Comments from the Victorian Departments of Health & Human Services, and Economic Development, Jobs, Transport & Resources, and Dairy Food Safety Victoria and PrimeSafe

Due date of submission – 27 February 2015

The Victorian Departments of Health & Human Services (DHHS), and Economic Development, Jobs, Transport & Resources, and Dairy Food Safety Victoria (DFSV) and PrimeSafe (Victoria) welcome the opportunity to provide comments on the *FSANZ Consultation Paper on Completing the Review of Microbiological Criteria.*

General comments

- Victoria supports the review of the microbiological criteria currently in the Schedule of Standard 1.6.1, the *User guide to Standard 1.6.1*, and the FSANZ *Guidelines for the microbiological examination of ready-to-eat foods*.
- The inclusion of Food Safety Standards (Chapter 3) and Primary Production and Processing Standards (Chapter 4) in the Food Standards Code (the Code) represents a through chain approach to food safety management. This review provides the opportunity for a consistent approach to develop or revise microbiological criteria at all relevant points in the supply chain.
- Victoria agrees that FSANZ should apply the Codex *Principles and Guidelines for the Establishment of Microbiological Criteria Related to Foods* (CAC/GL 21-1997). These principles should also be applied to the review, or possible inclusion, of criteria referenced in various guidance documents by regulators particularly of Chapter 3 and Chapter 4 Standards. FSANZ should work with those regulators, as appropriate, to enhance through chain continuity through the development and application of criteria to support food safety management.
- A through chain approach creates the opportunity to provide clarity around where in the chain a microbiological criterion is to be applied and what action should be taken, and by whom, when that criterion is not met. This

would address some current difficulties/issues around the application of existing guideline microbiological limits (see DHHS response to FSANZ specific requests for comment below).

- For imported foods it is generally not possible for enforcement agencies, in particular local government authorities (LGAs) and the Department of Agriculture (under its imported food inspection program), to scrutinise any 'through chain approach' apart from the ultimate process verification inherent in the microbiological criteria established for food for sale.
- Victoria advocates the development of further microbiological criteria for ready-to-eat foods, moving to horizontal standards which can be applied across most foods where appropriate, retaining the possibility of developing standards specific for foods, for example where the consuming population is particularly vulnerable.

Application and enforcement

- Food safety criteria for food for sale (domestic and imported) are critical for enforcement agencies and generally should be included in Standard 1.6.1 of the Code.
- In Victoria the Food Standards Code is applied as law through the *Food Act* 1984. Microbiological criteria in the Schedule to Standard 1.6.1 of the Code provide a regulatory requirement for microorganisms in a specified food. Where a microbial level is listed in the Code, and the product is sampled and tested as specified, proving a breach is relatively clear and enforceable. This is less onerous than having to prove, beyond reasonable doubt, that the food is 'likely to cause physical harm' (unsafe) due to the presence of certain bacteria or other microbial agents. This 'proof' would be most problematic when numbers of microorganisms are specified.

- Careful consideration needs to be given to what Food Safety Criteria or possibly what Process Hygiene Criteria might be included in a revised Schedule to Standard 1.6.1. For example, it should be relatively straightforward to prove that food for sale containing staphylococcal enterotoxin (SET) is unsafe, whereas it would be open to microbiologists to argue that Coagulase Positive *Staphylococci* (CPS) levels above 10,000 per gram would be likely to cause physical harm. Testing for CPS is

cheaper and conducted more commonly than testing for SET so it would be more sensible to include levels for CPS in a Standard.

Guidelines (and some Regulations) that support the application of Chapter 3 and Chapter 4 Standards often include microbiological criteria. For example; the FSANZ "*Guidelines for the microbiological examination of ready-to-eat foods"* includes under 'Categories of microbiological quality' advice such as: "**unsatisfactory** – results are outside of acceptable microbiological limits and are *indicative* of poor hygiene or food handling practices". Exceeding those limits does not mean that the food is unsafe or unsuitable. It indicates, as a worst case, only that the food may have been handled in a manner likely to render it *unsafe or unsuitable.* In this case the microbiological levels would form just one piece of the evidence required to support those Food Act offences**.** The guidelines support this by stating: "**action** - further sampling *may* be required and an investigation undertaken to determine whether food handling controls and hygiene practices are adequate".

