



Submission from the Australian Specialist Cheesemakers' Association (ASCA) to assist FSANZ's consideration of draft regulation measures P1017 and P1022

We greatly thank Food Standards Australia New Zealand (FSANZ) for the opportunity to provide comments on two proposals: P1017 which seeks to replace existing limits for *L. monocytogenes* in individual foods with two sets of criteria; and P1022 which was prepared to assess additional requirements for the safe production of raw milk products. We have also commented on P1007 which examines current processing requirements.

1. Overall comments

- Overall, ASCA applauds the work done by FSANZ in this area**

FSANZ should be applauded for their efforts to explore for raw milk products “whether an acceptable level of public health and safety can be achieved through alternative processing and/or production measures to those currently specified.” The documents provided indicate that FSANZ has taken an approach to this issue which is scientifically valid, flexible, and focused on protection of public health while simultaneously enabling regulations harmonised with international standards, which should ultimately provide increased opportunities for domestic cheesemakers residing in Australia and New Zealand. The move away from a product by product approach specifying *L. monocytogenes* limits for individual foods, to two sets of criteria for RTE foods is consistent with current knowledge of *L. monocytogenes* risk and public health protection. Guidance for raw milk processors on validation of control measures necessary to assure the safety of raw milk products certainly provides a framework which can be utilised in the formation of a food safety plan to assure product safety.

FSANZ's alternative processing requirements to pasteurisation are aligned with contemporary efforts around the globe and modern approaches to food safety assurance. In fact, the United States legal definition of pasteurisation was changed in the 2002 Farm Bill as “Any process, treatment, or combination thereof, that is applied to food to reduce the most resistant microorganism(s) of public health significance to a level that is not likely to present a public health risk under normal conditions of distribution and storage” (NACMCF, 2006). The FSANZ approach to alternative processing and/or production measures is consistent with this definition.

In preparing comments, 8 documents are referenced (#1-#8 below). On each of these documents, comments and questions which are of concern to ASCA are indicated.

ASCA has 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*. ASCA would be happy 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.

- **Areas of concern, in particular the need for government and industry support to enable artisan cheesemakers to meet the proposed requirements**

At the same time, there are several areas of the proposal and its supporting documents that should be clarified or corrected, and others where we consider there to be insufficient practical guidance and thought given to how smaller cheesemakers will be able to meet the requirements. We have attempted to identify these, with corresponding suggestions for change.

One of the key challenges for Australia's artisan cheese industry will be the validation requirements for raw milk products. 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.

2. Specific comments

#1 Approval Report-Proposal P1007

Three categories of raw milk products have been defined, with category 2 products being the topic of this proposal. Category 2 products are those which have properties or processing parameters that may allow survival of pathogens that may have been present in the raw milk, but the products will not support the growth of these pathogens. We appreciate FSANZ's willingness to be responsive to the concerns of artisanal cheesemakers in expanding permissions for category 2 products. This move will no

doubt assist in the continued development and growth of the vibrant Australian artisan cheese industry. This new industry will be best assisted when measures are in place to assure public health protections of consumers and processors alike. The implementation subcommittee of FRSC is a critical component to help provide a uniform national approach to inspection and regulation. Harmonising regulations with Codex and the EU should help create a vibrant cheese culture in Australia and New Zealand and assure artisan cheesemakers the opportunity to participate in a global economy, and for this proactive approach, we congratulate FSANZ.

#2-Proposal P1017 Criteria for *Listeria monocytogenes*-microbiological limits for foods

This standard is intended to revise Standard 1.6.1 whereby existing limits for *L. monocytogenes* in ready to eat (RTE) foods would be replaced with two sets of criteria:

1. RTE foods in which growth of *L. monocytogenes* will not occur (<100 cfu/g throughout shelf life)
2. RTE foods in which growth of *L. monocytogenes* can occur (not detected in 25 g)

We agree that the proposed standards are based on risk analysis using the best available scientific evidence, where low levels of *L. monocytogenes* equate to low risk and public health protection (ILSI Research Foundation, 2005).

The proposal, while providing greater flexibility to artisan and specialist cheesemakers, also presents some challenges. Unlike many commodity food products for which much knowledge and guidance has been published and is widely available in the scientific literature regarding potential to support growth of *Listeria*, there have been few published studies specifically on the topic of artisan cheeses and their potential to support *Listeria* growth. We hope that FSANZ will be willing to work with the ASCA and provide assistance and flexibility as we develop a database to assist our members' compliance with the new regulations.

