

## **Application P1007 – PRIMARY PRODUCTION & PROCESSING REQUIREMENTS FOR RAW MILK PRODUCTS**

### **Major Procedure – 1<sup>st</sup> Assessment Report**

#### **Summary**

The NSW Food Authority appreciates the progress made by FSANZ on P1007 and is generally supportive of the approach taken in the assessment report. We look forward to the Second AR and further details on the boundary between Category 2 and Category 3 products.

We believe that a simple outcomes-based standard would be difficult to implement and enforce consistently across jurisdictions and that greater prescription is needed to manage the risks identified in the assessment report and protect public health. Work to identify appropriate risk management tools should start as early as possible.

The Authority also seeks better characterisation of the risks associated with raw goat milk and explanation why these cannot be effectively managed.

When drafting amendments to Standard 4.2.4, the potential for Clause 2(3) to permit the sale of raw milk and other Category 3 products should be evaluated.

#### **Specific Issues**

##### Category Boundaries

One of the challenging issues for this standard is definition of the boundary between Category 2 and Category 3 products. Industry and regulatory agencies need a clear statement of product characteristics and critical control / control points that separate Category 2 from Category 3 products. Completion of this work is a critical prerequisite to the finalisation of a compliance plan.

##### Inclusion of Risk Management Elements in the Standard

Given the nature of the proposed Category 2 products, the Authority strongly believes that a simple outcomes-based standard will not be adequate to protect public health and will be difficult to enforce or comply with in both practical and resource terms. It is anticipated that the management approaches that need to be put in place to effectively control hazards and reduce risk will be different depending on the nature of the products. For this reason and to ensure consistency in implementation and enforcement, the essential elements of risk management, including any additional microbiological requirements, should be prescribed in the standard.

In particular, the Authority remains concerned that small and micro farm-house-cheese businesses will be attracted to raw milk cheese processing. Such businesses could provide a major challenge for risk managers. Standard 4.2.4 does not address 'skills and knowledge' requirements for dairy processing. It probably should do so.

Inclusion of competency requirements in the standard for persons seeking to process Category 2 products should be considered.

### Goat Milk Microbial Risk Assessment

The hazards associated with raw goat milk have been identified but the risks are not well characterised. The conclusions in the goat milk MRA reflect the acknowledged risks of raw cow milk and the reported presence of EHEC in goat milk. A robust statement of risk is important for NSW because we face overturning an existing permission for the sale of raw goat milk. This change could well result in the end of the goat milk industry in NSW. Given there is no history (or certainly no recent history) of the industry causing food poisoning the conclusions of the MRA will come under close scrutiny. The Authority considers that further work to improve the characterisation of risk, and explain why these risks cannot be effectively managed, would be needed to justify termination of the existing permissions.

### Drafting Issues

Clause 2 (3) of Standard 4.2.4, exempts 'retail sale activities' from the Standard, but does not provide a meaning for the phrase. The User Guide to Standard 4.2.4 states that –

*“Retail sale” refers to direct sale to the public and does not include sale to wholesalers, caterers or businesses that on-sell. Businesses that manufacture dairy products such as ice-cream, gelato, cheese and dairy desserts, only for retail sale, are not required to comply with Standard 4.2.4.”*

This seems to indicate that the processing requirements of clauses 15 and 16 of Standard 4.2.4 do not apply to the manufacture of dairy products by a retail business and intended only for retail sale by the business. Further consideration is required as to the current legal effect of clause 2 (3) and whether an amendment to that clause is required.

Editorial notes to clause 15 of Standard 4.2.4 referring to the phrase 'equivalent or greater lethal effect' state that any other process used would need to be validated by the business and verified by the Authority. In Standard 3.2.2 the phrase 'food business... demonstrates' is used to convey a similar meaning. The NSW Food Regulation 2004 defines 'demonstrate' and ideally usage within the Code would be consistent.

### Supplementary Data

A small number of additional results of raw milk testing have been identified. The following results are from spot samples of 'bath milk' and goat milk, taken and tested within shelf life, from a wholesaler.

Samples	<i>E. coli</i> MPN/mL	Coliforms (30 °C) MPN/mL	SPC <sup>1</sup> CFU/mL	Pathogens Detected
Bath milk (cow)	0.4	11,000,000	650,000,000	Nil
Bath milk (cow)	<0.3			Nil
Bath milk (cow)	4.3			Nil
Bath milk (cow)	4.3	>11,000	16,000,000	Nil
Bath milk (cow)	4.3	7,500	710,000	Nil
Bath milk (cow)	23	11,000,000	18,000,000	<i>Listeria</i> spp
Bath milk (cow)	2.3	930	7,200,000	Nil
Bath milk (cow)	2.3	2,400	11,000,000	Nil
Bath milk (cow)	4.3	430	6,300,00	Nil
Raw goat milk	0.9	430	8,000,000	Nil
Raw goat milk	15	93	6,300,000	Nil

Note 1: For comparison 9.4% of farm milk samples in 1997/98 had counts below 50,000 cfu/mL (Annual Report NSW Dairy Corporation 1997/98).

The following distribution of results was found during routine testing of raw goat milk samples for *E. coli*.

<i>E. coli</i> MNP/mL	Number of samples
<0.3	20
0.3	1
0.4	4
0.7	1
0.9	2
1.5	1
3	1
3.9	1
4	1
4.3	1
15	1
43	1
240	1
Grand Total	36

44% of samples of raw goat milk tested positive for *E. coli* with counts up to 240 MPN/mL.

#### Quantitative Microbial Risk Assessment – Raw Milk

Even given the continuing reports of illness attributable to raw milk the disease estimates in the MRA seem to be quite high. It is likely that some of the assumptions (e.g. zero lag and no influence of lactic acid or competitive inhibition) will result in conservative, fail safe models. This is acceptable so long as the authority of the MRA is not diminished. It may be preferable to report estimates relative to pasteurised milk rather than quoting absolute estimates.

Prepared by: Bruce Nelan

Date 22/02/10

Cleared by: Lisa Szabo

Date 23/02/10

Peter Day

Date 23/02/10

Peter Sutherland

Date 22/02/10

Approved by: Craig Sahlin

Date 04/03/10

**The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.**