- Similarly *Safe Food Australia* could usefully include process hygiene criteria such as 'an adequately cleaned and sanitised food preparation surface should have a total viable count not exceeding 100 cfu per sq cm'. Again, exceeding this level would not in itself breach any Food Act requirement particularly if the food was then to be cooked. In most cases food hygiene criteria through chain should remain in guideline documents and not be included in the Code. The status of *Escherichia coli* in food as an index of recent faecal contamination, and the increasing reports of pathogenic strains, requires consideration of the inclusion of criteria for *E. coli* in the Schedule to Standard 1.6.1 as it is relevant to both food safety and process hygiene criteria.
- There must be clear alignment of requirements in the Code and offences under the Food Act.

Responses to specific requests for comment

Separate responses are provided by *PrimeSa*fe, DFSV and DHHS.

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.

PrimeSafe

PrimeSafe does not undertake any microbiological testing. However, licensees perform a number of microbiological testing activities relevant to their business activities. These include:

- carcass swabbing for *E. coli* and *Salmonella* spp.
- environmental and product testing for *Listeria monocytogenes* if they are manufacturing small goods or processing cooked chilled ready to eat meat products.
- Uncooked, Comminuted Fermented Meat processers test end product for *E. coli*, *Salmonella* spp. and CPS.
- Seafood licensees are required to meet the testing requirements outlined in Standard 1.6.1 of FSANZ Code (for bivalves and cooked crustacea).

All microbiological limits applied are as per the Standard 1.6.1 requirements.

DFSV

Licensees in the Victorian dairy industry are required to meet the requirements of Standard 1.6.1 and the *User Guide to Standard 1.6.1*. Manufacturers of dairy products are required to undertake sampling and testing in line with these requirements, although the frequency and number sample units analyzed is less than that documented in the Code, where the n is specified as 5. Failure to meet the microbiological limits requires that product be withheld from the market and the manufacturer is obliged to analyse the failure for the cause and initiate corrective action. This testing serves the purpose of verifying that the manufacturer is achieving the goals of their documented food safety program.

DFSV also undertakes an annual product testing program, where approximately 1,200 samples of dairy foods are tested against limits in the Code. The existing limits provide an important means against which the safety of dairy products can be assessed. The criteria assist industry in identifying the organisms of concern, establishing sampling plans, and providing targets for their food safety programs against which batches are accepted or rejected. In the absence of microbiological criteria, industry (especially many small and medium sized enterprises) will be unable to identify organisms of concern and will not undertake monitoring activity.

DHHS

Food Surveillance

DHHS does not undertake routine food surveillance. Food sampling is the role of the 79 LGAs under the Food Act, with mandated minimum sample numbers provided annually for municipalities, based on the number of food premises in each. Approximately 10,000 samples are taken annually and tested for compliance with general requirements under the Food Act around safe and suitable food, conformance with FSANZ guidelines or compliance with various requirements in the Code. DHHS takes an oversight role in LGA risk based sampling activities.

The majority of food samples are submitted for microbiological examination and of these the majority are ready-to-eat foods (RTE) and generally not foods listed in Schedule to Standard 1.6.1 (with the exception of requirements around *L. monocytogenes* in RTEs). Most samples are taken of food for sale or for compliance with Chapter 3 requirements. Foods are tested for those pathogens usually associated with a particular food or for indicators of poor hygiene, temperature abuse, or cross contamination. In some cases testing for verification of critical control points in food safety programs is carried out. Food premises assessment, and even food handler hygiene assessment, can also be carried out using swabs or other environmental assessment measures.

The purpose of testing is focussed around public health and safety. This surveillance is intended to assess the performance of individual food businesses in managing the risks inherent in their products and processes and for LGAs (and in some cases DHHS) to instigate remedial action based on adverse results. The

numbers and types of samples taken also enables DHHS to monitor changes in the microbiological status of foods over time.

Use of microbiological limits

Where samples are taken for compliance with Standard 1.6.1 testing is usually confined to the parameters listed. Generally the foods listed have a history of ongoing risk and provided the sampling and analysis is as prescribed, there are few problems with addressing non-compliance issues or prosecution. The only issue that has arisen recently has been a perceived lack of clarity around obligations to appropriately test the required number of sample units. This could be made more explicit in the Standard.

The FSANZ *Guidelines for the microbiological examination of ready-to-eat foods* are probably the most used in assessing the surveillance samples. It is arguably more up to date than Standard 1.6.1 (apart from *L. monocytogenes*) and, in our view, more useful than the *User guide to Standard 1.6.1*. The Guideline document was well received on release, providing clear authoritative guidance on not only what to test for but how to interpret the results and what action should be taken when certain criteria were not met. The Guideline is used by industry and enforcement agencies and this template should be retained even if it is determined that a more horizontal approach to pathogens in RTEs should progress into the Code.

