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FSANZ: Applications and Submissions - Submission
Wednesday, 24 September, 2008

1. Assessment Report Number: P1007

2. Assessment Report Title: P1007 – PRIMARY PRODUCTION & PROCESSING REQUIREMENTS FOR RAW MILK PRODUCTS (Australia only)

3. Organisation Name: Department of Human Services

4. Organisation Type: Government Agency

5. Representing: Victorian Government

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12. Submission Text: Discussion Paper P1007 – PRIMARY PRODUCTION & PROCESSING REQUIREMENTS FOR RAW MILK PRODUCTS (Australia only) The Victorian Government provides the following comments in response to the Discussion Paper for Primary Production and Processing Requirements for Raw Milk Products. It includes the views of the Department of Primary Industries (DPI), Dairy Food Safety Victoria (DFSV) and Department of Human Services. 1. General Comments The Victorian dairy industry is a major contributor to Victoria's economy producing 64% of Australia's milk, the majority of which is processed into a range of products for export. Protecting public health and maintaining consumer and customer confidence in our food safety management systems is essential for the industry to prosper and for continued access to domestic and export markets. Victoria understands that a section of the community wishes to have access to raw milk products. However, Victoria emphasizes the Government's responsibility to protect public health and safety of the whole community. This leaves the challenge of how food safety hazards associated with raw milk products can be effectively and consistently managed. Victoria welcomes the discussion paper as a way to engage the community, industry and government in what has been seen to have become a debate

between “pro” and “anti” raw milk product advocates. As with all standards development processes, it is critical that decisions are made based on peer-reviewed scientific data and that management regimes are validated to ensure that they deliver a product that does not expose consumers to unnecessary food safety risks. 2. Objectives of FSANZ Proposal Victoria agrees that the current situation where the Food Standards Code (FSC) allows for State-based food safety systems for raw milk should be removed to enable a consistent and national approach as for other standards. Victoria notes that the existing State permissions are limited to goat’s milk, with very few producers licensed for this purpose. Victoria supports the need to remove current references to the legislation of other countries with specific control measures. Victoria acknowledges that the current situation is inequitable for local manufacturers. However, it is noted that the control measures currently in the FSC, by referencing the legislation of other countries, provide a very prescriptive approach that includes the regulatory oversight. This is significantly different from the control measures in current Australian standards (see Section 5 for further discussion). The third objective stated, which is to address current and future applications for extended permissions for raw milk products, may be more difficult to achieve. The success of this will be dependent on how well the categories listed in the paper can be defined, so that it will be clear where a specific raw milk dairy product will fit. It will also be dependent on whether associated control measures will be generic to the category or whether they will need to be specific to the product. If the standard relies on achieving specified outcomes, including the existing microbiological limits in the FSC (Standard 1.6.1), then state regulators will be required to assess whether or not a particular process and management controls could be validated to meet Standard 1.6.1. It is acknowledged that this will be increasingly challenging as industry innovation accelerates and consumer and market expectations for food safety become more demanding. This is discussed further in the submission. Victoria believes that in considering permission for raw milk products, the overriding objective should be about protection of public health and safety and not provision of information to enable consumers to make informed choice. The latter objective infers that a higher level of risk (or lower protection of public health and safety) would be acceptable providing consumers were made aware of it (as indicated in Section 8 of the Discussion Paper). Victoria would be concerned if, indeed, this was the direction intended. It is acknowledged that the Government permits the community to make informed choices over products or activities that are inherently risky. However, Government generally protects those sectors of the community who need special care, including children. Dairy products are seen to be an important part of children’s nutrition and Victoria believes that managing increased risk by provision of additional information to consumers is not appropriate in this case. 3. Microbiological limits Victoria has made the assumption that Standard 1.6.1 Microbiological Limits will remain and that any additional permission for raw milk products will be required to meet the current limits set. It may be necessary to review the adequacy of the current microbiological limits to consider other pathogens, specifically STECs as we are aware that they are present in the cattle population and the current standard for E. coli does not take account of the very low infectious dose for pathogens such as E coli O111 and O157. There is the potential for raw milk products to be vectors of human diseases that have not been associated with dairy products in the past. For example, norovirus has been isolated from cattle faeces and may contribute to the increasing prevalence of this in the human population. It is an example of a pathogen of recent significance, and of the potential for the emergence, or re-emergence, of pathogens with raw milk and raw milk products, which must be considered. 4. Categories according to risk Victoria supports taking an approach which categorizes products according to risk. This would appear to be the only workable solution to considering the large number of individual dairy products that are possible. However there is likely to be a wide range in the level of risk or impact on public health within the categories as defined, particularly within categories 2 and 3, depending on the pathogen that is present. The survival and growth of pathogens are also specific to the conditions

