Comments from the Victorian Departments of Environment & Primary Industries and Health and Dairy Food Safety Victoria

Due date for submissions: 21 August 2014

General comments

The Victorian Departments of Environment & Primary Industries and Health and Dairy Food Safety Victoria (referred to as Victoria) welcome the opportunity to comment on Proposal P1022 which is assessing additional requirements for the safe production of raw milk products.

In previous submissions on the consideration of raw milk products, Victoria has supported the risk-based, three tiered category approach which has been adopted by FSANZ. Victoria further supports the approach whereby Standard 4.2.4 provides a baseline set of regulatory measures from which further measures that enable higher risk products may be made, while continuing to provide adequate public health protection.

Victoria supports Option 1 – to prepare a draft variation to Standard 4.2.4 to permit Category 2 raw milk products on the basis that adequate public health protection is afforded and subject to the comments provided in this submission.

Victoria supports the two draft guidance documents, with some amendments, to ensure there is adequate information for both regulators and industry, and to support a consistent approach to implementation of the standard nationally.

Other issues of concern, that are further discussed below, include assessment of raw milk products at the border, the lack of data on pathogen levels in raw milk, microbiological limits and the costs for regulators implementing the standard.

Understanding the quality of raw milk

The FSANZ risk assessment previously identified the microbiological status of the raw milk used in the manufacture of raw milk products to have a critical impact on the safety of the final product. Knowing the status of the raw milk is fundamental to compliance with the standard as a key requirement in the Draft Standard states "Subdivision 4, Clause 34, (3) The level of pathogenic microorganisms in a raw milk product must not exceed the level of pathogenic microorganisms in the milk from which the product was made at the commencement of the processing of that milk."

With the new standard, there is an expectation that there will be monitoring of raw milk on farm and at the manufacturer. Victoria agrees this is critical to enable manufacturers of raw milk to comply with the overarching requirement of ***no net increase in pathogen levels during processing*** and to ensure public health is protected by excluding raw milk that would otherwise be unsuitable for use in raw milk products.

Given the importance of this step and the lack of background data, Victoria recommends that Supporting Document 1 (*Guide to the requirements for raw milk products in Standard 4.2.4* - page 9), includes **weekly pathogen monitoring of bulk milk on farm** for *Salmonella* spp, *L. monocytogenes, E.coli* and Coagulase Positive *Staphylococci (*CPS) rather than the more general requirements of 'routine monitoring' as currently drafted. Weekly testing had been included in the previous version. More specific guidance will also assist in facilitating

national consistency. Victoria notes and supports the recommendation in the guide that raw milk is also tested prior to each manufacturing run.

The requirement for monitoring total plate count (Page 8) should be consistent and use the term 'standard plate count'.

Imported products

Victoria previously raised concerns about the ability of the Department of Agriculture, as the responsible body for regulating imported food, to assess compliance with the draft standard. The concerns revolve around adequate protection of public health and 'equity' between requirements for local manufacturers with overseas manufacturers.

Victoria recognises the difficulty assessing compliance for imported raw milk products. In addition to the prescribed microbiological limits set in the Code, the Department of Agriculture will need to assess compliance with two fundamental requirements – that the raw milk cheese is a Category 2 product ie will not support the growth of pathogens, and that there is no net increase in pathogen levels during the process. The practicality of this will be challenging and additional tools, or proxies for these requirements may need to be developed.

Victoria is aware that there is a market demand for imported cheeses and would expect that once the standard is gazetted, importers will wish to import a broader range of raw milk cheeses.

Victoria is therefore particularly concerned with the statement on p7 of the proposal document that "border actions may not be finalised for implementation at the time of gazettal of the amended Standard, if approved". Victoria recommends that the status quo should remain limiting imported cheeses to those currently approved under Standard 4.2.4A until border actions are finalised that will address the concerns above.

The process for developing border requirements and final arrangements need to be transparent to give assurance that public health is adequately protected and that the local industry is not disadvantaged.

Microbiological limits and criteria

There are some inconsistencies between the current standard 1.6.1, requirements for raw milk products in the draft standard and Supporting Document 1.

