

Appendix 1: Details of submissions received on the New Zealand Food Safety Authority Public Discussion Document No 02/09 July 2009: Proposed regulatory framework for unpasteurised milk products.

The 15 submissions received on the discussion document are summarised in the following table. Seven submitters are classified as industry, four as interest groups, three as 'other', and one as an individual.

Any views, opinions, or proposals contained or summarised in this document (other than those prefaced or being an 'NZFSA response') are those of the submitters and should be considered as a whole. Furthermore, they do not reflect government policy.

NZFSA thanks all submitters for their comments.

Affiliation	Topic	Submission comment	NZFSA Response
1. Industry	Support for regulatory framework	Considers that the most important factor in controlling raw milk hygiene is the relationship between the producer and cheesemaker.	NZFSA would suggest that it is important for both producers and processors to have a clear understanding of what is required for their respective activities and a plan for consistently meeting these requirements.

		<p>A milk producer must be traceable but must also have an interest in the end product.</p> <p>There must also be a farmer quality payment scheme, and the cheesemaker must have access to the results.</p>	<p>Traceability is a current requirement for all supply of milk.</p> <p>NZFSA considers that a quality payment scheme is a commercial arrangement and it is not intended for the framework to mandate such a scheme. Manufacturers must respect any applicable process hygiene criteria, but there is flexibility in how this may be achieved. Milk may be sourced from multiple farms, in which case access to individual farm data may not be appropriate.</p>
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	<p>Proposed process for determining regulatory options for such products</p>	<p>Considers that mathematical models are not applicable to fermented foods as they do not take into account microbial competition. Cites United Kingdom Food Standards Agency report <i>B12006: Risk assessment of Listeria monocytogenes in UK retail cheese</i>, and the statement: “Unfortunately, as the role of the fermentative or ripening microflora is not modelled, the tool is of limited value. The use of the available predictive models should therefore be used with extreme caution.”</p>	<p>Predictive modelling is widely used in the food industry to evaluate the efficacy of food processing activities in reducing pathogens or controlling their growth. However, as noted in the UK report, there are limitations in the applicability of the current models to some stages of cheese processing, especially with respect to <i>L. monocytogenes</i>. This is due to the models not including the effects of competing microorganisms and this may play an important role especially during the maturation of cheeses. Considerable effort is being devoted internationally to improving the applicability of the models so that they will be of more value to the industry. Having a suitable predictive model provides an opportunity to reduce validation costs.</p>
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2. Industry	<p>Intended legal mechanisms for implementing the proposed framework</p>	<p>Commented that section 15(3) and 17(a) of the draft Notice should be amended, and propose that the two hour cooling period should include the transport time, i.e. it is not necessary that milk be held at less than 8°C prior to manufacture, as long as manufacture commences within two hours.</p>	<p>Based on currently available data, NZFSA does not consider that transporting warm milk is appropriate when the milk will be used for raw milk products.</p>

	<p>Proposed process for determining regulatory options for such products</p>	<p>Support hard cheeses such as cheddar, red Leicester, double Gloucester, and Cheshire being categorised as 'Products that can be produced under existing dairy regulatory requirements'; as <i>L. monocytogenes</i> cannot grow in these cheeses.</p> <p>Safety of products should be determined through scientific evidence and historical data and experience from other countries.</p> <p>Considers that mathematical models are not applicable to fermented foods as they do not take into account microbial competition. Also cites United Kingdom Food Standards Agency report <i>B12006: Risk assessment of Listeria monocytogenes in UK retail cheese</i>, and the statement: "Unfortunately, as the role of the fermentative or ripening microflora is not modelled, the tool is of limited value. The use of the available predictive models should therefore be used with extreme caution."</p>	<p>These cheeses will be permitted provided they meet the required criteria.</p> <p>NZFA agrees that these will be useful sources of information, but it will be important that the production processes and product characteristics in the evidence provided are comparable with those to be used by the applicant.</p> <p>See comments on predictive modelling as for submitter 2.</p>
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	Proposed technical requirements for raw milk products	Validation testing is prohibitive for small businesses. Only the largest companies would have the resources of time, people and money to undertake validation studies.	Other evidence can be used to demonstrate process safety and this should not require as much resource as a full challenge validation study. However there may be insufficient evidence from other sources making a challenge study necessary, or some processors may prefer this option.
	Impact of proposed new framework	Considers that the costs involved should be kept to a minimum so as to not discourage the small producer, as it is the small cheesemakers that have the interest in making raw milk cheese rather than larger producers. If the requirements are too costly then they will suffer as the proposed framework will open up the door to increased competition from overseas.	<p>Manufacture of raw milk products requires additional on-farm and processing steps to manage pathogen levels. These additional steps impose additional costs. These costs also apply to product produced overseas under appropriate hygiene conditions.</p> <p>Current overseas exporting programmes that produce raw milk cheeses and have been recognised by New Zealand under case-by-case assessments, do so by using stringent management of milk production and processing of the cheese. This increases the cost of the resulting product (as can be seen by Roquefort, which retails in New Zealand for approximately \$100 to \$130 per kilogram).</p> <p>Imported product will only be able to be imported once Ministry of Agriculture and Forestry Biosecurity New Zealand has conducted an animal health risk</p>