both within the product and environment and time in which it is stored. This will clearly affect the control measures. Whilst the category concept has merit, it remains to be seen whether it will work within the Australian dairy industry. The proposed category classification for raw milk products is based on the survival and/or growth of pathogens within that product. With a range of pathogens, variable processes including elevated temperatures, variable product environments, and poorly understood science behind the impact of one against the other, it will likely be difficult for FSANZ or the regulator to be able to assess the validity of the claims made by manufacturers of raw milk products as to which category their product belongs to. In addition, the categories do not include definitions of the moisture content or the pH of the cheeses. Both of these factors can influence the survival of bacterial pathogens in cheese. The focus of the assessment appears to be responding only to requests for the use of “traditional” methodologies for producing raw milk products. Victoria suggests that the assessment should be more forward looking to consider the use of a range of technologies to produce dairy products without a pasteurization step. These technologies may also provide greater health protection while still retaining the qualities some consumers are seeking from raw milk products. For example, alternative processing methodologies such as ultrafiltration or centrifugal separation may be capable of improving the safety of raw milk products through the reduction or removal of microorganisms. Such techniques could theoretically be used to manufacture other specialized products (e.g., raw lactoferrin powder) that will either be in category 1 or 2 by the end of processing and storage (at the point of consumption). The use of categories, as described in the Discussion Paper, infers that control measures will be made according to the three categories. This may be problematic because of the differences in risk, unless the control measures are targeted at managing the highest risk (or managing the most persistent hazard of public health importance). Listeriosis is of particular concern because of the wide range of environments within which Listeria monocytogenes survives and grows. (Note recent cases in Canada related to a number of raw milk cheese products.) In making these comments, Victoria acknowledges that any introduced contamination post production e.g., grating cheese, handling and packaging, is equivalent to pasteurised product and should be managed through normal hygiene requirements. In the US, raw milk cheeses represent a low proportion of total cheese production but appear to be disproportionately represented in food-borne outbreaks. A proportion of the community will be more susceptible to the pathogens that may be present in these products, including pregnant women and immunocompromised individuals, particularly people over 60 years of age. Victoria is concerned about how this potential risk will be communicated to these groups. 5. Control measures and their validation Unlike many other standards, specific management requirements and additional regulatory measures may be necessary within the standard should further permissions for raw milk products be approved. Without “control” measures such as pasteurisation, anything other than a Category 1 product, will rely on management systems to minimize the risk of pathogens within the system. This will present a significant challenge in regulatory management and the validation of control measures. Victoria suggests that measures will necessarily be prescriptive to provide assurance that a safe product will be consistently provided to consumers. Validation relies on a certain level of predictability that under a given set of circumstances, specific actions will reduce the risks of pathogens (or chemical residues) present to acceptable levels. In the case of raw milk and some raw milk products (Categories 2 and 3) validation is challenging because of the difficulty of predicting critical factors affecting pathogens in raw milk such as the health of individual animals (which can change almost on a daily basis) and the milk harvesting environment. This will need to be taken into account and may require a greater emphasis on end product assessment as part of the regulatory system. The likely producers of raw milk products will be small dairy businesses. While some small businesses will have sufficient knowledge of suitable management systems, experience shows that this size of business in general requires specific guidance. Victoria agrees with the FSANZ assessment that greater guidance will

