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

Due date for submissions: 10 January 2010

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.

Risk Assessment and risk management

Victoria notes the previous risks assessments that were conducted for P1007 assessing risks where there is low pathogen prevalence in raw milk. We note the conclusions of the Microbiological Risk Assessment of Raw Milk Cheese (FSANZ, 2009) that the "key determinant for safety of raw milk cheeses is the microbiological quality of the raw milk". The implications for control of the safety of these products for Australian consumers are discussed below.

Domestic production versus imported products

Victoria appreciates the trade implications that Australia faces with the existing restrictions on imported raw milk products that are freely traded internationally. However, the prime consideration is to ensure that public health is adequately protected and that products (and the processes) can consistently meet relevant microbiological limits and any other factors that affect the safety of the product. These considerations must apply equally to domestically produced raw milk products and imported products.

The proposed requirements rely on validation of all processes to deliver the required quality of the raw milk, as well as those required during production and maturation stages for cheeses, and the interaction of these to deliver a predictable outcome that meets final product safety parameters for consumers. As discussed below, this will be complex, costly for both business and regulator and require specialist expertise.

Victoria is concerned that, as has been the case for other standards that rely on production and processing requirements in Chapter 4, it may be difficult to ensure imported products are compliant with the standard. Permission for Category 2 raw milk products will be particularly challenging and have the potential to cause industry concern if the regulatory requirements, which will be administered by state regulators, appear to act as a barrier for domestic production while permitting imported product to compete with local products.

Scope of products covered

Cheese is the most likely raw milk dairy product to qualify under the parameters being considered in P1022 where no net growth of pathogens is possible in the manufacturing process and where products must not support the growth of pathogens at any time in the product's shelf life.

It is possible that butter made from raw cream may satisfy proposed parameters and if so it should be noted that the protective nature of such high fat foods for *Listeria monocytogenes* (LM) and *Salmonella* spp may add to the risk posed by this food. We note that the supporting guidance documents for producers are limited to cheese making. The proposal will need to consider other raw milk products, such as butter, which potentially fall within Category 2.

Victoria notes that FSANZ will not be considering the exemption that currently exists in some jurisdictions regarding the sale of raw goat milk to consumers, on the grounds that this is a State and Territory issue. However, the risk assessment conducted under P1007 concluded that raw goat milk has the potential to be contaminated with, and support the growth of, a range of pathogenic organisms. Raw goat milk would be classified according to the FSANZ categories as a Category 3 product. Products of this category have been broadly considered to be of too significant a risk to consumers to be permitted. Victoria remains concerned that this product is to be treated differently to other Class 3 products, and that Victorian consumers may be at risk if they purchase these products from other jurisdictions where the exemption exists.

Validation requirements

Cheese is a dynamic system that goes through processes of change throughout its shelf-life due to the ongoing metabolic activity of the starter bacteria, enzymes, and flora in maturation rooms. It is possible that at different stages in its shelf-life, physico-chemical properties may be such that they will prevent the growth of pathogens but at other stages the combination of physico-chemical properties may produce the opposite effect.

Importantly, for example, the pH of some cheeses is known to increase throughout maturation (*e.g.* surface ripened cheese) and this might increase the likelihood that it will support the growth of pathogens as it gains age. At the same time, as a cheese ages, it is likely to dry out to some degree thus reducing the ability for pathogens to grow. This dynamism is a complicating factor when it comes to validating a raw milk cheese's conformance to the criteria proposed in P1022.

Recent work conducted by the University of Tasmania[1] has emphasised the diversity in physiochemical properties between cheeses of the same type and within batches of the same cheese type. The validation process will most likely require significant investments in time and money, and address any variation in physicochemical parameters of the products. As described above, these can vary throughout the product's shelf life. The composition and protein quality of raw milk can vary throughout the year in response to seasonal variation, feed, cow condition and other factors, and this may further add to the variability of properties of the raw milk cheese. This suggests that a product may well satisfy the P1022 raw milk product qualifying criteria when made in one season but not in another. Therefore, repeated validation throughout each proposed production season may also be necessary. Victoria understands that New Zealand Ministry for Primary

[1] Co-funded by New Zealand MPI and Department of Health Victoria, final report pending.

Industries (MPI) has shared progress results with FSANZ. Victoria is happy to discuss this further with FSANZ if necessary.

Guidance

Victoria agrees with the view that it will be essential that user-friendly scientific guidance is available for both potential manufacturers and also regulators, noting that, as expressed above, guidance documents for other raw milk products should be considered. A key component of any guidance will be clear advice as to what is meant by the terms 'no net increase in pathogens' and 'will not support the growth of pathogens'.

