



Nestlé Submission

FSANZ Consultation Paper on Completing the
Review of Microbiological Criteria

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Executive Summary

This submission is made on behalf of Nestlé Australia Ltd and Nestlé New Zealand Ltd.

Nestlé welcomes the opportunity to provide comments in response to Food Standards Australia New Zealand (FSANZ) Consultation Paper on Completing the Review of Microbiological Criteria

The submission put forward by the Infant Nutrition Council is fully supported by Nestlé in relation to these infant products specifically.

This submission is primarily focussed on the application of this consultation paper to general food categories.

[1] Proposed approach to include food safety criteria and process hygiene criteria

Nestlé **supports** differentiation of Food Safety Requirements and Process Hygiene Requirements (monitoring).

The differentiation of requirements for pathogen testing for food safety and requirements for hygiene indicators in order to verify hygiene programs would harmonise with the approach used in some CODEX Codes of Hygiene Practices. Pathogen criteria are a direct indicator of any potential presence of pathogens in the product. The hygiene criteria is intended to be used by the manufacturer to assess the effectiveness of their hygiene programs.

[2] Corrective actions with Failure of Process Hygiene Criteria

Nestlé **does not fully support** regulation requiring a specified and 'prescribed' corrective action

Nestlé does not support regulating the requirements for hygiene indicators with the requirements for end products. The finished products requirements are clearly defined, and should not be subject to interpretation depending on hygiene criteria. Also, we consider that it may not be necessary to include prescribed corrective actions into regulations, as it takes away other possible solutions better adapted to the particular situation. We can however support a general requirement (not prescriptive) for increased pathogen monitoring of the processing environment and lines, in case of repeated failure of hygiene indicators.

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Response to Assessment Questions

Comments 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)

Nestlé notes that the current Standard 1.6.1 Microbiological Limits in Food primarily only includes requirements for pathogens (food safety criteria)

We note that some specific food categories in Standard 1.6.1 still include what were called hygiene criteria and today are referred to as Process Hygiene Criteria.

In the last major redrafting of the Food Standards code a number of these Process Hygiene Criteria were moved to a guideline (User guide to Standard 1.6.1 – Microbiological Limits for Food with additional guideline criteria July 2001) and this pool of knowledge has been added to (Guidelines for the microbiological examination of ready - to - eat foods (December 2001)) in order to create what is a very helpful set of codes for Industry to follow regarding process hygiene expectations.

Nestlé believes it is the correct approach to set food safety requirements in legislation and to provide guidance information via codes of practice and guideline documents.

This is important for a number of reasons.

1. There is great potential for hygiene criteria to be applied with mandatory effect resulting in artificial trade barriers. This was flagged in the work of CCFICS and was an issue in the formulation of the TBT standards by WTO. It is interesting to note that the EU Dairy Standards have been reformulated to only include *Listeria* and *Salmonella* for Dairy Products for this very reason.
2. There is potential for misdirection of resources by short circuiting of a proper investigation. Indicator organisms may or may not share the same vector routes as pathogens even where they are related. Indicator organisms by their nature are more ubiquitous in the environment and hence in the product.
- Oversimplification. There is no simple and specific relationship between the Process Hygiene Criteria (hygiene indicator micro-organisms) and the pathogenic micro-organisms. Deviations in hygiene indicator micro-organisms are likely to arise from reasons completely unrelated to the risk of pathogen presence.

As an example, in many cases Nestlé uses Enterobacteriaceae (EB) as a hygiene indicator for *Salmonella*. EB are a large family of Enterobacteria including several well-known pathogens that are more frequently encountered than *Salmonella*. Consequently, this allows a better trending and faster warning signal, and allows manufacturers to better manage the manufacturing environment. Prescribing a certain course of action, based on Process Hygiene criteria, which has undue emphasis on pathogens, means that an underlying issue may not be discovered until it is too late to correct the issue.