Concerns-on page 13, growth has been defined as an average of 0.5 log cfu/g increase in *L. monocytogenes* levels for at least the stated shelf life of the product. This definition should be expanded to state “under conditions of normal use and storage”. The definition does not specify abuse temperatures/conditions to which products may be subjected. Is normal use and storage implied in the definition?

#3-Supporting document 1-Guidance on the application of microbiological criteria for *L. monocytogenes* in RTE food

Concerns-The guidance provided in the proposal will certainly benefit industrial cheesemakers who have access to appropriate scientific and technical resources. How will small scale cheesemakers be assisted with predictive modelling and challenge studies?

#4-Supporting document 2-Scientific basis for *Listeria monocytogenes* limits-Proposal P1022

Executive summary-paragraph 3 states “Foods containing low levels (<100 cfu/g) pose very little risk, even when consumed by vulnerable individuals.” In the case of butter, this may not be true. Butter will not support the growth of *L. monocytogenes* but has been linked to an outbreak involving vulnerable individuals. How will FSANZ address this issue?

Update page 4, #2-International risk assessments (last paragraph) should be updated to include the Draft Joint FDA / Health Canada Quantitative Assessment of the Risk of Listeriosis from Soft-Ripened Cheese Consumption in the United States and Canada (see <http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM338617.pdf>) as it is particularly relevant to the issues being addresses by FSANZ.

Page 5, last line, “This emphasises the importance of having control measures that reduce the frequency of contamination and prevent occurrence of high levels at consumption.” Will FSANZ be offering educational programs to help producers of raw milk products achieve compliance? If not, which organisations will be offering such programs? The most effective means of achieving compliance involves environmental sampling and prevention of post-process recontamination. Both cheesemakers and regulators (inspectors) would benefit from education and training regarding best practices for environmental sampling and testing, identification of niches of *Listeria*, and best methods to prevent product recontamination through good manufacturing practices and other measures. As the artisan cheese industry in Australia is new and evolving, it is critical that technical assistance for this important sector be provided in this early stage.

#5 Call for submissions-Proposal P1022

Executive Summary-comments: The ASCA formally applauds FSANZ’s development of Proposal P1022, particularly option 1 which provides an excellent, proactive approach to utilisation of raw milk products. We wish to express our support for Option 1, and state that Option 2 (status quo) is not favoured.

Page 3, paragraph 9-The ASCA acknowledges the risks associated with raw milk consumption. Artisan/specialist cheesemakers utilising raw milk process this product for safety. We fully understand that one outbreak linked to an artisan/specialist cheese will jeopardise the entire industry with respect to consumer confidence. As such, we ask for FSANZ’s assistance, and that of other relevant government agencies, in implementing the new proposals to assure the safety of our products.

The Risk management approach under option 1 (page 7) is likely to require regulator training. As discussed above, training is critical for both cheesemakers and regulators.

Standard 4.2.4 (page 8)

Inclusion of a new division to the standard that would set out additional requirements for primary production, transport and processing for raw milk products, is encouraged. This approach is very proactive and appropriate.

1.1.1.3. Standard 1.6.1 (page 9)

For raw milk products, FSANZ proposes that sampling plans are established for *Salmonella* and Staphylococcal enterotoxin. The EU has moved away from this approach. Has FSANZ considered adopting EU microbiological criteria in which limits for coagulase positive Staphylococcus have been established? EU Regulations (No. 2073/2005) specify microbiological criteria for raw milk cheese, with coagulase positive *Staphylococcus* being the target pathogens ($n=5$, $c=2$, $m=10^4$, $M=10^5$) for which limits are applied. Cheesemakers must define the point in cheese making where counts are expected to be the highest and monitor these for compliance. Additionally, Regulation no. 2073/2005 utilises *E. coli* (instead of *Salmonella*) as a hygienic index. Published studies and practice indicate that it is very rare to find *Salmonella* either in raw milk or in finished cheese products. We therefore suggest that requiring sampling plans for *Salmonella* is not necessary or appropriate.

