



## **Submission from the Australian Specialist Cheesemakers' Association on FSANZ's P1022**

**21 August 2014**

The Australian Specialist Cheesemakers' Association (ASCA) once again appreciates the opportunity to provide comments on Proposal P1022 - Primary Production and Processing Requirements for Raw Milk Products.

We applaud the many changes in Proposal P1022, and we thank FSANZ for consideration and incorporation of our previous comments. We remain strongly committed to food safety and the safety of cheeses produced within Australia and New Zealand, and we look forward to continuing to work with FSANZ in implementing changes to assure the safe production of dairy products derived from raw milk. To that end, we again offer comments on Proposal P1022.

ASCA has once again been greatly assisted in its review of the documents and preparation of this submission by Professor Catherine Donnelly of the Department of Nutrition and Food Sciences at the University of Vermont, an acknowledged worldwide expert on the microbiology of cheese and other dairy products, in particular, *L. monocytogenes*. We previously offered to facilitate any discussion FSANZ may wish to have with Professor Donnelly in relation to this submission or more generally in relation to the proposal. FSANZ did not respond to that invitation, but we would like to make it again, as we think this will enable better discussion and shared understanding of the issues that are troubling us, as explained below.

### **Overall comments**

Our comments relate primarily to the establishment of limits for *E. coli* in bulk tank milk and in raw milk cheese. We assume the reference to *E. coli* refers to nontoxigenic species. This should be clarified in the proposal.

We acknowledge that an *E. coli* limit for all cheese will be addressed through separate proposal in later half of 2014. However, we do have several concerns relating to P1022, set

out below, which we strongly believe must be rectified for the proposal to be scientifically correct, and also meaningful for the safe production of raw milk products in Australia.

In addition to our specific comments set out below, mainly concerning *E. coli*, we remain very concerned that no answer is yet proposed to one of the key challenges for Australia's artisan cheese industry, the validation requirements for raw milk products. As explained in our earlier submission, this is a key issue for the following reasons.

- Australia's specialist cheese industry generally, and artisan cheesemakers in particular, do not have access to the appropriate scientific and technical resources to do predictive modelling and undertake challenge studies.
- Without adequate support for Australia's artisan industry we will not be able to achieve the potential cost benefits to our industry outlined in P1022 Section 2.5 FSANZ Act Assessment Requirements 2.5.1.1.
- While industrial cheesemakers and importers will benefit from the proposals, without the technical support that artisan cheesemakers such as current ASCA members will need, the Australian artisan cheese industry may not be able to make raw milk products.
- These concerns can and should be addressed through an assistance package developed in consultation with the industry and this could achieve excellent economic outcomes for Australian specialist cheesemakers and rural economies and communities.

### **Specific comments on *E. coli***

1. Supporting Document 1 Page 7: The proposed process verification policy of <10 *E. coli* in raw bulk milk does not correlate with any known safety benefit - nor is it related to insanitary conditions or filth. The EU does not have guidance for generic *E. coli* for cheese. In the United States, for the most sensitive product the FDA regulates, powdered infant formula, in the revised Infant Formula Act, (CFR 106) there is no specification or guidance for non-pathogenic *E. coli*. Historically, generic *E. coli* has been used as an indicator for pathogenic bacteria. As direct testing methodology is available for pathogens, there is no scientific reason to test raw milk or raw milk cheese for generic *E. coli*. The establishment of monitoring targets in bulk tank milk for the pathogens *Salmonella*, *L. monocytogenes*, and *S. aureus* is more appropriate to provide assurance of milk safety. What benefit will *E. coli* testing provide over and above limits for the aforementioned pathogens? FSANZ will need to scientifically document its rationale for establishment of *E. coli* levels in raw milk and raw milk cheese. Why would *S. aureus* be permitted at levels of <100 cfu/ml in bulk tank milk, yet *E. coli* levels targeted at <10 cfu/ml? Our Independent Subject Matter Expert does not consider non-pathogenic *E. coli* to be a safety hazard or a meaningful indicator of the sanitary history of the product.
2. Supporting Document 1 page 24: The proposal suggests monitoring a representative sample of each raw milk tank/silo prior to manufacture, with *E. coli* limits of <100

cfu/ml proposed. This contradicts *E. coli* limits of <10/ml stated on page 7. This further calls into question the validity of the stated limits, along with supporting scientific evidence that established limits serve to advance cheese safety and provide public health protection.

