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Dairy Food Safety Scheme

Periodic review of the risk assessment

November 2014

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Executive summary

This report updates the Dairy Food Safety Scheme Risk Assessment published in 2009. Prior to the publication of the 2009 assessment and since, Food Standards Australia New Zealand (FSANZ) was very active in the area of dairy food safety during development of proposals for the sale of certain raw milk products. The New South Wales Food Authority accepts the findings contained in FSANZ's reports. Readers are encouraged to refer to those reports. They have not been further summarised or extracted here.

A scan of the literature has identified some useful guidance on botulism in dairy herds. The UK Advisory Committee on the Microbiological Safety of Food (ACMSF) advised the UK Food Standards Agency (UKFSA) that, in the absence of other signs, there should be no requirement to restrict sales of milk from clinically healthy cattle from farms where there have been clinically suspected cases of botulism in cattle. Subsequently they also provided the same advice about clinically healthy sheep or goats from farms where there have been clinically suspected cases of botulism in sheep and goats.

An expert review of the 2009 assessment found that more information on chemical hazards in dairy products was required. FSANZ has commissioned a comprehensive assessment these risks. They found there are extensive regulatory and non-regulatory measures in place to ensure that chemicals used or present in dairy products present a very low public health and safety risk.

FSANZ also found that for unpasteurised goats milk the level of public health risk cannot be reduced sufficiently and such products present a medium to high level of public health and safety risk. Sale of raw goats milk has a long history in NSW and risk management practices were implemented two decades ago. As far as can be determined the risk management procedures have not failed consumers and not failed the goats milk industry. While there is a risk to consumers of raw goats milk, the level of risk relative to commodities where risks are tolerated is not clear. Without that quantification and given the lack of evidence of foodborne illness it could be difficult to justify withdrawing the approval to sell raw goats milk in NSW.

Introduction

The previous risk assessment (NSW Food Authority, 2009) of the Dairy Food Safety Scheme was published in March 2009. The risk assessment was part of a comprehensive review of food safety schemes undertaken during the remake of Food Regulation (2004). At the completion of this process, the simplified and refined Food Regulation (2010) was made. That regulation provides for continuation of a Dairy Food Safety Scheme.

In parallel with the remake of the regulation, FSANZ had been considering Proposal 1007, *Primary Production & Processing Requirements for Raw Milk Products*. During this consideration there was considerable scrutiny of dairy food safety and the issues relating to raw milk and raw milk products. FSANZ has published 8 related background papers on topics including: microbiological risk assessments of raw milks and cheeses, a risk profile of Australian dairy products and a scientific review of pasteurisation for pathogen reduction in milk and milk products. The papers are available from FSANZ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1007primary3953.aspx> .

Following three rounds of public consultation, FSANZ has decided to amend the Code to permit products for which the properties and/or processing factors eliminate pathogens that may have been present in the raw milk (Category 1 products). A new proposal was to be prepared to consider permissions for products for which the properties and/or processing factors may allow survival of pathogens that may have been present in the raw milk but do not support the growth of these pathogens (Category 2 products). Those products for which the intrinsic properties and/or processing factors are likely to allow the survival of pathogens that may have been present in the raw milk and may support the growth of these pathogens (Category 3 products), FSANZ found the level of risk cannot be reduced sufficiently and such products present a high level of public health and safety risk.

Proposal P1022, *Primary Production & Processing Requirements for Approved Raw Milk Products*, is now under consideration. P1022 includes the development of technical materials that would be required to implement the safe production of Category 2 products. To date three further background papers have been published to support this Proposal. The papers are available from FSANZ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1022primary5627.aspx> .

As a result of these activities the safety of dairy products has been under close scrutiny since the 2009 risk assessment. This periodic review will focus on the findings of P1007 and P1022, particularly the emerging risks related to the local production of Category 2 products following the likely approval of P1022 and the continuing sale of raw goats milk in NSW.

Category 1 – products for which the properties and/or processing factors eliminate pathogens that may have been present in the raw milk.

Category 2 – products for which the properties and/or processing factors may allow survival of pathogens that may have been present in the raw milk but do not support the growth of these pathogens.

Category 3 – products for which the intrinsic properties and/or processing factors are likely to allow the survival of pathogens that may have been present in the raw milk and may support the growth of these pathogens.

Update of the 2009 risk assessment

Upon completion the NSW Food Authority commissioned an expert review of the 2009 risk assessment. The review resulted in a number of observations that spanned suggestions for improved clarity through to identification of technical issues for further investigation. One technical issue has been addressed in this review.