			<p>assessment of the exporting country.</p> <p>Importers will only be able to import and sell products that meet the requirements of the Food (Imported Milk and Milk Products) Standard 2009. This standard lists permitted processing methods and recognised equivalent overseas sanitary standards. At present only specified raw milk cheeses produced in Switzerland and the EU can be imported. The Food (Prescribed Foods) Standard 2009 allows for raw milk products to be required to be accompanied by individual consignment certification issued by the competent authority of the exporting country.</p> <p>Imported raw milk products will only be able to be imported if they are produced to an equivalent level of safety as required by the New Zealand regulations, or comply with New Zealand regulations. Products that have not been assessed via one of the methods outlined above would not be able to be imported into New Zealand.</p> <p>Guidance for importers in the form of an Imported Food Requirement (IFR) will be developed. The IFR will describe the import procedures and requirements for</p>
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			import of raw milk products. Specific options for import of unpasteurised milk products will be communicated to importers via the NZFSA website and other communications.
	Proposals for labelling raw milk products and risk communications	Products should be labelled as unpasteurised but warning statements should not be on the label, as it implies that the product is unsafe, which it is not if it is made in accordance with approved methods. The most vulnerable groups (e.g. pregnant women) are already aware of the dangers for them of consuming unpasteurised milk as they are educated about this in antenatal classes.	Noted. There will be a requirement for the ingredient declaration for unpasteurised products to include the statement that the milk is raw or unpasteurised. As far as warning labels are concerned, the Australia New Zealand Food Standards Code (developed and administered by Food Standards Australia New Zealand) does allow for mandatory advisory statements to be used when consumption of a food exposes the general population, or a population subgroup, to a health and safety risk, or where guidance about a food is needed to maintain public health and safety. No such mandatory advisory statements or any other warnings are currently required on the labels of unpasteurised milk products. NZFSA intends to collaborate and consult with FSANZ about the possibility of introducing this requirement. Any such requirement, if agreed, would not be introduced until FSANZ has finalised its future policy on unpasteurised milk products.
3. Industry	Support for	The change will allow consumer demand for raw	Noted.

	regulatory framework	milk products to be safely satisfied.	
	<p>Intended legal mechanism for implementing the proposed framework</p>	<p>Section 7 of the draft Notice (animal health) details a veterinary inspection for all animals twice each season. Considers that as there is no specific need; that it will be a rubber stamping exercise only.</p> <p>Also, considers tuberculosis (TB) testing is not needed for sheep.</p>	<p>The purpose of clause 7(1) of the draft Notice is to ensure that farmers are milking healthy animals.</p> <p>However, NZFSA will amend clause 7(1) to clarify that vet inspections are only required during milking periods when the milking herd is producing milk that will be directed to raw milk products. For example, if a farmer only produces milk for raw milk products between 1 August to 30 November (and not in the period between 1 February to 31 May) then a vet inspection will only be required for the period between 1 August and 30 November.</p> <p>NZFSA will amend the requirement to exempt non-bovine species under certain circumstances. NZFSA agrees that there is no need for TB testing of non-bovine milking animals when there are no bovine animals or deer on the property; the milking animals do not come into contact with bovine animals or deer; the milking animals never move outside a TB vector free area; and no other factors indicate potential exposure (e.g. inspection at slaughter or status of neighbouring</p>

		<p>Queries if sheep milk has been tested for <i>campylobacter</i>.</p> <p>Considers section 13 of the draft Notice (farm dairy assessments) will result in increased and excessive inspection costs.</p> <p>Considers section 17 in the draft Notice (milk acceptance and storage) should be amended so that milk is able to be held for 72 hours before manufacture.</p>	<p>farms).</p> <p>NZFSA has not undertaken testing of raw sheep milk for <i>campylobacter</i>.</p> <p>NZFSA considers that the specified frequency of farm dairy assessments is appropriate given the nature of the intended product.</p> <p>NZFSA considers that the age of raw milk at the commencement of manufacture is appropriate.</p>
	Impact of proposed new framework	A great deal of care needs to be taken with imported raw milk products and the possible risk of animal disease.	See earlier comments on importing in response to submitter 3.
4. Industry	Support for regulatory framework	Supports the framework as they want to offer their customers both raw and pasteurised cheese. Would like the very small cheesemakers to be accommodated within the framework.	NZFSA agrees that the framework needs to accommodate companies of all sizes, but irrespective of company size the requirement to have a validated process is the same.
	Intended legal mechanisms for implementing the	A veterinary inspection twice a year for all animals seems excessive and expensive for small farms (section 7 in Notice).	See comments as for submitter 4.

	proposed framework	<p>Tuberculosis testing is not needed for goats.</p> <p>Considers section 13 in Notice requiring farm dairy assessment twice a year is excessive for small farms.</p> <p>Asks if procedures they currently have in place would be adequate.</p>	<p>NZFSA will amend the requirement to exempt non-bovine species under certain circumstances. NZFSA agrees that there is no need for TB testing of non-bovine milking animals when there are no bovine animals or deer on the property; the milking animals do not come into contact with bovine animals or deer; the milking animals never move outside a Tb vector free area; and no other factors indicate potential exposure (e.g. inspection at slaughter or status of neighbouring farms).</p> <p>NZFSA considers that the specified frequency of farm dairy assessments is appropriate given the nature of the intended product.</p> <p>Self monitoring is expected of all farm dairy operators. However, farm dairy assessment is an independent assessment and goes beyond those checks.</p>
	Proposals for labelling raw milk products	If products are made from raw milk then labelling them as such is a must.	Noted.
	Proposed technical	Testing all milk for pathogens before cheese production would be an expensive and prohibitive	Cheesemakers may need to undertake some testing of milk for a limited range of pathogens to monitor the