3. Supporting Document 3 page 29: Data from Frank and Marth (1977) is presented to show behavior of *E. coli* when co-cultured with lactic starter. As stated in SD3 “For example the non-pathogenic *E. coli* K-12 strain had the greatest growth, while enteropathogenic strains A-4 and H-1 performed poorly in all experiments.” These data illustrate the lack of correlation between performance of nontoxigenic *E. coli* versus enteropathogenic strains and further call into question the value of establishment of *E. coli* limits in milk and cheese.
4. Supporting document 1 page 28. In the section “Microbiological monitoring of raw milk products”, the establishment of “*E. coli* <10 (target)” is problematic. The EU has recently raised concern over FDA’s establishment of *E. coli* limits in raw milk cheese. EU cheesemakers argue that while *E. coli* testing may be used within the food industry to monitor gross contamination of products, the production of raw milk soft and semi-soft cheeses often involves long acidification times. During the acidification process, levels of non-toxigenic *E. coli* may grow to detectable levels, even though the raw materials can be shown to contain <10 MPN/g *E. coli*. For this reason, there is no legal limit for non-toxigenic *E. coli* levels in raw milk cheese within the EU. The U.K. Specialist Cheesemakers Association advocates a target of <1000 MPN/g *E. coli* in soft or slow-acidifying raw milk cheeses, but acknowledges that in certain cases even higher levels are not necessarily indicative of a hygiene lapse. Such cheeses are not made from compromised raw materials, nor do they present a risk to consumers’ health.

FDA’s Defect Levels Handbook

(<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/SanitationTransportation/ucm056174.htm>) acknowledges that ‘it is economically impractical to grow, harvest, or process raw products that are totally free of non-hazardous, naturally occurring, unavoidable defects’ and proposes ‘Food Defect Action Levels’ ...of natural or unavoidable defects in foods for human use that present no health hazard.’

With these principles in mind, we ask FSANZ to consider abandoning the use of non-toxigenic *E. coli* as an indicator of gross contamination in raw milk cheese unless a strong and reasoned scientific case can be presented for the value of establishment of *E. coli* limits over and above specific pathogen testing.

## Additional Comments

Throughout the proposal and supporting documents, references are made to “milk for **raw milk products**” yet only specifications for cheese are provided. Page 8 of the proposal (Table 1: Summary of issues) states “A submitter queried whether raw milk products other than raw milk cheese will be permitted under P1022 (eg butter).” The FSANZ response does not clearly answer this question, but it does imply that products such as cultured

butter, yoghurt, crème fraiche, kefir, etc, would be included. If this is the case, will guidance be provided on processing requirements for these products? Or is this covered adequately on Page 8 of SD2 (5. Validating control measures)?

It is not clear whether the primary production and processing requirements are specific to locally-produced cheeses, or whether they will also apply to imports. While Page 7 of the proposal states “demonstrating assurance that product has been produced under conditions at least equivalent to domestic requirements”, how realistic is it to assume that importers will be able to provide evidence of this? We are concerned that local producers will be at an extreme disadvantage compared to producers of imported products if this is not adequately addressed.

Page 9- 3<sup>rd</sup> dot-point under FSANZ Response to **Cost-benefit analysis**: we are very surprised at the inclusion of the statement “few, if any, suppliers are likely to produce products under the standards”. Contrary to this statement, ASCA is aware that many of its cheesemaker members, in particular those which are farmhouse cheesemakers or otherwise have good control over the source and quality of their milk supply, would welcome the opportunity to safely make and sell raw milk cheese. ASCA does not understand the basis on which this statement has been made, as ASCA's experience and understanding of the small artisan cheesemaker industry in Australia is completely different to the picture portrayed by such a statement.

Page 10- we welcome FSANZ's assessment that existing generic labelling requirements are deemed appropriate for Category 2 raw milk products.

Page 12- Figure 1 is a welcome addition to P1022.