A scan of recent literature and foodborne illness reports was also completed. No material that would change the assessment of pasteurised dairy products has been identified. The scan uncovered some potentially useful information on botulism in dairy animals.

Botulism-affected dairy animals

Supplementary information about botulism in milk, which doesn't alter the assessment's conclusions, has been identified

- The UK Advisory Committee on the Microbiological Safety of Food (ACMSF) advised the UK Food Standards Agency (UKFSA) that, in the absence of other signs, there should be no requirement to restrict sales of milk from clinically healthy cattle from farms where there have been clinically suspected cases of botulism in cattle (ACMSF, 2006).
- The ACMSF advised the UKFSA that, in the absence of other signs, there should be no requirement to restrict sales of milk from clinically healthy sheep or goats from farms where there have been clinically suspected cases of botulism in sheep and goats (ACMSF, 2009).

There are 4 recent reports of botulism in Australian dairy herds; 2 NSW dairy herds (file note) and 2 reports in one South Australian dairy herd (SA Dairy Authority *pers comm.*). The ACMSF documents could provide a useful resource in the event of a botulism outbreak in NSW dairy animals.

Chemical hazards

FSANZ (2009a) published a comprehensive risk profile of dairy products in Australia. The profile included an in-depth consideration of chemical hazards. The 2009 NSW FA risk assessment only reported a subset of the hazards identified in the FSANZ risk profile and focused on those hazards where on-farm controls are critical to contamination management. However, the Authority supports the conclusions of the risk profile:

'There are extensive regulatory and non-regulatory measures in place to ensure that chemicals used or present in dairy products present a very low public health and safety risk.

'Continuation of the current management practices, particularly monitoring programs for chemicals along the primary production chain, will ensure that the dairy industry continues to maintain a high standard of public health and safety'.

FSANZ papers

P1007 Approval Report

FSANZ (2012A) found that for Category 1 and 2 products, there are combinations of specific production and processing controls that can provide a product with an acceptable level of public health risk. However, the variation to the Food Standards Code that was prepared did not extend to Category 2 products. The variation did provide for cheese and cheese products to be prepared from heat treated but not pasteurised milk coupled with extended storage times prior to sale and for certain cooked curd cheeses. These changes meant that specific permissions for nominated Swiss cheeses were no longer required and could be removed from in Standard 4.2.4A. The NSW Food Authority supported the variations and supported further work on Category 2 products being continued as P1022. Revised Standards 4.2.4 and 4.2.4A commenced on 28 June 2012.

The Approval Report also found that for Category 3 products the level of risk cannot be reduced sufficiently and such products present a high level of public health and safety risk. Even so, the report did not seek to vary the clause that allows States or Territories to permit the sale of raw goats milk. The NSW Food Authority supports these two seemingly conflicting approaches. FSANZ has provided convincing evidence of the risks of Category 3 dairy products. However, the risk management approach that has been in place in NSW for over 20 years, as far as can be determined, has not failed consumers or the goats milk industry. For this reason the NSW Food Authority will continue to monitor the goats milk industry rather than move to compulsory pasteurisation. Details about risk management in the NSW industry are included below.

FSANZ assembled a very large amount of information to support P1007 (FSANZ 2009A, B, C). The information is drawn together in Supporting Document 1 (FSANZ 2012B) for the Approval Report. No attempt has been made to extract or summarise this information. The NSW Food Authority endorses FSANZ's summary and the back ground documents. With the exception of raw goats milk, the Authority's risk management activities are consistent with the Food Standards Code and their risk profiling documents.

P1022 Call for submissions

P1022 is about Category 2 products where the intrinsic physico-chemical characteristics of the finished raw milk product do not support the growth of pathogens, and there is no net increase in pathogen levels during processing. The second *Call for submissions* report was released in July 2014 (FSANZ 2014A). It has three supporting documents (FSANZ 2014B, C, D, described as SD 1, 2 & 3 below).

SD1 is *Guide to the requirements for raw milk products in Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products – Proposal P1022*. It identifies known risks and proposes suitable through-chain risk management approaches.

SD2 is *Guide to the validation of raw milk products – Proposal P1022*. It is concerned with processes to separate Category 2 products from Category 3 products. In essence it sets out approaches to determining that pathogens will not grow in the final product and determining that no net growth of pathogens occurs during processing. These determinations will be used by processors of raw milk dairy products and regulators to categorise products.

SD3 is *Scientific information for the assessment of raw milk products – Cheeses – P1022*. This document examines the range of scientific information that may be required to demonstrate no pathogen growth in the final product and no net increase in pathogens during processing. Examples of the application of existing tools such as default criteria and predictive equations are presented to aid decision making. A focus is on the range of pathogen challenge studies available to meet the food safety outcomes. This includes demonstrating that the physico-chemical characteristics of the cheese do not support the growth of pathogens through to determining the time limits required for no net increase in pathogen concentration. The document is to be considered in conjunction with the FSANZ *Guide to the Validation of Raw Milk Products* document (SD2).