	requirements for raw milk products	step for small cheesemakers as they will not have laboratory facilities on-site.	effectiveness of the on-farm practices. Testing of the milk for a batch of product may also be required if this is identified as an 'operator defined process measure'. Testing would need to be carried out in an appropriate laboratory which may not be at the factory.
5. Industry	Support for regulatory framework	Supports the availability of unpasteurised milk products as they produce cheese with a complex range of flavours. Raw milk cheeses are made by artisans, and having healthy animals, pristine milk and controlled cheesemaking can produce safe and delicious raw milk cheese. Raw milk cheeses produced under European Union (EU) and other international regulations should be freely available within New Zealand.	Noted. EU cheeses will be permitted to be imported if the production processes have been validated as capable of meeting the criteria.
	Proposed process for determining regulatory options	Considers the process in the discussion document is confusing, as at no point does it clearly state what cheeses will be allowed to be made or imported. Queries if soft cheeses are to be excluded altogether, or if they can be produced if the production process has been validated as capable of meeting microbiological food safety criteria.	Soft cheeses would be permitted if the production process has been validated as capable of meeting the microbiological food safety criteria.

		<p>Considers the development of a predictive mathematical model sounds like ‘science gone mad’. It seems a time-consuming and distracting element of research which may hinder the development of RMPs. Asks why it is necessary for NZFSA to impose its own, more stringent criteria on imported cheeses when there is no scientific evidence that these raw milk cheeses pose a danger to health.</p> <p>Testing of raw milk undertaken by Fonterra for the discussion paper has shown that only a tiny fraction of its milk contained pathogens. Small scale milk harvesting for raw milk cheesemaking with an appropriate testing regime should be adequate to ensure a clean milk supply.</p> <p>Disagrees with the implication in the discussion document that soft cheeses become a medium for pathogenic growth at the ripening phase. Assuming that cheesemakers start with ‘clean’ raw milk, harvested under an risk management programme (RMP), then post contamination and growth of pathogens is no different than with</p>	<p>See comments on predictive modelling as for submitter 2.</p> <p>While good hygienic practices on the farm should minimise the potential for pathogens to be present, they cannot ensure that pathogens will never be present as animals may shed pathogens into the milk. ‘Clean’ milk may not be pathogen-free.</p> <p>As ‘clean’ milk may contain low levels of pathogens it will be important that conditions during processing of raw milk products do not allow any pathogens present to grow in number and reach unsafe levels.</p>
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		<p>pasteurised milk.</p> <p>Levels of risk should not be considered when deciding what cheeses should be made or imported, especially as it is noted in the discussion document that illness has rarely been associated with unpasteurised milk cheeses. Instead the focus should be placed on ensuring healthy animals and clean milk supply and storage.</p>	<p>NZFSA disagrees with this statement. Cheesemakers need to be, and are usually aware of, the levels of risk associated with their processes and ensure that they apply the appropriate controls. This awareness will have contributed to the low levels of illness currently associated with raw milk cheeses manufactured legally in countries with robust regulatory systems for raw milk cheese production.</p>
	<p>Intended legal mechanism for implementing the proposed framework</p>	<p>The requirement for importing cheeses (that it needs to be recognised and comply with the New Zealand standard) would then be excluding soft cheeses (i.e. French camembert), from import into New Zealand when they are currently accepted as meeting EU criteria.</p> <p>The UK Specialist Cheesemakers Association already has a functioning Code of Best Practice for cheesemakers using raw milk, and the EU has legislation that supervises the safe production of all types of raw milk cheese.</p>	<p>NZFSA disagrees as this is not necessarily the case. Soft cheeses will be permitted to be imported if the production process has been validated as capable of meeting the criteria.</p> <p>NZFSA has purchased a copy of this publication and will consider the contents in developing the supporting guidance material that will include a Code of Practice for processing in New Zealand.</p>

	<p>Proposals for labelling raw milk products</p>	<p>All blue and soft cheeses (whether pasteurised or unpasteurised) have potential for contamination once for sale. For 'at-risk' groups appropriate labelling would provide advice that cheeses have acidity and moisture levels where pathogens can grow.</p>	<p>There will be a requirement for the ingredient declaration for unpasteurised products to include the statement that the milk is raw or unpasteurised. Advice to 'at risk' groups is provided by NZFSA via consumer communication and education strategies.</p>
	<p>Impact that the proposed new framework would have on business</p>	<p>Impact on business will be significant, as currently feel are unable to reach full potential. Customers are constantly asking for unpasteurised cheese, so there is demand. However have concerns that compliance costs will not make importing and production of unpasteurised products viable.</p>	<p>Consultation on the framework has indicated widespread support for the proposal from both consumers and industry.</p> <p>Producers and importers of unpasteurised milk products may incur one-off costs as they work through the steps required to determine whether their products can be made and sold according to existing dairy regulations, or under the proposed new specifications. Where validation is required, such studies would be conducted at the cost of the producer or importer. Such costs would vary depending upon the pathogens and parameters requiring validation. NZFSA has progressed criteria to avoid the need for validation where feasible, and is working on developing additional tools which could in future further reduce the work that would need to be done when categorising</p>

			<p>unpasteurised milk products.</p> <p>Producers of unpasteurised milk products would also be subject to the usual ongoing costs associated with making products under an RMP under the APA, or a food safety programme (FSP) under the Food Act. Such costs include those incurred when RMPs or FSPs are evaluated and verified/audited.</p>
6. Industry	Support for regulatory framework	<p>Supports the principle that alternative technologies to pasteurisation in dairy production be provided for, as long as an appropriate level of risk management is achieved.</p> <p>Makes it clear that their submission on the first discussion document did not express a view as to whether or not they favoured raw milk products becoming more available, although the second discussion document states that all submissions from the dairy industry for the first discussion paper were in favour. Their submission stated they were in favour of the use of alternatives to pasteurisation provided it achieved an appropriate level of food safety.</p>	<p>Noted.</p> <p>Comments are noted, and NZFSA apologises for any confusion. It was not the intention to misrepresent comments from submitters.</p>