D'Amico, Groves and Donnelly (2008) examined overall milk quality and prevalence of four target pathogens in raw milk destined for farmstead cheese making. Of 133 milk samples collected from 11 farmstead cheese establishments, *S. aureus* was detected in 46 of 133 samples (34.6%); *L. monocytogenes* from 3 of 133 samples (2.3%), *E. coli* O157:H7 from 1/133 samples (0.75%) and *Salmonella* from 0/133 samples. These authors concluded that most raw milk intended for farmstead cheese making is of high microbiological quality with a low incidence of pathogens. This finding was reaffirmed in a follow-on study conducted by these authors (D'Amico and Donnelly, 2010).

D'Amico and Donnelly (2011) further analysed results of FDA's Domestic and Imported Cheese Compliance results for the years 2004-2006. Of 2,181 cheese samples analysed for *L. monocytogenes*, 2.4% were positive, with 52% of positive samples consisting of Mexican-style soft cheese, or soft-ripened cheese. Of 3,520 cheese samples tested for *Salmonella*, only 1.3% were positive, with the majority of positive samples being soft or soft ripened cheeses produced in Mexico or Central America. *Staphylococcus aureus* was detected in 6.9% of 3,449 cheeses tested, making it the most commonly detected pathogen of concern.

2.4.1 Previous consultation-outreach to specialty cheese manufacturers is excellent and we hope these efforts will continue as the proposal becomes implemented.

2.5 Page 11, Industry-Data should be included citing the potential for positive economic impact to rural communities.

Page 13-The desirability of an efficient and internationally competitive food industry is to be applauded, and ASCA wishes to thank FSANZ for these efforts.

#6 Supporting Document 1- Guide to the requirements for raw milk products in Standard 4.2.4- Proposal P1022

The implementation of a documented food safety program will be of great help to ASCA cheesemakers wishing to export products to meet U.S. FDA requirements, particularly those of the U.S. Food Safety Modernization Act, as well as EU and other requirements.

Standard 4.2.4 specifies that the processing of milk from raw milk products must ensure: no net increase of pathogens; and the characteristics of the final product do not support growth of pathogens. Will verification of strict hygiene and sanitation achieve the standard? As shown by Lafarge et al. (2004), dynamic changes in the bacterial population of raw milk was documented as a result of refrigerated holding at 4°C, with emergence of *L. monocytogenes* in samples compared to milk which was not held at refrigerated temperatures. Direct utilisation of milk of high hygienic quality in cheese making (without refrigeration) may have a protective effect on public health in reducing presence of *Listeria*. Could verification of this be utilised by artisan cheesemakers to achieve the standard?

Bullet after “A mastitis control program is implemented”

- Consider feed source (no silage?)

Page 7, Pathogen monitoring: one test per week on farm bulk milk. It may be prudent to test milk filters (instead of milk) for *S. aureus*, *Salmonella* and *Listeria*. VanKessel et al. (2011) found this to be a highly sensitive way to determine the prevalence of bacterial pathogens in dairy operations, and was found to be more sensitive than bulk tank milk testing.

Page 9-management of chemical and microbiological hazards in conserved fodder-for raw milk intended for cheese making, the hazards associated with the presence of *Listeria* in silage should be noted, and silage feeding should be avoided or carefully monitored. On page 10, 3rd bullet: insert after 1st sentence “There is a direct correlation between mouldy, poor quality silage and presence of *Listeria*.”

Paragraph 1-a specific provision is included for fermented feeds-excellent. The silage guidance is excellent, particularly the advice to farmers to regularly monitor silage pH as an efficient and effective means to monitor silage quality and potential for presence of *Listeria*. In this recommendation, FSANZ may wish to consider elimination of silage as a source of feed for animals whose milk will be used in raw milk cheese production.

Page 11, Premises and equipment-Standard 4.2.4 requires a dairy primary production business to control the potential food safety hazards arising from the design, construction, maintenance and operation of premises and equipment as part of its food safety program. Research by D’Amico and Donnelly has found these areas to be the largest source of microbiological problems plaguing artisan cheesemakers.

Page 11-12 Cleaning and sanitising: guidance on foot traffic in facilities is needed; sanitiser frequency and efficacy needs focus (also on page 14 under cleaning and sanitation requirements).

Page 15: after “Inspection of milk filter after use to check for abnormalities” insert “Testing of milk filters for presence of pathogens.”

Page 18, number 1. Controlling food safety hazards: Under "Cleaning and sanitation programs" guidance should be provided regarding frequency and efficacy; establishment of standard sanitation operating procedures (SSOPs).