SD3 assembles some very useful information. It provides a classification system to establish super-families of cheese based on manufacturing procedures which work towards explaining the resultant physio-chemical characteristics. It introduces tools to establish 'no growth' in the finished product: default criteria and predictive equations. Augustin model #8bis was found to be useful and reliable but certain combinations of water activity and pH produce results that are inconclusive and challenge testing is required to decide 'growth' or 'no growth'.

SD3 goes on to discuss how 'no-net increase in pathogens during processing' might be determined. This is complex material. It will be useful when designing processes, selecting starter cultures etc. Challenge trials covering both coagulation and cheese maturation will generally be required to decide the issue.

After reading the documents associated with P1022, it seems apparent that processors of Category 2 products and food agencies will have to retain considerable technical competence. There are also technical difficulties associated with challenge studies and scale up to commercial production:

- Are laboratory scale studies sufficiently representative of commercial manufacture?
- Are cheese pilot plants available that can and will handle pathogenic bacteria?
- Can commercial production routinely result in uniform pH and water activity levels that equal those used during categorisation studies?

However, work completed as part of P1007 found that for Category 2 products prepared with certain controls the risk to public health is low for both general and susceptible population groups. The challenge comes in differentiating Category 3 products from Category 2 products.

Unpasteurised goats milk

FSANZ's risk assessment

FSANZ has completed a microbiological risk assessment of raw goats milk (FSANZ 2009b). The report runs to 159 pages and the key findings are:

- A range of pathogenic microorganisms may contaminate raw goats milk.
- Enterohaemorrhagic *Escherichia coli* (EHEC) poses a high risk to the general population.
- Enterohaemorrhagic *E. coli*, *Toxoplasma gondii* and *Listeria monocytogenes* pose a high risk and *Salmonella* spp. pose a moderate risk to susceptible populations.
- The key risk factors during primary production and processing affecting the microbiological status of raw goats milk are:
 - Disease status of the animal.
 - External contamination from the farm and processing environment.
- The relative contribution of each risk factor to the overall risk to public health and safety will differ for each pathogen
- While the volume of raw goats milk consumed in Australia is very low there are risks for both general and susceptible populations consuming this product. Raw goats milk is frequently provided to members of the population who are more susceptible to infection by *L. monocytogenes*, enterohaemorrhagic *E. coli* and *Salmonella* spp. Raw goats milk is often provided to very young children, children with special dietary needs, older people and people convalescing. These sub-populations are at-risk, and exposure to even low levels of these microbial pathogens may result in serious illness.

The First Assessment Report for P1007 summarises the findings as "For ... raw drinking milk the level of public health risk cannot be reduced sufficiently and such products present a medium – high level of public health and safety risk".

The history of raw goats milk in NSW

The sale of raw goats milk has a long history in NSW. A paper on the bacteriological quality of raw goats milk in NSW (Hughes and Jensen, 1981) noted that over 90% of goats milk produced in NSW was marketed as raw milk.

The current approach to risk management in the industry has a shorter history. It began with work undertaken by (as they were then) the Department of Health NSW and NSW Agriculture and the milking goat industry in the 1980s. Following consultation with industry during several workshops and at meetings of the New South Wales Goat Milk Study Group from 1985–87, a technical sub-committee was established to develop a "quality milk" scheme for goats milk. The proposed scheme was discussed and ratified at the First Annual Conference of the New South Wales Goat Milk Industry held in November 1988, and subsequently the New South Wales Goat Milk Industry "Quality Milk" Scheme was launched.

The Codes of Practice central to the Scheme covered a wide range of hygienic requirements, including cleaning and sanitation, hygiene and health of personnel and goat health with

specific mention of tuberculosis, brucellosis and leptospirosis. Standard plate and coliform counts were required. *Listeria monocytogenes* and pathogenic *E. coli* were not considered.

At that time the Department of Health NSW issued permits (an exemption from compulsory pasteurisation under the Food Standards Code) to goat dairies that complied with the quality milk scheme. NSW Agriculture drafted two codes of practice and provided an advisory service on goat husbandry and sound management practices. The goat industry applied documented quality standards and undertook regular testing of goats milk samples.