	<p>Impact that the proposed new framework would have on business</p>	<p>The reputation of the New Zealand dairy industry for producing safe and nutritious products is of paramount importance and this must not be put at risk by any outcome of the proposed considerations for raw milk products.</p>	<p>NZFSA acknowledges that the reputation of the New Zealand dairy industry, both nationally and internationally, for producing safe and nutritious products is important. NZFSA is aware that any future production of unpasteurised products must be balanced against the need to ensure that the current significant New Zealand trade in pasteurised dairy products is safeguarded.</p> <p>While the regulatory framework has the aim of allowing for greater choice for consumers, as well as facilitating business diversification and new export opportunities, it is intended to also maintain an acceptable level of protection for consumers, using the best available risk assessment information and risk management methods. The combination of hygiene measures and control methods is intended to ensure only a low risk to the general population but allows a higher risk to vulnerable subgroups of the population. In New Zealand, risk communication strategies will be used to target vulnerable consumers of the potential hazards in unpasteurised products, and the products will be labelled as made from raw or unpasteurised milk.</p> <p>We do not expect that the nutritional reputation of dairy</p>
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			products will be affected by the proposals.
	Proposed process for determining regulatory options	<p>Considers the proposed terminology is confusing: notes that the term ‘raw milk product’ to refer to a specific defined sub-group of products made from unpasteurised milk does not align with the FSANZ P1007 terminology. The term ‘unpasteurised milk products’ is used in a generic sense in several parts of the discussion document, when it includes both ‘unpasteurised milk products’ and ‘raw milk products’ as defined in the proposed regulatory framework part of the document. Suggest reverting to the terminology used in the first discussion document.</p> <p>Pathogen elimination should be referred to as pathogen reduction, and the third category in table 1 (unpasteurised milk products not able to be produced in New Zealand) should be referred to as ‘raw milk products’.</p> <p>Notes that there are incidences of poisoning linked to the consumption of raw milk with <i>staphylococci</i> and <i>E.coli</i> O157:H7 present.</p>	<p>NZFSA commissioned a market research survey to gain information about public understanding of unpasteurised milk products. Findings of the survey indicated that the term ‘unpasteurised’ was a more meaningful and useful term than ‘raw milk’; nearly one third of the general public thought that ‘raw milk’ meant simply fresh milk or milk in general.</p> <p>The terminology used in the discussion paper was for the ease of the reader, as the document was aimed at both a general and technical audience.</p> <p>Eliminate means the use of a process or processes that will achieve an overall reduction of the specific pathogens of at least 5 log.</p> <p>Noted.</p>

		<p>Strongly disagree with the statement ‘milk that is raw may contain pathogenic bacteria’, as it gives the impression to farmers that it may be possible to produce pathogen-free unpasteurised milk, when this is not the case. Recommend that the scientific position is made abundantly clear, and provides a quote from the <i>Bulletin of the International Dairy Federation 372/2002</i>: “while modern hygiene can reduce bacterial contamination of the milk, it cannot eliminate it. Farm milk is always susceptible to contamination, and it is inevitable that bacterial pathogens, albeit even at a low level, will always be present’.</p> <p>Notes that there are major limitations in the use of mathematical models for cheeses, especially for small-scale cheesemaking where there are many variables. Modelling small-scale pathogen challenge trials in at least three dimensions is a huge task just for one cheese type.</p> <p>Agrees with the need for extensive robust data.</p>	<p>While good hygienic practices on the farm should minimise the potential for pathogens to be present, they cannot ensure that pathogens will never be present as animals may shed pathogens into the milk.</p> <p>See comments on predictive modelling as for submitter 2.</p>
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	<p>Intended legal mechanisms</p>	<p>Have concerns about the required control measures and the measurement of the effectiveness of the draft Notice, and in particular the lack of detail on how to monitor the key manufacturing parameters that affect product safety (i.e. the rate of acid development, pH, moisture, and salt in moisture).</p> <p>The regulatory regime depends on the draft Notice providing a basis for producing lower pathogen level milk than existing regulatory requirements. However New Zealand milk currently has very low levels of pathogens, and it is debatable whether following the specifications in the Notice will have a marked effect on microbial levels, as the majority of the actions are already part of good practice, or not measurable. However it would result in an increase in labour costs.</p>	<p>The Animal Products Act 1999 is non-prescriptive legislation which stipulates specific outcomes, without stipulating exactly how those outcomes are to be achieved. This gives businesses the flexibility to develop their own ways of complying and allows for innovative approaches to compliance. Key manufacturing parameters will depend on the nature of the process and the product. However guidance will be provided with respect to identifying and monitoring operator defined process measures.</p> <p>Noted. The purpose of the draft Notice is to ensure that low pathogen levels in milk are achieved consistently.</p>
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		Consider a performance based verification approach is necessary, given the risk being managed. The issues in the specification notice should be addressed in Regulations or a Standard, or as part of the RMP approval process or code of practice. Preference is for a code of practice.	Noted.
	Proposed technical requirements for raw milk products	<p>It needs to be highlighted to the cheesemakers and general public that as there are several thousand types of cheeses, each with has its own unique processing parameters. Therefore it is not possible to complete a general risk assessment that includes all unpasteurised milk cheeses.</p> <p>Notes that a second definition of thermisation has been introduced in the discussion document (62 C for 15 seconds), which differs from the definition of thermisation in the glossary, as defined in the Food (Milk and Milk Products Processing) Standard 2007.</p>	<p>Noted.</p> <p>NZFSA acknowledges that the requirement for heating to 62 C for 15 seconds is a mistake. The correct parameters are in the glossary: heating the milk or milk product to at least 64.5 C for 16 seconds; with cheese storage at 7 C or above for at least 90 days.</p>
	Proposals for labelling raw milk products	Clear labelling of unpasteurised milk products is essential. The consistent use of both labelling and education as risk mitigation strategies should	Noted. There will be a requirement for the ingredient declaration for unpasteurised products to include the statement that the milk is raw or unpasteurised. NZFSA