For all manufacturers, this guidance must also provide a clear indication of the barriers to entry that manufacturers will face due to the onus of validation for each raw milk product, which will rest with them. For regulators, guidance will be essential in order to facilitate nationally consistent, safe, and fair decision making. The guidance should also enable either party to screen concepts in order to facilitate decisions as to whether to progress to full validation.

FSANZ will need to provide this guidance material in a user friendly form that provides definitive distinction (including a safe margin of error) between those products that will qualify as Category 2 raw milk product and those products that will not comply with the criteria proposed in P1022. A more prescriptive system of classification should be considered as an alternative, noting that consequently this may require a greater safety margin due to the variability discussed above.

Review of microbiological standard 1.6.1

Victoria notes that the revision of the microbiological standard (1.6.1) may recommend that the limit for LM in ready to eat foods that do not support the pathogen's growth will be increased to up to 100 cfu/g in all five samples (n=5, c=0, m=10^2 cfu). This determination may conflict with the guidance proposed under P1022 for LM which targets absence in raw milk products. Any incongruence between these two standards must be avoided. The inherent risks associated with production of raw milk products, are considered to be higher than pasteurised milk products that may support the growth of LM. We recognise that this will give rise to the situation where the standards for some pasteurised products may be more stringent than standards for certain raw milk products that are classified as not supporting the growth of LM (the perception being that there will be a more stringent standard for pasteurised product than for raw milk products) but potentially carry a higher level of risk.

Requirements on farm

Victoria supports the parameters set out for guidance for the management of on-farm practices where the milk will be supplied for raw milk products (SD1). We recognise that the practicality of implementing some details in the guidance documentation will only be tested once the system is in place and some modifications may be necessary where it can be demonstrated that the raw milk quality is not compromised.

Given the additional requirements Victoria expects that these farms will require separate accreditation and strict traceability requirements to ensure that milk of suitable quality is being

supplied. Regular testing to verify compliance with the overall validated processes will need to occur.

Victoria noted in its original submission to P1007 that there was a data gap of on farm milk quality. This was also noted in the microbiological risk assessments of raw milk and raw milk cheeses completed as part of P1007. It is disappointing then that, in the intervening time, there have not been efforts made to fill this information gap.

Victoria supports the additional work to develop guidance regarding herd/animal status for Enterohaemorrhagic *E.coli* (EHEC) and Shiga toxin-producing *E.coli* (STEC) that is identified in SD1. The University of Tasmania study[1] supports the conclusions of the earlier risk assessments that the control of growth of any pathogenic *E.coli* species is difficult in these products. This emphasises the need for further work to understand the prevalence of EHEC/STECs in dairy herds and defer proposed amendments to 1.6.1 in relation to *E.coli* limits until this work has been completed.

Regulatory Impact Analysis and costs

Victoria questions the decision by FSANZ that it is not necessary to undertake a Regulatory Impact Statement. We note that this decision was based on advice provided by the Office of Best Practice Regulation, however, there may not have been full consideration of the cost implications to industry and regulators as set out below.

While it will be a business's decision as to whether the business chooses to make raw milk products, 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.

Additionally, it is important that farms and manufacturers have some concept of the costs involved in validation and ongoing verification of systems that will meet the standard before they embark on the process of planning the supply of raw milk and/or manufacture of raw milk products. A RIS process would make some assessment of these costs.

In addition a thorough RIS makes clear the pros and cons for the preferred approach against real alternatives. The rather unusual situation presented by the raw milk product standard is that it is allowing an agreed risky practice to occur. This is not, of itself, a problem providing the regulatory options have been properly and transparently considered, and that the proposed approach as outlined in P1022 is the best approach to manage the risk. For example, in this instance it may well be more cost effective to develop a prescriptive, and less outcome-focussed, standard for these products even if this means that the margins for food safety have to be increased.

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.

Recent research co-funded by the Department of Health and New Zealand Ministry for Primary Industries has highlighted the difficulty and potential risks of relying on standard values for particular cheese types for the parameters that are proposed to be used to define safety limits for growth/no growth boundaries.

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

However, Victoria suggests that a RIS process would assist in the final design of the standard and provide some indication to regulators and industry of the likely costs of implementation, noting that state regulators will be required to implement the system even if there is limited uptake by industry.

Equity between requirements for local producers and imported products will need to be addressed by FSANZ in consultation with the Commonwealth Department of Agriculture both to protect public health and to prevent the standard being seen as a barrier to entry for local producers.