### **Comments on Supporting Document 1 (SD1): Guide to the requirements for raw milk products in Standard 4.2.4-Primary Production and Processing Standard for Dairy Products**

Page 6, line 2- change “diary” to “dairy”

Page 7- Recommended monitoring criteria: *E. coli* <10 cfu/ml; Cessation of milk supply if >100 cfu/ml *E. coli*. What is the scientific basis for this recommendation? Again, we argue that these criteria may be too strict and may not advance public health goals as compared with direct testing for the pathogens. The proposed routine farm bulk milk limits: *Salmonella* 0/25ml; *L. monocytogenes* 0/25 ml and *S. aureus* <100 cfu/ml should be adequate without the need for *E. coli* testing.

Page 12- We applaud inclusion of recommendations for fermented feeds

Page 14- “...visitors to a dairy farm producing milk for raw milk products should be excluded.” If taken literally, this statement could be interpreted to mean that no visitors are allowed anywhere on the farm at any time. Clarity should be provided to limit this requirement. Likewise if a farm is interested in pursuing agi-tourism opportunities, as

various government bodies are currently encouraging, how will these be impacted by such a requirement? There is no business case for attracting tourists to a farm then denying them access to see farming activities such as milking, etc.

Page 14- “Hand washing”-wording in the sentence “If gloves are used, new, clean, latex-type gloves **at each** should be worn...” doesn’t make sense.

Page 16- The provision that “cooling requirements do not apply if processing commences within 2 hours of milking” will be of help to artisan and farmhouse cheese producers who will likely produce milk on-farm from closed herds.

Page 19- We suggest addition of a section on minimizing foot traffic. The document as written emphasizes transport, but artisans will likely utilize milk without transport. This section is written with consideration for industrial processors, but does not address practices likely to be utilized by artisan and farmhouse cheesemakers. Specific guidance for production and utilization of milk on-farm without transport is needed.

Page 19, para 2- “Persons undertaking activities related to the production of milk for raw milk products should **fully understand any implications** the activities they undertake may have on the microbiological status of the milk.” If taken literally, this implies that any person involved in any aspect of milk production needs a very good understanding of microbiology, regardless of what they are actually doing. The wording of the previous paragraph seems more appropriate, ie “...that persons undertaking primary production activities must have skills and knowledge of food safety and hygiene matters **commensurate with their work activities.**” Suggest paragraph 2 is removed, as paragraph 1 covers the matter appropriately.

Page 19/20- As previously indicated, the document emphasizes transport but what about farmhouse cheese makers who produce and use their own milk? Does transportation infer pipelines from milk house to cheese room? As written, the recommendations may be appropriate for industrial scale cheese making operations, but not necessarily directive for artisan/farmhouse cheese makers.

Page 20, para immediately before section 29- wording in the sentence “...to ensure that there is no cross-contamination between milk for **suitable for** raw milk products...” doesn’t make sense.

Page 20, text box- wording of Clause 29 Subclause (2) (a) is ambiguous and implies that if the milk is **collected** within two hours of being milked it can exceed 8°C. It does not clarify that the milk must be **processed** within two hours of milking, as specified in Clause 33 Subclause (2) (a) on page 27. Clarity and consistency is needed regarding collection and processing, relative to milking.

Page 21- We suggest placement of the section on raw milk handling requirements before transport.

Page 25/26- statements such as “combination of control measures”, “concentration required for safety” and “for the type of cheese being produced” suggest that it won’t be simple to clarify which control measures are deemed appropriate for each type of cheese produced. While this information can be found in Supporting Document 3, it is difficult to locate and therefore open to interpretation by producers and regulators. We suggest inclusion of a table clearly listing the acceptable pH reduction, salt concentration, moisture content, etc, specifications for each type of cheese detailed in SD3 would be a useful addition, and help to eliminate potential confusion. Regulatory requirements such as these should be clearly and logically expressed, so that both cheesemakers and regulators can be sure about the precise nature of the requirements.

Page 26- We suggest addition of a sentence requiring microbiological monitoring of brine tanks; also include a discussion of washed rind cheeses and the need for microbiological monitoring of the wash solution along with brushes, sponges and other tools which may be used to apply the wash solution.

Page 28, (5) 1<sup>st</sup> sentence- change “diary” to “dairy”

Page 29- As indicated previously, the raw milk tank/silo *E. coli* <100 cfu/ml target contradicts the *E. coli* target indicated on page 9 (<10 cfu/ml).

Page 30- Regarding process verification, we believe the *E. coli* <10 target for raw milk products is problematic. If 100 cfu/ml *E. coli* were present initially in raw milk, you will have 1000 *E. coli*/g in cheese product due to physical entrapment in the curd following whey removal (see D’Amico et al 2010).