need to be provided to industry. 6. Impact analysis Victoria supports the points in the discussion paper that will need to be considered under the impact analysis. Experience from overseas and the initial risk assessment suggest that rigorous and prescriptive regulatory management will be required to assure a safe product for consumers. The quantity of product likely to be produced and the size of the businesses will mean that there will be a disproportionate level of regulatory resources required to assure that a relatively small section of the community has a product of their choice. This will need to be taken into account when studying the impact analysis. In Victoria, where the regulatory management of dairy (and other foods) is funded by industry, DFSV would need to consider a mechanism by which businesses that wish to produce raw milk products, would pay the additional costs for regulating these (as opposed to pasteurized product). DFSV envisages a separate certification scheme to ensure that integrity of the supply chain is guaranteed to ensure only milk from accredited farms would go into raw milk products. The costs associated with all regulatory controls would need to be borne by these producers and would then be reflected in the price to consumers. Victoria is aware that some companies will want to manufacture products from both raw milk and pasteurized milk. This will create challenges for regulators in managing compliance because of the necessity to segregate milk, the risks of cross contamination and the difficulty in assessing whether this has occurred. At this stage, it is not possible to estimate these costs until further work is done on which categories are likely to receive permission and what control measures will be necessary. This may also affect the number of businesses that will want to move away from pasteurized product to any new arrangements for raw milk products. Therefore, the responses received by FSANZ to the discussion paper on numbers of businesses interested in producing raw milk products may be an overestimate. 7. Consumer issues 7.1 Views on benefits of raw milk A fundamental question to consider is whether in this assessment it is appropriate (or necessary) for FSANZ to investigate the validity of additional benefits from raw milk (compared with pasteurized milk) products. If FSANZ were to assess raw milk as a novel food, the fundamental hurdle that would need to be overcome is whether adequate protection of public health could be assured. Similarly in this case, can adequate protection of public health be assured? Whether pasteurisation reduces the health benefits of milk or not, or to what extent this is the case, is a major study and given the contrasting views, either pro or anti raw milk product advocates will disagree with the conclusion reached. The focus should remain on whether adequate and effective controls of the public health risks associated with consumption of raw milk products are possible and economically viable. The discussion paper notes anecdotal evidence of consumption of raw milk and raw milk products in the Australian community. Care must be taken in extrapolating this to a commercial context where the supply chain is changed and consumer understanding of the nature of these products can be completely different. For example, farmers who may consume raw milk from their farm have daily access to the milk and have no need to store the product for any length of time. Furthermore, any contamination and illness in the past has likely resulted in the development of some degree of resistance to subsequent infection. 7.2 Understanding risks of raw milk products Australian consumers only have experience in handling and storage of pasteurized milk products and in general, products are considered to be suitable for all sectors of the population. Consumers are also used to a relatively long shelf-life for these products. Handling, storage conditions, shelf-life and suitability for the immunocompromised will be different, yet from a consumer's perspective, the product will appear the same. Victoria suggests that consideration of these issues needs to be built in to the assessment and standards development process. Reliance on labelling will not be adequate given the way cheese products in particular, are sold and presented to consumers (i.e., portions cut at point of retail sale). 8. Production processes and overseas experiences While it can be argued that some raw milk cheeses made from milk of good microbiological quality can be safe for consumers, the variation in the production systems makes the verification of each batch problematic. In Victoria's view, approving raw milk

cheese production would require FSANZ to seek expert advice and research best practices in a range of cheese products and production systems to ensure product safety. The experience from the UK demonstrates that critical factors in managing risks is the short supply chain and direct relationship between the farmer and the manufacturer supported by intensive end product testing. A significant parallel in processes can be drawn between the manufacture of raw milk cheeses and yoghurts and the manufacture of uncooked fermented meats where a process analogous to “backslopping” may be used to introduce starter culture to new cheese batches. Lessons learned from this, and the problems that occurred in the smallgoods industry should be considered in assessing the risks of manufacture and the standards required for inputs. 9. Imports There appears to be as greater level of interest in importing raw milk products as there is for local manufacture. For these reasons, it is essential that there is confidence that any standard in the Food Standards Code can be adequately enforced for imported raw milk products. Current approved imported raw milk products are specifically regulated by the Government of the country of origin and have been separately assessed by FSANZ as to their adequacy. Given that there is now some history of imported raw milk products, it may be useful for FSANZ to discuss with AQIS Imported Foods the compliance levels and effectiveness of the current arrangements. There has been a question over how AQIS can apply requirements for on farm and production activities prescribed in Primary Production and Processing Standards (PPPS) to imported foods and indeed, whether standards identified as “Australia only” apply to production methods in other countries. AQIS legislation may therefore not allow for prevention of entry of food not produced in accordance with the PPPS and AQIS will have to continue to depend on assessment of compliance with the FSC at the border (i.e. microbiological limits). This will become a more significant issue for raw milk products because of the unreliability of sampling and testing as a means to assess compliance due to the inherent variability of the products. Victoria understands the limitations placed on AQIS in relation to assessment of compliance of imported foods. However, these issues will need to be considered during standards development to ensure that adequate protection will be afforded Australian consumers and if necessary, engagement with DAFF and AQIS where the solution is beyond the standard itself. A greater use of certification arrangements may need to be considered as part of ensuring compliance for imported foods. The health status of animals will be an important consideration in assessing the suitability of milk for raw milk products. A country’s status for presence of diseases, such as brucellosis and bovine tuberculosis, will need to be considered and which may preclude imported product from certain countries. FSANZ may need to investigate whether AQIS quarantine restrictions for dairy products adequately address zoonoses of concern.

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