Page 21: Cheese style-provide outline of families?

Page 22: Other treatments-include bandage/cloth wrapping for Cheddar cheese.

Page 23: Food handling controls: change bullet to read "cleaning, sanitising and maintenance of equipment and premises through implementation of good manufacturing practices (GMPs)"

Page 23, last paragraph change "Diary" to "Dairy"

Page 24: Monitoring criteria: consider testing for adopting a standard for coagulase positive *Staphylococcus*. Acceptable limits, Page 24, Monitoring criteria: If the standards are going to have - Total plate counts at 30C for 72 hours - can we ask that acceptable limits for goats, sheep and buffalo be provided?

Page 24, Deviations from temperature requirement of 8C-As stated previously, Lafarge et al. (2004) documented dynamic changes in the bacterial population of raw milk as a result of refrigerated holding at 4°C, with emergence of *L. monocytogenes* in samples compared to milk which was not held at refrigerated temperatures. Direct utilisation of milk of high hygienic quality in cheese making (without refrigeration) may have a protective effect on public health in reducing presence of *Listeria*. Would raw milk and curd testing documenting absence of *Listeria* provide adequate verification to achieve the standard?

-As stated previously,

Page 25, Raw milk processing: include management of chemical composition through monitoring of % salt in moisture and other chemical parameters.

Page 25, management of acidification/pH reduction: encourage cheesemakers to maintain records of acidification profiles for each batch produced during cheese making.

Page 27, Ripening; bullet under cheese washing or brushing. Cheesemakers should be encouraged to regularly test brine wash for presence of *Listeria*; guidance on treatment of brushes should be given. Failure to properly decontaminate brushes has been a factor in several outbreaks of listeriosis linked to washed rind cheeses.

Page 27: Skills and knowledge: The proposal states that "It would be expected that the technical control of the process is under the supervision of a designated operator (e.g. cheese maker) who has the appropriate skills, knowledge and experience in the manufacture of raw milk dairy products." The cheese maker must have relevant experience, qualifications and training as required by the competent authority.....". Who will ensure/enforce this aspect of the regulations, and how will it be done? In the U.S., trends in the artisan cheese industry reveal that many new cheesemakers come to the artisan

cheese community lacking the requisite technical skills and knowledge. Further, there are few resources available to the artisan cheese community to provide the missing education/technical knowledge. How will FSANZ and other government agencies address these needs? This is critically important to the success of the artisan industry and to the safety of cheeses produced by this industry.

Page 28: Microbiological sampling and testing: As indicated previously, we recommend utilisation of EU microbiological limits for *Staphylococcus*. Eliminate testing for staphylococcal enterotoxins-difficult and impractical; eliminate testing requirement for salmonella and adopt instead a hygienic index for *E. coli*.

Chemical sampling and testing: identify deviation from norm through trend analysis

#7 Supporting Document 2-Guide to the validation of raw milk products-Proposal P1022

Hazard Identification (page 3): We agree that specific validation data for *Campylobacter* may not be required. However, we disagree with the recommendation regarding *S. aureus* for the reasons previously stated. It is easy for cheesemakers to monitor levels of *S. aureus*. As previously stated, we recommend elimination of validation for *Salmonella*.

Page 4, Food Safety Outcome: Add bullet "Prevention of post-process recontamination from the processing environment."

Page 4, Initial level of the hazard-The document states "The main source of the pathogen(s) of concern is the raw milk." This is not true for *Listeria* contamination of cheese where post process environmental recontamination has been identified as the main hazard. Recent surveys conducted by the United States Food and Drug Administration have revealed the presence of *Listeria* in 31% of tested cheese facilities. Similarly, it is not true for outbreaks of *Listeria* associated with Australian cheese, where the production facilities or some form of post-process cross-contamination have been found to be the likely source of the contaminant.

Page 11, Provide evidence that there is no net increase of pathogens during the processing steps: scientific literature-under important factors that should be included, include a bullet for the method of inoculation-surface inoculation to show fate of *Listeria* as a post processing recontaminant.

Page 12, Same comment under challenge studies-natural modes of contamination-include post-process recontamination

#8 Supporting document 3: Scientific information for the assessment of raw milk products-Cheeses-P1022

Executive Summary:

Page i "there is no net increase in pathogen levels during processing" should this be further defined to specify the conditions under which the increase is tested-abuse versus normal processing/storage?