		be an important part of the proposed regulatory framework.	is reviewing its risk communication strategy for raw milk products with a view to strengthening communication with affected groups.
7. Industry	Support for regulatory framework	NZFSA has adopted a conservative well considered draft regulatory framework that aligns with international provisions in Codex and takes into account other legislation.	Noted.
	Intended legal mechanism for implementing the proposed framework	<p>Considers that the definition of 'raw milk product' in the draft Notice precludes the dairy industry the opportunity of considering alternative processes to a pathogen elimination step for colostrum products.</p> <p>Considers that the APC limit in table 1 (section 22(2)) of the draft Notice can be lower for cow's milk.</p> <p>Considers it essential from an industry perspective that FSANZ and NZFSA collaborate and introduce legislation that is comparable in both countries.</p>	<p>The exclusion for colostrum products is intentional. However the Notice only deals with raw milk products, i.e. products with no pathogen elimination step.</p> <p>This limit applies immediately prior to manufacture as opposed to the more usual limit applied at collection from the farm bulk milk tank.</p> <p>NZFSA has worked together with FSANZ in respect of the technical requirements and anticipates that the outcomes will be similar. However, FSANZ is required to follow its own process and procedures.</p>

	<p>Proposals for labelling raw milk products and risk communications</p>	<p>Labelling should be addressed in Part 1.2 of the Australia New Zealand Food Standards Code. Should it be deemed necessary to include an advisory or mandatory statement, this should be incorporated into Standard 1.2.3 of the Code.</p> <p>Considers that NZFSA has recognised the need for risk communication for unpasteurised milk products, and notes that multiple communication channels and strategies will reach the majority of the population.</p>	<p>NZFSA notes that this statement is correct. See comments on labelling as for submitter 3.</p> <p>Noted.</p>
	<p>Plans for implementing the framework</p>	<p>In order to enable producers to assess the costs and benefits of validating unpasteurised milk, a guidance paper is needed. Validation will also need to take into account statistically significant variations in process conditions. The cost of validation will be significant and time consuming.</p> <p>Further guidance in the form of a Code of Practice is also recommended, as this would have benefits for manufacturers and assist with validation and verification of processes.</p>	<p>Guidance for validation will be developed to assist industry and evaluators, and this may be issued as part of the proposed Code of Practice or separately.</p> <p>A Code of Practice is being developed.</p>

		<p>Noted that at the workshops advice was given that NZFSA would require unpasteurised milk products to be produced under the guidance and/or control of person(s) with experience in manufacturing the relevant unpasteurised milk products.</p> <p>There was also mention of a training module for New Zealand manufacturers. Further consideration needs to be given to recognition of qualifications and what constitutes experience in unpasteurised milk products.</p>	<p>The requirement for competent staff in a manufacturing process is a requirement for all animal products businesses.</p> <p>NZFSA has indicated that they are prepared to work with the Specialist Cheesemakers Association if the Association wishes to develop a unit standard or similar tool.</p>
8. Interest group		No comment to make.	
9. Interest Group	Support for regulatory framework	Support the proposed regulatory framework to allow New Zealand farmers to use or sell their milk for the production of unpasteurised milk products, as currently they are legislated against in favour of imported products.	Noted.

		<p>Disappointed that the proposed framework does not allow for the sale of unpasteurised milk for drinking. It makes no sense that a farmer will be able to sell unpasteurised milk for making into cheese, but not for drinking, especially as farm gate sales of raw milk are currently allowed.</p>	<p>New Zealand law has allowed limited sales of raw milk at the farm gate for several decades. Currently, section 11A of the Food Act 1981 allows for producers to sell up to five litres of raw milk at any one time from their farm gates to people who intend to consume it themselves, or to provide it to their families. This is a traditional, long-standing right for farmers, and allows those consumers who buy this milk to trace it back to its source.</p> <p>There is no intention to change requirements so that raw drinking milk can be sold more broadly, as it poses an unacceptable level of risk to the general population. Products made from unpasteurised milk allowed under the framework will have to demonstrate that they do not support the growth of pathogens to levels in excess of food safety criteria. Raw milk does not have inherent characteristics or undergo processing techniques to demonstrate this.</p>
10. Interest Group	Support for regulatory framework	Supports the removal of restrictions on the manufacture, sale and export of unpasteurised milk products.	Noted.
	Proposed	Welcomes the development of appropriate	Noted.

	technical requirements	technical criteria and guidance to ensure food safety standards are managed.	
	Intended legal mechanism for implementing the proposed framework	Supports the maintenance of specific controls imposed by the country of origin for unpasteurised cheeses, and that these controls extend to other unpasteurised milk products. Wants importation of unpasteurised milk products from countries where food safety standards are less stringent than New Zealand to be restricted unless production meets controls acceptable to New Zealand.	See earlier comments on importing in response to submitter 3.
	Impact that the proposed new framework would have on business	Will allow more variety and diversity in food processing businesses, especially in many rural boutique businesses, and for New Zealand to remain a leader in diverse high quality food production.	Noted.