For example, monitoring of *E. coli* levels in raw milk is critical in establishing whether a milk producer is meeting (and has systems capable of meeting) requirements for the hygienic production of raw milk *i.e.* absence of faecal contamination. Supporting Document 1 lists a limit of E. coli/ml <10 as the target and suggests investigation if the level is above 100/ml. On the assumption that there is no reduction during the processing steps, product made from milk with E. coli levels above 100/ml would fail the standard and should be rejected for use in raw milk products. Victoria recommends that there should be a definitive *E. coli* limit imposed for milk to be used for raw milk products.

The current limit in Standard 1.6.1 for *E. coli* in 'all cheese' should be extended to apply to 'all raw milk products' and be maintained at the current conservative levels. This is of particular importance given our current knowledge (or lack of) of pathogenic *E. coli* in milk

and the inability to routinely and rapidly test for the presence of *stx* and *eae* markers. The presence of *E. coli* in a dairy product signals recent exposure of the product to faecal contamination and the potential presence of human pathogens.

Victoria does not support the move to test for the presence of coagulase-positive staphylococcal enterotoxin (which is potentially present when counts exceed 10,000 *S. aureus*/g). It is expected that raw milk products will be made in small scale operations, where there is expected to be high level direct physical handling of raw milk products. Victoria recommends prescribing a limit for CPS of <100/g in all raw milk products, to be reviewed two years after promulgation of the new standard. This is a cheaper option for manufacturers and while it is a more conservative approach, Victoria believes that this is justified because of the lack of data available under conditions that would be expected in small scale operations.

Guidance documentation

Aside from the specific concerns outlined elsewhere in the submission, Victoria is pleased to see the further development of the guidance documentation. The guidance will not only provide the necessary information to assist industry understand its obligations, but will also facilitate a consistent approach nationally to implementation.

Regulatory Impact Analysis and costs

In its previous submission Victoria questioned the decision by FSANZ that a Regulatory Impact Statement was not required and acknowledged that this was on the basis of advice from the Office of Best Practice Regulation.

Even if a RIS is not undertaken, it is important to assess the costs to regulators and to business. In the case of businesses, it is clear from the New Zealand experience there will be many more businesses that will aspire to making raw milk products than actually proceed to manufacture. Some concept of the costs involved in validation and ongoing verification of systems that will meet the standard would be helpful to enable a more realistic assessment before prospective manufacturers commence business planning and before approaching regulators for assistance.

Victoria noted that regulators will be forced to establish a system to ensure public health is protected even if only one business chooses to apply to make these products. These costs are likely to be high with only a few regulators (if any) having the technical expertise to assess the validation of processes and resultant food safety programs.

DFSV has documented the steps that it will need to take to establish the regulatory framework, assess individual applications and deal with the businesses that start the process, but do not reach the application step. Attachment 1 provides a detailed description of the steps that will be needed to establish the regulatory framework and assess applications. This has been based on the guidance documentation and expected industry and regulator capabilities.

In aggregate, the expected costs will be:

- Establishment costs (regulatory system design and documentation, IT changes, staff training) $74,000
- Application assessment and approval:
    - per manufacturer applicant - $9,000;
    - per farmer applicant - $ 2875
- Enquiry service per year - $64,000 (anticipated for two years after which the demand would be expected to decrease).

In Victoria's case, establishment costs and the enquiry service would likely have to be borne by the whole industry as these costs would be difficult to recover from individual businesses. While the application and assessment costs could theoretically be borne by the individual applicant, these costs could be viewed as a regulatory barrier to entry. (Note that the current application fee for farmers in Victoria is $176, considerably less than the costs that would be incurred in accrediting a farmer supplying milk for raw milk products.) Recognition of these costs and the necessity for suitable risk-based regulation to protect public health in the FSANZ final assessment report will assist regulators in making the case for the new regulatory requirements within their jurisdictions.

Summary

Victoria supports the general direction that is being taken in P1022 for the development of additional requirements in the Dairy Primary Production and Processing Standard that would permit the production and sale of Category 2 raw milk products.

Victoria is pleased to see the extent of guidelines that have been developed to assist industry and regulators implement the standard.

