SUBMISSION TO FOOD STANDARDS AUSTRALIA NEW ZEALAND

by the Victorian Department of Primary Industries, the Department of Health and Dairy Food Safety Victoria.

Proposal P1007: First Assessment Report Primary Production & Processing Requirements for Raw Milk Products (Australia only)

1. Introduction

In December 2009 FSANZ released for public comment a First Assessment Report (together with supporting documents) on Proposal P1007. This follows earlier public consultation on a suggested approach to use three categories, based on public health risk, to deal with the complex nature and variation in the types of products covered by this proposal. The First Assessment Report includes FSANZ's preferred option to vary the Code by introducing requirements that would permit the production and importation of raw milk products within Categories 1 and 2 as defined in the Report.

The Victorian Department of Primary Industries (DPI), the Department of Health (DH) and Dairy Food Safety Victoria provide the following comments in response to P1007 First Assessment report (FAR).

2. Executive summary

We support development of requirements and subsequent amendments to the Code to allow for the production and importation of certain raw milk products provided that the requirements can adequately protect public health and safety.

We recognize that there is interest from some sections of the community and industry in having access to these products. However, in acknowledging this, and noting that the community currently has access to an extensive range of dairy products to meet both nutrition and food enjoyment purposes, we would want to see that the introduction of any new requirements as proposed and consequential regulatory arrangements:

- Enable the community to be well informed about possible increased public health risks due to these products being produced from milk that has not been pasteurised;
- Allow for clear differentiation of raw milk products from pasteurised products to protect vulnerable populations in the community
- Do not increase regulatory costs to industry producing pasteurised dairy products;
- Do not increase the costs to the community for existing dairy products; and

- Protect the existing industry's reputation in both domestic and export markets should a failure occur.

We support the further development of the preferred option in the FAR (Option 3) as a potential means of meeting the objectives of consumer choice, while protecting public health and safety. Our submission outlines areas where additional safeguards or information is needed to satisfy the over-riding requirement of protection of public health and safety should Option 3 be adopted.

We recommend that should Option 3 be adopted, consideration be given to a phased introduction of the standard, depending on the extent of data that is available at the time of gazettal. It is critical that there is sufficient data under Australian conditions to allow adequate validation of management systems that will achieve the required outcomes of the standard. It may be advisable to delay the introduction of the higher risk Category 2 products to allow regulators and industry to gain experience and produce relevant data to be assured that the outcomes can be consistently met.

3 DISCUSSION

3.1 Problem and Objectives

We accept the problem as defined by FSANZ and agree with the objectives as stated. In relation to the objective to enable all domestic producers to compete fairly with international products, we note that because of limitations on AQIS ability to ensure that on farm production practices are complied with for imported product, domestically produced product producers may still be at a disadvantage because requirements are more stringent than those for imported product.

3.2 Definition of raw milk products

We note that the proposed definition of raw milk products is not that used in Codex. We question why the same definition has not been used and what impact this may have on importing countries in assessing products that would be approved under the category framework.

3.3 Risk Management Framework and Category Classification

As previously expressed to FSANZ we support the three categories as described, to enable an effective means of managing the large number of potential raw milk products and processes. Additional analysis of the categories will be required, particularly those at the interface between categories 2 and 3, to enable industry and regulators to assess which category a particular product/process might fit.

It is not clear from the FAR as to the process and responsibility for assessing the category of a particular product/process and whether, once agreed to be within a particular category, the product type and process would be listed in the Standard.

We suggest that the Codex standards that describe the essential composition and quality factors for individual cheese types would be useful in providing a standard description in identifying the cheeses in the three categories. Use of Codex standards as a basis for product description would also make it clear for importers.

We recognise that the individual processes adopted within a business will affect the ability to meet the standard; however some general assessment of product types

within each category would guide industry to those products/processes more likely to be approved. Listing in the standard would also assist regulators, at the point of retail as to whether a particular raw milk product, including imported product, is approved.

We recommend that the assessment of product/processes should be undertaken by a single expert panel to ensure consistency, transparency and adequate expertise. FSANZ may need to consider whether the critical elements that affect the ability to meet the expected outcomes (eg pH, maturation time/temperature as identified in Technical Assessment) are included in the standard. This would not remove the onus on a business to provide sufficient evidence to enable the panel to make its assessment. We suggest that there will also need to be consideration of how such a system would operate for imported raw milk products.

3.4 Statutory Considerations

Regulatory costs: Victoria has adopted principles that the level of regulation should be commensurate with the risk and that the businesses should bear the costs of that regulation. In this case we suggest that the additional costs of regulating raw milk products to provide adequate protection of public health and safety and meet the proposed requirements should be met by the producers (and ultimately consumers) of these products. This should be reflected in the cost benefit analysis to ensure that the additional regulatory costs are directly borne by producers of the raw milk products and are not spread over, nor subsidised by the whole dairy industry. This would also provide a more realistic picture of potential costs for those sections of the dairy industry, who are considering the production of approved raw milk products.

Additional amendments to the Code: We support national consistency and supports removal of the State/Territory exemption for pasteurisation requirements. This has no impact on businesses within Victoria as no exemptions are made under Victorian legislation to allow products to be processed without pasteurisation as prescribed in the Code. However, we acknowledge that if Option 3 is adopted, some businesses providing raw goats milk from other states will be required to incorporate a suitable heat treatment.

Labelling: We suggest that the labelling requirements will need to be reviewed to enable adequate differentiation of raw milk products from pasteurised milk products. While we acknowledge that there are existing requirements for identification of raw milk as an ingredient for cheese, this may not be sufficiently prominent to inform consumers of the difference in products and potential risks from consumption by vulnerable populations.