<p>11. Interest Group</p>	<p>Support for regulatory framework</p>	<p>Supports expanding the variety of production methods available to New Zealand's dairy farmers to include supplying milk for unpasteurised dairy products. The proposed framework would also level the playing field between New Zealand and imported dairy products.</p> <p>However have concerns about the precedent that the new framework may set. Would not want to see moves towards applying the proposed requirements to all milk produced in New Zealand, as the current requirements for pasteurised products are adequate. Asks NZFSA to ensure that the on-farm requirements for unpasteurised milk products, do not, in the future, encroach on the requirements for the production of milk for pasteurised products.</p>	<p>Noted.</p> <p>This regulatory framework only covers unpasteurised milk products, and to allow these to be produced to an acceptable level of food safety. It is not the intention for them to apply to pasteurised products at this time.</p>
	<p>Proposed process for determining regulatory options</p>	<p>Notes that the review of the human disease evidence associated with the consumption of raw milk and raw milk cheese omits consideration of <i>mycobacterium avium paratuberculosis</i> and <i>Group B streptococci</i>.</p>	<p><i>Mycobacterium avium paratuberculosis</i> and <i>Group B streptococci</i> were addressed in the review when <i>Streptococcus spp.</i> and Crohn's Disease were evaluated.</p>

		<p>It provides little guidance on the safety of products manufactured from a herd with TB reactor animals.</p>	<p>NZFSA disagrees, but acknowledges that criteria for non-conforming milk already exists elsewhere and NZFSA is not proposing a change to the handling of non-conforming products.</p>
	<p>Intended legal mechanism for implementing the proposed framework</p>	<p>Regulations should not preclude the adoption of new technologies which are coming into more widespread use, such as robotic and automated milking operations.</p> <p>Section 7 of the draft Notice (animal health) is specific for TB, but it should include mention of Johne's disease and <i>Group B streptococcal infection</i>.</p> <p>Section 8 of the draft Notice (water and feed for animals in the milking herd) should include guidance (either by reference to a quality test or guidance to control) of the required hygienic standard for water.</p>	<p>New technologies may be adopted provided they meet the requirements.</p> <p>NZFSA disagrees in respect of Johne's disease as it is not recognised as a human pathogen. The review of human disease evidence concluded that due to the lack of research, there is not sufficient evidence to support the hypothesis that consumption of raw milk/unpasteurised cheese was the causal factor of <i>Streptococcus</i> infection in humans.</p> <p>NZFSA agrees that guidance is required for a number of the measures included and these are intended to be included in a code of practice.</p>

		<p>Section 9 of the draft Notice (milk cooling and storage) specifies a cooling to 6C within two hours. All milk vats in New Zealand meet the current specification for pasteurised products for cooling to 7C within three hours. A holding temperature of 6C may be too high, and therefore query whether a lower temperature can be specified.</p> <p>Section 10 of the draft Notice (milk harvesting) is poorly specified and ambiguous. It should provide further guidance, including hygiene standards. Query whether requirements for operator hygiene (e.g. use of disposable gloves) have been considered for inclusion in the draft Notice and deemed unnecessary.</p> <p>Section 13 (farm dairy assessment) does not define who can be 'a suitably qualified person'.</p>	<p>This requirement is based on Codex. There are many ways in which a farmer may choose to achieve the outcome (with or without additional refrigeration equipment). These might include improved primary cooling, daily processing or processing within 2 hours.</p> <p>This draft section will be amended and guidance will also be provided on this matter. It should be noted that the requirement for clean teats and udders currently applies to all farms.</p> <p>Noted. The words 'suitably qualified person' will be substituted with 'farm dairy assessor'. Farm dairy assessor is defined in the draft Notice. However the definition will be amended to include competencies for a farm dairy assessor.</p>
12. Other	Support for regulatory	Supports the development of the risk management framework for unpasteurised	NZFSA agrees that a food safety incident related to unpasteurised dairy products could potentially be

	<p>framework and impact that the proposed new framework would have on business</p>	<p>products in such a way as to minimise the risk of damaging the reputation of the wider New Zealand dairy industry due to food safety incidents related to unpasteurised products. If there is a food safety incident related to unpasteurised products, there is a need to ensure that the current significant export of pasteurised milk products as well as future unpasteurised products is protected.</p>	<p>damaging to the New Zealand dairy industry with potential consequences for exports. While the regulatory framework has the aim of allowing for greater choice for consumers, as well as facilitating business diversification and new export opportunities, it is intended to also maintain an acceptable level of food safety, using the best available risk assessment information and risk management methods. All unpasteurised products manufactured in New Zealand will need to be produced in accordance with the existing dairy regulatory requirements and any additional requirements in the draft Raw Milk Specifications Notice. These requirements are intended to ensure there is only a low risk to the general population but a higher risk to vulnerable populations. The labelling and risk communication proposals for product sold in New Zealand are intended to ensure that vulnerable consumers avoid the potential hazards in unpasteurised products.</p> <p>In addition, unpasteurised products exported from New Zealand will need to be produced in accordance with the requirements of the country to which they are being exported. NZFSA will continue its rigorous standard of enforcement of the requirements applying to both</p>
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			pasteurised and unpasteurised products, including management of food safety incidents.
13. Other	Intended legal mechanisms for implementing the proposed framework	<p>Concerned that when non-conforming raw milk is redirected to be supplied for processing into a heat treated product, it is not required to meet the criteria for raw milk outlined Animal Products (Dairy Processing Specification) Notice 2006 and DPC2. This is of particular concern when the raw milk has been withheld due to Tb or abnormal milk.</p> <p>Recommend that section 25 of the Notice be expanded to state that the procedure must also include an assessment for the eligibility of this milk for further processing to heat treated products.</p> <p>Recommend that corrective actions include additional product testing requirements where high APC results are identified in the raw milk supply.</p>	<p>NZFSA will clarify clause 12(1)(b) by adding words to the effect of 'if it is suitable for such processing' at the end of the clause.</p> <p>Noted. NZFSA will consider expanding clause 25(2).</p> <p>Noted. NZFSA will include further detail either within the draft Notice or in the code of practice.</p>

