency with respect to the pathogens and other indicator organisms selected.

FSANZ seeks input for prioritising the work. Information that may assist includes:

- whether the proposed order is appropriate
- issues related to specific commodities/commodity groups that should be considered under this review and the rationale
- resources available to assist in the application of microbiological criteria

References

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