3.5 Outcomes based standards

The principle of outcomes based standards has generally been supported as it facilitates improvements and innovation in the way that a required outcome can be achieved. Guidelines provide an important support for those sections of industry that may have more limited expertise in identifying what processes/practices will enable them to comply with a standard's requirements.

In the case of raw milk products, this approach may need to be modified to ensure that the risks are effectively managed. The likely demand for manufacturing raw milk products will be from small "artisan" businesses. Our experience with regulating

small dairy manufacturers is that many of these businesses require additional advice and more direction to effectively managing food safety risks and do not have the breadth of skills inherent in the larger manufacturers. Coupled with the lack of validated processes under Australian farm management and processing systems, the standard may need to incorporate a more prescriptive approach including requirements for monitoring certain parameters as identified in the FSANZ Technical Assessment.

4. Discussion of Option 3

4.1 On farm requirements
We note the intention under Option 3 to allow production where it can be "shown to meet on-farm controls to achieve very low (not detectable) levels of pathogens in raw milk"

There is general agreement that the quality of the raw milk is critical for achieving a final raw milk product that will pose a lower risk to public health. Since the time when mandatory pasteurisation was introduced, there have been many improvements to both the health of dairy cattle (eg eradication of tuberculosis and brucellosis) and to the general hygiene of milking practices in the Australian dairy industry which will have improved the quality of raw milk. However, there is limited baseline data on the pathogen levels in raw milk, which is the basis for assessment of suitability and compliance. Companies regularly test raw milk for aerobic mesophilic organisms (total plate count) that provides a general indicator on the hygiene of the milking process, health of cattle (mastitis) and quality of milk for processing with any low levels of pathogens that may be present, being managed through pasteurisation.

It will be extremely difficult for both farmers to demonstrate and regulators to assess whether the on-farm practices will reliably deliver raw milk with no level of detection of pathogens without the following:

4.1.2 Assessment of the health of the cattle
We consider that the proposed control measures in the Proposal are inadequate to effectively manage hazards identified in the risk assessment associated with the health of the dairy animal. In particular, carrier animals pose a risk that is not catered for in the proposed measures. The measures could target notifiable diseases as prescribed in state animal health legislation rather than clinical disease. This would then include tuberculosis and brucellosis, which are adequately managed in Australia but are relevant in some other dairy producing countries. Rather than increased veterinary inspections as proposed in Appendix 4, it is recommended that additional veterinary requirements should be related to the investigations when milk does not meet Microbiological Criteria (see below) and include the exclusion of infected (carrier) animals from the herd.

4.1.3 Defined microbiological criteria for raw milk to be used in Category 2 products
In order for producers and regulators to be assured that the raw milk meets the definition of "no detectable pathogens", we recommend the inclusion of microbiological criteria in the Code for raw milk that will be used in Category 2 ie milk that is delivered to the manufacturer for processing into Category 2 products. We note that Standard 1.6.1 currently contains microbiological limits for raw milk and

includes all pathogens of significance except for *Staphylococcus* sp. We support the review of microbiological limits by FSANZ and suggests that this will need to be completed as part of the Draft Standard.

4.1.4 Validation of on farm processes
In practical terms, compliance with the existing standard for raw milk has not been widely tested as the Code requires pasteurization or thermisation of milk: consequently there is little, if any baseline data to check microbial levels in raw milk. Additionally, validating which on-farm practices will reliably deliver raw milk according to the limits specified in the existing standard has not occurred.

This is particularly important given there is limited data on the prevalence of pathogens and the links of presence (or absence) of pathogens to particular management practices (eg teat washing, observable disease symptoms in animals). Other factors such as size of herd, animal species (goat versus cow), length of supply chain between farmer and manufacturer may also impact on the ability to reliably deliver raw milk that has no detectable pathogens. Developing this body of knowledge will take some time.

We therefore recommend that consideration be given for a phased approach to the introduction of Category 2 products where the raw milk status will determine the final product safety. (While raw milk quality is still important for Category 1, there are other attributes required for this category to protect public health and safety.) During this time, baseline data from the introduction of Category 1 products may be developed and validation of which on-farm practices will be essential for consistent production of raw milk that will meet the standard could occur.

4.2 Imported Raw milk products
4.2.1 On farm controls for imported products – limitations of existing controls
We note that currently imported food legislation does not give AQIS the legal capacity to investigate on-farm production or processing controls for imported raw milk products. With the exception of Roquefort cheese under government certification, action at the border is limited primarily to end product testing. However, such certification is voluntary.

We note that the regulatory system and performance of Australian dairy farms and processors are regularly audited for compliance by overseas regulators, and that the Beale Review recommended legislation governing imported food safety be amended to give AQIS powers to mandate certification requirements for some foods. However, we understand that there are no definitive timelines for the legislation covering imported food to be amended as recommended.

Without this, we have concerns that adequate protection of public health and safety related to imported raw milk products will be possible and that the objectives of enabling domestic producers to compete fairly with international producers will not be realised.

4.2.2 Importation under the Trans Tasman Mutual Recognition Agreement (TTMRA)
We note that New Zealand has progressed its assessment of raw milk products ahead of Australia. We suggest that FSANZ will need to consider any differences in

approach and the likely impact on the assessment of which raw milk products would be permitted. Past situations where products could be imported into New Zealand that were not permitted under the Food Standards Code, but allowed via the TTMRA should be avoided.