		Recommend that section 23 of the Notice directly references the base criteria contained in DPC1 and the Australia New Zealand Food Standards Code.	Clause 3(2) provides that the requirements in the notice are in addition to any other applicable requirements set out in the Animal Products Act, the Food Act, or any other regulations, notices, or standards made pursuant to those Acts.
	Ideas on guidance material	<p>Water and feed for animals (Section 8 of the Notice) would be difficult to determine at the farm level, therefore the Code of Practice will be imperative in assisting operators and verifiers as to what constitutes compliance for this requirement.</p> <p>Recommend that the guidance material includes minimum sampling and testing plans, as this would be of benefit to operators, evaluators and verifiers. Considers that this is one of the most difficult areas to establish in the RMP and likely to be one of the most debated aspects for raw milk products.</p>	<p>Noted.</p> <p>Noted.</p>
14. Other	Support for regulatory framework	Supports the proposed framework, especially for the importation of raw milk products.	Noted.

	Impact that the proposed new framework will have on business	The framework recognises that increased New Zealand demand exists for cheeses freely available in Europe, as evidenced by the public acceptance of Roquefort and other similar cheeses. The regulatory framework will facilitate increased trade in European raw milk products to New Zealand.	Noted.
	Intended legal mechanisms for implementing the proposed framework	Raised concerns about the limit of the criteria for 'coagulase positive staphylococci' on Section 22 (Table 1) of the draft Notice.	The Process Hygiene Criteria in the draft Notice will be modified to remove coagulase positive staphylococci and to insert <i>Staphylococcal enterotoxins</i> in to the Food Safety Criteria. Expectations for monitoring coagulase positive staphylococci and the trigger for S. enterotoxins testing will be set out more fully in the code of practice. This amendment reflects that it is the toxin that is the pathogen food safety concern.
15. Individual	Support for regulatory framework	Would like to see greater choice of cheeses in New Zealand and strongly supports any process that will allow production and importation of unpasteurised cheese. Supports the preferred option of a regulatory framework that covers all unpasteurised milk products and would allow those that can be produced to an acceptable level of safety to be produced, sold, exported and	Noted.

		imported.	
	Proposed process for determining regulatory options	<p>Considers that development of a mathematical model sounds like 'science gone mad'.</p> <p>Considers that NZFSA should be managing risks rather than managing hazards, whilst accepting that good process is a necessity.</p> <p>Considers that Table 1 in the document is oversimplified. It relates a level of risk to a hazard, without indicating how the hazard turns into a risk. The discussion document uses the words 'risk' and 'hazard' indiscriminately and makes it hard to understand.</p> <p>Supports the three general levels of risk identified, which is a pragmatic approach to scoping possible levels of risk, and provides a baseline for further identification and assessment of risks.</p>	<p>See comments on predictive modelling as for submitter 2.</p> <p>NZFSA acknowledges that the submitter is correct with regards to the terminology for 'hazard' and 'risk'. However, the document was written for both industry and a general audience, and some may not be aware of the differentiation.</p> <p>Noted.</p>

		<p>There is no indication of why raw drinking milk and colostrums produced under proper hygienic conditions are deemed to pose an unacceptable risk.</p> <p>Supports the importation of unpasteurised and raw milk products under pre-clearance arrangements, as long as the criterion is 'producing an equivalent food safety outcome'; rather than necessarily complying exactly with specific New Zealand criteria, i.e. supports a performance based rather than prescriptive</p>	<p>Good hygiene will minimise the potential for raw milk to become contaminated with pathogens during harvesting. However pathogens such as <i>Listeria</i> and <i>Campylobacter</i> may be shed into the milk from the mammary glands of animals with sub-clinical infections or in the early stages of an illness before the animal is observed to be clinically unwell and can be removed from the herd. As long as the pathogen numbers are low, healthy adults may be able to consume this milk or colostrum without becoming ill, but infants and adults with compromised immune systems may not be able to deal with even low numbers of pathogens and could become ill. These infections may have serious consequences and can lead to death of the individual. If pathogen numbers are high in the raw milk, even healthy adults will become ill.</p> <p>NZFSA will operate a pre-clearance regime for imported pasteurised products.</p>
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		<p>approach.</p> <p>There are many codes of practice and standards already in existence that have developed to protect consumers, and these should be utilised as much as possible.</p>	<p>Noted.</p>
	<p>Intended legal mechanism for implementing the proposed framework</p>	<p>Queries why specific cheeses are listed in section 10 of the Food (Imported Milk and Milk Products) Standard, as this is contrary to a performance based approach.</p>	<p>Clause 10 of the draft Food (Imported Milk and Milk Products) Standard 2009 recognises equivalent overseas sanitary standards. Those cheeses listed are currently able to be imported into New Zealand. NZFSA is unable to monitor the performance of producers in other countries. However, it can recognise the sanitary measures applied by certain countries in respect of certain products. Clause 11 provides for alternative overseas sanitary standards to be approved.</p>
	<p>Consultation process</p>	<p>Concerned that the general public is not aware of the consultation process, as indicated by the small number of submissions on the first discussion paper. Considers that the documents can be quite daunting, and a series of questions in the document would have been preferable.</p>	<p>43 submissions were received on the first discussion paper, which is a much larger than usual number than would normally be received on a technical food safety issue. NZFSA acknowledges that the document is lengthy, but there was a need to strike a balance for industry and for consumers, and to ensure all processes followed by NZFSA in developing the framework are transparent and explained fully. The</p>