Page i, paragraph 1 “This includes demonstrating that the physico-chemical characteristics of the cheese do not support the growth of pathogens.” What if a decrease over time can be documented? Will this provide adequate confirmation?

Page i, paragraph 2 “Methods available to assess the likelihood of pathogen growth in cheeses can include default physico-chemical parameters, predictive equations using growth rates or probability of growth and cheese challenge studies.” Cheese challenge studies will be difficult for artisan cheesemakers as conditions in the lab may differ greatly from actual ageing/affinage facilities. How will FSANZ address this?

Page i, paragraph 4 “Pilot scale production of raw milk cheeses could be used to determine the variability in the raw milk cheese.” This will require assurance that the lab scale cheese is the same in content as natural ageing conditions, where a complex microbiological flora is established (see Quigley et al. 2012). How will FSANZ approach this issue?

Page 1, Background. “Other types of cheese types (Cheddar, Feta, Camembert) were considered high risk due to growth and/or survival of pathogens during cheese making.” Eliminate Feta as an example. As indicated by Papageorgiou and Marth (1989), “Camembert and Feta have nearly identical composition in terms of moisture content, water activity, % salt-in-water and ripening temperature, but fully ripened Camembert has a pH of 7.5 versus Feta which has a pH of 4.4 that prevents *Listeria* growth.”

Page 1, “The risk assessment identified factors during cheese making which have the greatest impact on the safety of raw milk cheeses”: Add bullet “prevention of post process environmental recontamination”

Page 1, “The food safety outcomes to be achieved for the production of a raw milk product are: there is no net increase in pathogen levels during processing.” Could this be rephrased to “there is no net growth of pathogens during processing.” As written, the statement could be problematic. In general during cheese making, counts of pathogens in milk do not change significantly during coagulation, but do increase following expulsion of whey due to concentration in the curd. This is a concentration, not growth, effect due to removal of water and curd concentration.

Page 1: The same problem exists with wording in the following paragraph: “Section 3 of the report analyses the available scientific evidence for assessing the probability of no net increase in pathogen concentration during the production of cheese products.” When whey is drained, you will always have concentration of pathogens in the curd as a result of water removal. This is different from increases due to growth during cheese making, which we believe the risk assessment is trying to address.

Page 3, Table 1. Modify description of heat/acid cheese, last line “The most common varieties include Ricotta and Queso Blanco” to reflect current global demand for Mexican-style cheeses.

Page 8 and throughout documents: Guidance should be provided regarding ideal initial target levels of *L. monocytogenes* for challenge and modeling studies.

Page 10, paragraph 3, last line: Change sentence “The cheese inoculation studies may be used to investigate the intrinsic characteristics of cheeses that inhibit growth of pathogenic bacteria or the fate of pathogens introduced via post-process recontamination.”

Page 12, first line: “The feta study falls into the no growth area due to a low pH of 4.3” This is inconsistent with previous parts of Document 3 which lists Feta as a high risk cheese. The statement here is correct and Feta should be removed as an example of a high risk cheese in Document 3.

Page 30, last paragraph: “If another starter culture, a higher inoculum size or temperature profile was used then the actual growth could be different.” Does this suggest the need for individual challenge studies for each starter utilized? This would not only become cost-prohibitive, particularly for small scale cheesemakers, but also impossible for any government agency to monitor and enforce.

Page 33 “It is therefore important that decisions regarding the selection of starter and adjunct (and secondary) cultures influence the characteristics of the cheese and the response of pathogens. The design of a challenge study must adequately reflect the processes used to make the raw milk cheese, including consideration of variability.” An issue likely to arise is the reality of use of a number of starter cultures in a rotation in order to reduce attack by bacteriophage. Will all starters in a rotation need to be validated for potential pathogen growth inhibition?

References:

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Papageorgiou, D.K. and E.H. Marth. 1989. Fate of *Listeria monocytogenes* during the manufacture, ripening and storage of feta cheese. J. Food Prot. 52:82-87.

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Van Kessel, J., J.S. Karns, J.E. Lombard and C. A. Kopral. 2011. Prevalence of *Salmonella enterica*, *Listeria monocytogenes*, and *Escherichia coli* virulence factors in bulk tank milk and in-line filters from U.S. Dairies. J. Food Prot. 74:759-768.