There have been issues with some laboratories and LGAs not adhering to the action recommended in the guidelines and in some cases taking inappropriate action on even ‘marginal’ results. DHHS addresses these matters when they are raised.

The User Guide to Standard 1.6.1 is still useful but is limited in that it is out of date, and is not presented with the same clarity of the ‘test/result/consequence’ template of the RTE guidelines. As noted for the Guideline above, there have been issues where the legal status of a guideline has been confused with a standard.

As part of the review, where a type of criterion is considered for inclusion in the Code, the purpose of the criterion will need to be clearly described, and reflect the different purpose and consequences to the business if the limits are not met. For example, for a food safety criterion, the consequences may include product

withdrawal or recall if on the market; and for process hygiene criteria, a review of the process and associated controls will be required if a criterion is not met.
Please note that further comments around including process hygiene criteria in the Code are made below.

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)

PrimeSafe

Food safety criteria for high risk poultry products, shellfish and cooked chilled RTE products should remain in the Code while the process hygiene criteria should be reserved for any associated guidelines.

DFSV

DFSV fully supports the use of both process hygiene and food safety criteria. Process hygiene criteria serve an important role in identifying system failures and the potential for pathogens to contaminate products. Such criteria may also apply to finished products, and the failure to meet such criteria must result in investigation to determine the cause and to identify corrective action. Process hygiene criteria related to product in process are best placed in guidelines
A challenge for process hygiene criteria is identifying suitable index organisms that will adequately demonstrate system failures. Organisms such as coliforms and *E. coli* have long been used in the dairy industry, with the latter considered to be indicative of recent faecal contamination. Unfortunately most index organisms have limitations: while the testing methods for these organisms typically have the advantage of being simple, rapid, and requiring basic analytical facilities, they often fail in terms of accurately or reliably indicating the presence of a pathogen.

DHHS

The Schedule to Standard 1.6.1 should generally only contain food safety criteria with the exception of the consideration of *E. coli*, as outlined above.

In most cases process hygiene criteria should be developed in guidelines with clarity around point in chain application and appropriate action when they are not met. If there is a case to include certain criteria in the Code, they should not be in the Schedule to Standard 1.6.1, as failing to meet a process hygiene criterion by itself would generally not create a breach of any Application Act offence. They could, however, be included in Chapters 3 or 4 for example with the consequential action. Our preference would be to include them in guidelines whether for Primary Production and Processing Standards or Chapter 3 standards, as guidelines can be readily updated and thus be responsive to technological advances in production and processing.

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

PrimeSafe

We suggest the following order for review:

- cooked - chilled ready to eat foods
- seafood
- dairy foods
- meat
- poultry products
- low moisture foods; and
- other

Note that in this list we have separated meat and poultry.

PrimeSafe is unable to assist financially but can provide some in-kind support through involvement in forums and contributing to the revision of documents.

Industry Research and Development Corporations should be invited to assist as relevant.

DFSV

The proposed order of review should be reconsidered. FSANZ should explore the possibility of developing horizontal criteria (rather than vertical standards), as it has done with the recent criteria for *L. monocytogenes* in RTE. Standards should address this group of foods, and consider criteria for *Salmonella* spp. and possibly CPS in RTE foods.

The listing of specific commodities in the consultation paper shadows recent activities in the Codex Committee for Food Hygiene. It is recommended that FSANZ addresses Australian priorities when selecting which commodities to address if vertical standards are to continue, and revise the proposed order to reflect these local priorities.

The merits of establishing microbiological criteria for raw foods need to be given some consideration, as limits on foods which will typically be cooked or given some form of kill step are of limited value for enforcement, but they can provide guidance for process hygiene.

DHHS

DHHS concurs with the view that the review should include consideration of horizontal standards for RTE foods. Apart from this consideration, the proposed order suggested by FSANZ appears to be appropriate.

DHHS will continue to provide input into the review.

Concluding remarks

- Victoria supports the review and the through chain approach proposed by FSANZ. This has the potential to enhance national consistency around food safety management across different industry sectors
- The application of the Codex *Principles and Guidelines for the Establishment of Microbiological Criteria Related to Foods* (CAC/GL 21-

1997) through the review will enhance consistency and Australia's international reputation around the production of safe and suitable food.

- Victoria requests that FSANZ holds another workshop with jurisdictions to discuss comments raised in submissions, prior to the progression of further work or the development of any proposals.