			workshops held in Auckland, Hamilton and Christchurch provided another avenue for giving feedback.
	Proposals for labelling and risk communications	Considers labelling is generally adequate, but that some additional publicity might be required to alert vulnerable groups.	NZFSA is reviewing its risk communication strategy for raw milk products with a view to strengthening communication with affected groups.

Workshops

Hamilton, Tuesday 9 June 2009

Questions asked	Response given
<i>Processing specifications</i>	
What are typical values for process hygiene criteria?	APC: 50,000 graded at farm level. Most premises won't exceed 300,000.
Would every batch of raw milk be tested?	A monitoring programme would be established.
What needs to take place in a veterinary inspection?	This will be determined by vets.
Will there be testing of water quality standards?	Water is to be potable, like a factory. This will be in the proposed code of practice.
What is the logic behind cooling milk to 6C within two hours?	It is taken from Codex.
Can the same line be used for raw and pasteurised product?	If cleaning is sufficient.
<i>Supporting criteria and guidance</i>	
Will this mean a separate RMP for raw milk products?	No - raw milk production can be included in an existing RMP (as a significant amendment), including the additional requirements needed.
Individual validation will be very expensive for small	Currently trying to establish costs with laboratory work.

cheesemakers.	
Who is responsible if a raw cheese product causes illness but it was produced within specifications?	Ultimately the cheesemaker as the onus is on them to provide safe product.
What is the timeframe for implementation of the specification?	At this stage expected to be October 2009.
Would the same (milk harvesting and manufacture) requirements be expected from imported products?	Not necessarily, but sanitary arrangements will achieve the same outcome as New Zealand expectations.
The discussion document and specifications are directed at larger companies, and artisan cheesemakers will struggle.	Smaller companies have an advantage as they have direct control over milk and surety of meeting those requirements.

Auckland, Wednesday 10 June 2009

Questions asked	Response given
<i>Processing specifications</i>	
What is the timeline for implementation?	October, although will need to factor in number of submissions received and other policy processes.
Will I need a stronger risk management for raw milk?	Yes.
Will animals be unable to drink from certain wells?	Will either supplement the NZCP1 document with additional requirements or

	provide a stand-alone document.
Will 'wash' be specified?	This will be in the proposed code of practice.
Will raw milk products be allowed to be produced in the same plant?	While NZFSA is not advocating this, an RMP could specify how this was done: e.g. raw milk products may be manufactured at discrete times of the year. The separation of activities would have to be validated.
<i>Supporting criteria and guidance</i>	
What is regarded as low moisture?	The discussion document defines this in point 6.2.1.
Would validation prove a challenging scheme?	Possibly – NZFSA is looking to model this at a suitable facility.
Will there be labelling implications?	Yes.
Will there be templates for raw milk manufacturing?	Potentially, although could be problems with product classification.
What is segregation?	Non-mixing of milk intended for raw milk products with either milk not intended for raw milk products or pasteurised milk, e.g. not in the same tanker unless full clean in place.
Will it still be legal to sell 5L of raw milk?	Yes, but only at the farm gate.

Christchurch, Thursday 11 June 2009

Questions asked	Response given
<i>Processing specifications</i>	
Would high pressure (HPP) be considered a treatment step?	Yes but it would have to be proven as valid.
If there is a maturation that lasts months, will there be a requirement to log a temperature for the whole process?	There will be an expectation to log temperature, but possibly only once a day. COP will give practical advice of how the monitoring can be achieved, without 'over-monitoring'
Will small scale operators have a 25g sample taken out of each cheese?	An appropriate monitoring system will be put in place.
Will there be a code of practice for on-farm practice and manufacturing?	Yes, although for farms there may be an appendix to NZCP1 or a stand-alone document.
How will water standards be achieved?	Will not be asking for regular monitoring, but this will be addressed in the RMP.
What is the definition of commencement of the manufacturing process?	This will be defined in RMPs.
<i>Supporting criteria and guidance</i>	
What is Australia's position in regard to exports?	If a product is on the market in New Zealand it can be in Australia as well.
What does NZFSA want achieved by October?	October is the target for introduction of raw milk specification. However those who are most likely to want to make raw milk products will need tools (i.e.

	validation guide).
Will there be a three month window before going 'live'?	No. However the process for an individual producer/product to be up and running may take up to a year.
Why are the current sanitary arrangements between countries not enough to satisfy importing requirements?	Equivalence of sanitary standards need to be assessed and approved on a country-by-country basis, based on import standards. Imports will also have to meet Biosecurity NZ standards.
It seems there are no clear guidelines for importers of unpasteurised products.	New cheeses will have to be on a case-by-case basis which may be lengthy. However the mechanisms are already in place for importation of cheeses.