Victoria makes the following recommendations in this submission:

- Supporting Document 1 (*Guide to the requirements for raw milk products in Standard 4.2.4* - page 9), should include weekly pathogen monitoring of bulk milk on farm for *Salmonella* spp, *L. monocytogenes, E.coli* and CPS.
- The requirement for monitoring total plate count (Page 8) should be consistent and use the term 'standard plate count'.
- The status quo should remain limiting imported cheeses to those currently approved under Standard 4.2.4A until border actions for the Department of Agriculture are finalised.
- The process for developing border requirements and final arrangements need to be transparent to give assurance that public health is adequately protected and that the local industry is not disadvantaged.
- There should be a definitive *E. coli* limit imposed for milk to be used for raw milk products..
- A limit for CPS of <100/g in all raw milk products should be prescribed and be reviewed two years after promulgation of the new standard.
- Recognition of the costs associated with the additional risk-based regulatory framework should be included in the FSANZ final assessment report.

Attachment 1

Raw Milk Products Standard Implementation and Resource consideration

System Establishment (one off costs)

In preparation for the regulation of the production of raw milk products, DFSV will need to develop, document and implement systems that are able to deliver:-

1. Accreditation, Monitoring, and Risk Management systems for:
    - Farms
        - Herd health monitoring and management
        - Milk sampling and testing
        - Milking practice and cooling verification
        - Preventative and corrective action monitoring
        - Monitoring frequency and system proportionate to new risk classification (hazards introduced at this stage will not be controlled by a CCP further down the chain)
        - 6 monthly audits (as opposed to 24 monthly), more frequent monitoring of performance data (requires DFSV resource)
    - Carriers
        - Temperature control
        - Cooling controls
        - Contamination prevention
        - Monitoring frequency and system proportionate to new risk classification (hazards introduced at this stage will not be controlled by a CCP further down the chain)
        - 6 monthly audits (as opposed to none), more frequent monitoring of performance data. (requires DFSV resource)
    - Manufacturers
        - Validation system

          The development of a system through which to validate that a product qualifies against the criteria and can be produced to consistently qualify will be of critical importance. It is here that the heaviest regulatory risk resides. Regulators will be called upon to provide approval of the food safety system as it relates to production of raw milk products on the basis of this validation. The criteria that SRA's use to construct an appropriate validation program may become a significant barrier to entry to the market. National consistency may be an issue here and implementation should be considered by the SRA's in a suitable forum.

        - Communication program
        - Sampling system (risk management, in-process samples, finished product)
        - Production/GMP
        - Product controls
2. Food Safety Manager and in-house Technical Services Provider training
3. Licencing processes: the additional criteria and standards that farms, carriers and manufacturers must meet will require specific approval from the licensing regulator which may take the form of a new licence category or an endorsement on an existing licence. The regulator will need to examine and endorse the validation of production

processes and products and the necessary controls and provide specific approval that would preclude existing licensees incorporating raw milk products under an existing licence. Dairy farms and carriers that seek to participate in the raw milk product chain will potentially increase in their risk classification and therefore level of compliance monitoring again necessitating new licence categories.

4. IT support changes (Licence Manager - to facilitate licence endorsement fields, additional checklists etc)

Costs

36 people days - $24,000)

IT development costs - $50,000

TOTAL $74,000

System implementation (ongoing)

1. Pre-validation processes at a manufacturer level (per business): (5 days Technical Services, 10 days Compliance Staff)
   - Technical advice on validation plans and expectations (including critical limits) (2d Technical Services)
   - Pre-screening of product phys/chem parameters to qualify for validation (1d Technical Services)
   - Review and approve validation plan (incl critical limits) (2d Technical Services)
   - Site Inspection/Approval (Compliance Staff 2 Days)
   - Compliance advice (Food Safety Program, Product testing, raw milk receival etc) Farm/Carrier accreditation (Compliance Staff 4)
   - Monitoring of validation phase (sale/no-sale of product?) 12 months (Compliance Staff 4 days)
2. Accreditation at farmer (5 FTE days $2876)
   - Review individualised FSP (iterative process that can take large amounts of time) not cost-recovered
   - Inspect dairy
   - Approve system/licence endorsement
3. Enquiry handling
   - Technical Services 0.5 FTE for first two years (NZ experience = 1 FTE x 2 years)
4. DFSV participation in SRA proposed "expert assessment committee" (Executive)

Costs

Manufacturer: Technical services 5 days- $3282; Compliance staff 10 days - $5752 Total $9034

Farmer: Compliance staff 5 days - $2876 (Note: Current Application fee is $176.41)

Enquiry service 0.5 FTE $64,000 per year for 2 years