In December 2003 regulatory responsibility for goats milk food safety was transferred to, the then, SafeFood Production NSW (SafeFood). SafeFood undertook a business profile of the goat and sheep milk industries in NSW and commissioned an external risk assessment by AgriQuality NZ. As a result, the Food Production (Dairy Food Safety Scheme) Regulation 1999 was amended to broaden the definition of milk to include goat and sheep milk and include the exemption for goats milk from pasteurisation. The main elements of risk management for the industry were:

- Full implementation of on-farm HACCP, including continuation of the sampling and testing requirements of the Quality Milk Scheme, as a condition of licence.
- Introduction by SafeFood of a 2-year program of sampling and testing goats milk for generic *E. coli* and pathogenic bacteria, including *L. monocytogenes*.
- Regular audit of farms for HACCP compliance.
- Revocation of licence to produce unpasteurised goats milk upon identification of critical nonconformity.
- Mandatory pasteurisation (or equivalent process) should microbiological testing demonstrate significant risk of harmful microorganisms occurring in the product.
- Use of a warning label on product regarding the hazards of unpasteurised milk.

The NSW Food Authority was formed in April 2004 and in September 2005 the provisions of the Dairy Food Safety Scheme were carried over into Food Regulation (2004). The approach to risk management remained unchanged except the responsibility for pathogen testing was handed back to industry at the completion of the 2-year program. The required frequency of sampling was reduced from that specified by SafeFood NSW.

International food safety interventions for raw drinking milk

The sale of raw drinking milk is permitted in a number of countries or states around the world. Regulation (EC) No 853/2004 of the European Parliament (Eur-Lex 2012) permits the sale of raw drinking milk in Europe but member states are able to prohibit or restrict the sale of raw milk or cream for direct human consumption (UKFSA 2009). Section 9 of the US Pasteurized Milk Ordinance (USDHHS 2009) prevents the trade in raw milk for human consumption across state borders but individual states have approved the sale in various forms such as retail sale, farm sale or by cow share programs (Farm-to-Consumer 2010). Section 11A of the New Zealand Food Act allows dairy farmers to sell a maximum of five litres from their farm to people who intend to consume it themselves or give it to their family. In May 2014, the New Zealand Ministry for Primary Industries opened for public consultation options to change the Act concerning the sale of raw milk. MPI gathered data that suggested raw milk consumption is increasing. Balancing this against the food safety

risk, MPI have put forward three options that limit the daily quantity of raw milk sold from farms (40 L is proposed) and introduce production and labelling requirements.

European Regulation (EC) No 853/2004 (Eur-Lex 2012) sets out requirements that are generally applicable to milk for human consumption. The requirements are more demanding where the milk or milk product is to be consumed with a heat treatment process:

- There is no option to use milk from healthy herds or flocks that do not have tuberculosis free status and only a limited option for those without brucellosis free status.
- Raw drinking milk and raw milk products must carry a label that says 'raw milk' or 'made from raw milk'.

In California sales of raw milk and raw milk products are legal both in stores and on the farm. In order for raw milk to be sold legally, it must be 'market milk'. This is milk that meets the standards provided in the Milk and Milk Products Act of 1947. Under the Act, market milk is graded and designated into three classes: 'certified milk,' 'guaranteed milk,' and 'Grade A milk'. Of the three classes, only Grade A raw milk is available for sale today in California (Kennedy 2004).

Section 35891 of California Food and Agriculture Code, Division 15, Milk and Milk Products Act of 1947 (California Law undated) requires:

- Grade A raw milk is market milk which conforms to all the following minimum requirements:
 - a) The health of the cows and goats shall be determined at least once in two months by an official representative of an approved milk inspection service, or a milk inspection service which is established by the director.
 - b) It shall be produced on dairy farms that score not less than 90 per cent on the dairy farm scorecard.
 - c) It shall be cooled as provided in Section 35782 and so maintained until delivered to the consumer, at which time it shall contain not more than 15,000 bacteria per millilitre or more than 10 coliform bacteria per millilitre.

In New Zealand farmers making farm gate sales of raw milk are required to operate under a registered 'Risk Management Plan' (RMP) but there are no registered RMPs for farm gates and the Ministry of Agriculture and Fisheries (MAF) has not enforced the requirement. MAF recognises that developing an acceptable RMP for harvesting and storage of milk for farm gate sales would be very difficult. MAF is currently considering how to provide for continuing farm gate sales of raw drinking milk (MAF 2011). There is no intention to outlaw the practice.

NSW requirements for raw goats milk

Food Regulation (2010) permits the sale of raw goats milk only if it has been produced in compliance with a food safety program and if the milk bears the appropriate warning label. The NSW Food Safety Schemes Manual requires unpasteurised goats milk for human consumption to be tested for *Campylobacter*, *E. coli*, *Listeria monocytogenes* and *Salmonella* at a frequency of 1 batch in 20. Buildings and equipment must comply with *The Code of Practice for Dairy Buildings*.