We suggest that *E. coli* targets should be removed, and that monitoring of Staph populations be used consistent with EU criteria, along with verification that *L. monocytogenes* is absent in environmental samples during processing.

Further, an explanatory paragraph should be provided regarding the importance of verification that cheese composition targets have been met for the specific variety being made. This would include measurement of % moisture, moisture nonfat substance (MNFS), fat in dry matter (FDM) and salt in moisture phase (SM). It has been our experience that microbiological defects in cheese arise when cheese composition is altered. Verification that correct compositional targets have been reached can help assure cheese quality and safety.

### **Comments on Supporting Document 2 (SD2): Guide to the validation of raw milk products**

Page 4- Validation Requirements, 1<sup>st</sup> paragraph: what about potential increases due to concentration effects beyond growth or entrapment during curd formation?

Page 4- “The main source of the pathogen(s) of concern is the raw milk”. This may not be true in an artisan farmhouse operation and this is not supported by extensive research conducted by D’Amico and Donnelly and others; control of pathogens in the cheese

processing environment may be more important to assure cheese safety and protect public health.

Page 9, Figure 2- change in pathogen concentration during milk coagulation stage-this is due to concentration effects, not growth. Perhaps use the term “change in pathogen **levels**” not “change in pathogen **concentration**” as more descriptive and will help avoid confusion. Also, page 10 states “including concentration effect due to curd formation”. D'Amico et al (2010) found a ten-fold increase in *E. coli* O157:H7 populations in Gouda cheese due to whey expulsion and contraction of the curd.

Page 12- typographical error on dot-points (remove dot-point iv) and replace “v)” with “vi)”]

### **Comments on Supporting Document 3 (SD3): Scientific information for the assessment of raw milk products-Cheeses**

- i. “This includes demonstrating that the physico-chemical characteristics of the cheese do not support the growth of pathogens through determining the time required for no net increase in pathogen concentration” problematic-concentration occurs when whey is removed; use the term “pathogen levels” as opposed to “pathogen concentration”
- ii. Demonstration of the food safety outcome 3 requires evidence of no net increase in pathogen concentration through the entire cheesemaking process-problematic as worded-see D'Amico et al 2010.

The entire document as written is appropriate for industrial cheese makers, but not necessarily the artisan/farmhouse community. Development of an artisan/farmhouse cheesemaking community represents an exciting economic opportunity for Australia and New Zealand. More focus on this sector and more assistance will accelerate the production of new cheeses. With this will come requests for technical support. For instance, the proposal calls for challenge studies to document the inability of a cheese variety to support pathogen growth. Within the artisan community, the ability to do this is limited. The use of predictive modeling and the conduct of challenge studies assumes technical expertise. Who will provide technical support for the artisan community?

Page 25, Paragraph 2, line 3- should be “pH faster **are** more likely”.

Page 29, last paragraph- the example provided illustrates the confusion around *E. coli* data and is not predictive of pathogen fate.

The problem of concentration is addressed on page 34.

The standard of no net increase in pathogens may penalize those who produce milk for cheesemaking with stringent microbiological criteria

Page 46, paragraph 1- “This finding highlights the importance of minimizing the amount of growth of pathogens during the early stages of cheese making.” This statement presumes pathogens are present; what about milk meeting stringent micro criteria where pathogens are absent? In a traditional industrial milk production model where bulk tank milk from multiple farms is co-mingled and transported to large silos for processing, there is much more of a chance for pathogen introduction and subsequent contamination of the entire load of milk. In a farmhouse setting with a closed herd where transport and co-mingling do not occur, the chances for pathogen contamination are much less. How will incentives be provided for producers who achieve milk production with stringent criteria? Are there alternate risk management tools or risk management approaches? The entire proposal addresses reduction of pathogens in raw milk with the assumption that they are present. How will the standards address production of milk free from pathogens? There is too much focus on industrial models and assumptions without consideration of data from farmhouse surveys and practices.

## **Reference**

D’Amico, D. J., Druart, M. J. And Donnelly, C. W. (2010) Behavior of *Escherichia coli* O157:H7 during the Manufacture and Aging of Gouda and Stirred-Curd Cheddar Cheeses Manufactured from Raw Milk. J Food Protect. 73: 2217–2224