- Narrowly Focussed: Only looking at hygiene indicator micro-organisms in the products may not be relevant or sufficient – whilst processing (eg heat

treatment) can be used to eliminate pathogens, it is also important that the environment and subsequent post handling do not cause recontamination. In principle, further intensive investigation of a product with non-complying Process Hygiene Criteria may or may not show any issues with the presence of the target pathogen, however monitoring the hygiene of the environment is a much better indicator of the risk of recontamination.

- Wrongly Targeted: In many cases the Process Hygiene Criteria are intended to relate to different facets of the process and are unrelated to the target micro-organism – e.g. Staphylococci are often used as Process Hygiene Criteria for dairy products where the main concerns are Salmonella and Listeria – the presence and levels of Staphylococci are in most cases unrelated to these target micro-organisms and the significance of Staphylococci has to be looked at in the nature of the product and foreseeable use of the product. A regulatory approach is more likely to result in misdirection and a false sense of confidence.
3. Indicator Micro-organisms or Process Hygiene Criteria are used to provide an actionable parameter. The indicator micro-organisms must be relevant to the potential pathogens and to the process characteristics. The Indicator Micro-organisms are important both in the process (contamination) and in the environment (recontamination)
 - As an example, in many cases Nestlé uses Enterobacteriaceae (EB) as a hygiene indicator for Salmonella. EB are a large family of Enterobacteria including several well-known pathogens that are more frequently encountered than Salmonella. Consequently, this allows a better trending and faster warning signal, and allows manufacturer's to keep the environment consistently under control. When EB trends increase and exceed the established limits, the factory must carry out a root cause analysis (water leaks, condensation issues or other), and by correcting any potential deviation, the factory can reduce the EB levels and in general reduce the likelihood. If the same approach would be used with Es any potential increased trend /level will be discovered too late.
 4. Counterproductive: Nestlé believes the formulation of Process Hygiene Criteria in Standard 1.6.1 Microbiological Limits in Food will be counterproductive because it will restrict the advice that FSANZ is able to provide to the Food Industry. Whilst larger manufacturers have their own resources and are able to establish the necessary levels of hygiene parameters and indicators – smaller operators in the food industry do rely on this information. By its very nature a regulatory limit interferes with the greater flexibility provided by Guidelines and Codes of Practice. We believe the approach of Guidelines and Codes of Practice strikes the proper balance in this area – these guidance documents are tight enough to require cause to be shown but not so restrictive as to inhibit appropriate actions to be carried out.
 5. Uncertain Territory: In general the stipulation of corrective actions in law is generally not a good practice. Similarly the principle of mandating corrective actions breaks uncertain ground – it presupposes there is a case to answer before there is even a case.

Nestlé believes that the approach to incorporate Process Hygiene Criteria (hygiene indicator micro-organisms) into Standard 1.6.1 Microbiological Limits in Food is not the most effective and collaborative approach. There may be specific situations where there is a need for Process Hygiene Criteria (hygiene indicator micro-organisms) to be part of the specific product standard and these should be approached on a case by case basis. In our view the incorporation of Process Hygiene Criteria (hygiene indicator micro-

organisms) into Standard 1.6.1 Microbiological Limits in Food is an undesirable approach and would:

- Escalate the potential for arbitrary and artificial technical barriers to trade.
- Have potential to misdirect the proper course of investigations when Process Hygiene Criteria (hygiene indicator micro-organisms) exceed nominal levels – this misdirection can have serious implications.
- Risk superseding the advice and guidance FSANZ and other regulatory agencies can provide to industry. It is likely that documents such as the Guidelines for the Microbiological Examination of Ready - to - Eat Foods (December 2001) would be less useful and extensive if they were to be published as a Regulatory Standard.

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

• whether the proposed order is appropriate

Nestlé considers the following proposed order is appropriate, noting that a different rationale may need to be applied to infant formula products

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

• issues related to specific commodities/commodity groups that should be considered under this review and the rationale

The submission put forward by the Infant Nutrition Council is fully supported by Nestlé in relation to infant formula products specifically. It is recommended that infant formula products are considered as a separate matter to that of the other food groups in this review.

• resources available to assist in the application of microbiological criteria.

Nestlé would be very interested to support initiatives in this area.