As Australian goat herds are TB and *Brucellosis* free and the basic requirements for the supply of milk NSW requirements are comprehensive, NSW's requirements for raw goats milk are broadly equivalent to overseas programs.

The NSW goats milk industry in 2014

An examination of licensing records identified 15 businesses that undertake one or more activities in the goats milk industry in NSW: 12 produce goats milk; 10 process raw goats milk for sale and 9 process pasteurised dairy products. Five of the goat farmers also farm sheep and/or cows.

In 2011 an experienced food safety auditor with considerable experience in the dairy goat industry surveyed 7 goat farmers. Based on the information provided, and some assumptions regarding the seasonal nature of goats milk production, five farmers who only sold raw milk placed about 100,000 litres of raw packaged goats milk on the NSW market each year. The point of sale was mostly local retail outlets (mainly health food stores) but local delivery, farm gate sales and farmers' market sales also occurred. Prices were significantly higher than cows milk and average sales of 20,000 litres per farm could amount to \$100,000 income for those farmers with a significant proportion of sales at retail prices.

Four of the 5 raw-milk-only farmers felt they would exit the industry if pasteurisation was mandated. The other farmer had not investigated costs related to pasteurisation. Two farmers that sold raw goats milk and pasteurised products were deeply concerned by the prospect of losing their raw milk sales.

The raw milk sales of the farmers who both package raw milk and process pasteurised products could not be determined. However, the farms had larger than average heard sizes and it is plausible that the 2 farms could equal the production of the 5 raw milk only farms. If so, then packaged raw goats milk from the 7 farms could approximate 200,000 litres and the whole industry in 2014 could be 400,000 litres or 1.6 million serves per year. For comparison NSW milk production in 2012/13 was reported to be 1,070 million litres (Dairy Australia¹) and consumption of packaged milk for the same period was 734 million litres (Dairy Australia²) or 2,936 million serves. For reference, the population of NSW as at June 2012 was reported to be 7.29M (ABS) and so there were about 0.2 serves of goats milk compared to 402 serves of milk per capita per annum.

Have NSW interventions been effective?

The purpose of risk management interventions is to reduce foodborne illness. If the interventions are effective then the number of foodborne illnesses where the root cause is raw goats milk should be low, perhaps zero. However, given the nature of the commodity traditional epidemiological surveillance could well fail to detect any problems. The difficulties arise because:

¹http://www.dairyaustralia.com.au/~media/Documents/Stats%20and%20markets/Production%20and%20sales/Latest%20stats/NSWMilkProduction_June14.xls

²<http://www.dairyaustralia.com.au/~media/Documents/Stats%20and%20markets/Production%20and%20sales/Latest%20stats/Milk%20Sales%20National%20Apr%202014.xls>

- Goats milk is a low volume commodity with a comparatively small number of consumers.
- It is rarely sold through mainstream retail outlets such as supermarkets.
- Goats milk consumers are likely to be in geographically diverse regions not contained within a single local government area.
- Outbreaks are likely to present as sporadic illness within a single household and such incidents are very difficult to resolve.

It must be noted that illnesses caused by enterohaemorrhagic *E. coli*, *Listeria monocytogenes* and *Salmonella* spp., which were identified in the FSANZ risk assessment as posing a medium or high risk to general or susceptible populations, are notifiable in NSW. Notification and the associated investigation offsets, to some extent, the difficulties in detection identified above.

FSANZ identified two Australian incidents of foodborne illness associated with raw goats milk. A report of *Cryptosporidium* infection in a mother a child appeared in 1984. The family had consumed raw goats milk 5 days prior to the onset of illness, but the relevance of this incident could not be established. It is not clear in which state the incident occurred. In 1990 salmonellosis was reported in Perth WA and a link to raw goats milk was identified. Literature searches and review of OzFoodNet data have uncovered no further cases or cases subsequent to the preparation of FSANZ's assessment.

The lack of reports about foodborne illness in NSW associated raw goats milk, at least since the introduction of quality milk schemes, provides some comfort but the limitations of epidemiological surveillance for the commodity must be acknowledged. The aphorism 'lack of evidence does not equate to evidence of lack' should also be recognised. However, the community risk attributable to consumption of raw goats milk is seemingly low. There is a risk to consumers of raw goats milk but the level of risk relative to commodities where risks are tolerated is not clear. Without that quantification and given the lack of evidence of foodborne illness it could be difficult to justify withdrawing the approval to sell raw goats milk.

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