

**FULL ASSESSMENT REPORT**  
**AND REGULATORY IMPACT ASSESSMENT**

**SUBJECT: A357 - SWISS RAW MILK CHEESES**

**EXECUTIVE SUMMARY**

- The Australia New Zealand Food Authority received an application (A357) from the Swiss Federal Veterinary Office on 24 March 1998, requesting a variation to Standard H9 - Cheese and Cheese Products, in the Australian *Food Standards Code* (AFSC). The variation would permit the use of fresh milk that has not been pasteurised or thermised in the making of both hard and semi-hard specialty cheeses namely, Swiss Emmental, Swiss Gruyère, Swiss Sbrinz, Swiss Appenzeller, Swiss Tilsiter, Vacherin Fribourgeois and Tete de Moine.
- In 1994 the then National Food Authority (NFA) advised the Australian Quarantine and Inspection Service (AQIS) that the product made by the Swiss cheesemaking method constituted a level of public health and safety equivalent to that afforded by pasteurisation. However, a formal application process to reflect this in the Code was not undertaken.
- The applicant claims that:
  - free trade of these products has occurred for approximately thirty years with no adverse health or safety incidents;
  - in 1994 the then NFA had already approved the importation of certain Swiss cheeses.
- The import of these products ceased in 1997 following a review by AQIS of their quarantine requirements, at which time the products were found not to comply with the technical requirements of the Code (Standard H9).
- Australian and New Zealand regulations require that milk and milk products used for cheese production are either pasteurised or subjected to a minimum heat treatment at a temperature of 62°C for a period of not less than 15 seconds (thermised) prior to cheesemaking,
- There is ongoing international debate on the use of unpasteurised milk in cheesemaking. The Codex Committee on Food Hygiene had agreed to develop a Draft Code of Practice for Milk and Milk Products which will encompass products including cheese made from raw milk. Legislation already exists within European Union (EU) provisions for raw milk and products derived therefrom.

- Thirteen submissions were received in response to the request for public comments published at Preliminary Assessment by the Authority. Four of these respondents did not support the use of unpasteurised milk in cheesemaking for public health and safety reasons, and concerns that acceptance of the Swiss application may negatively influence consumer confidence in domestic dairy products. Other submitters were generally supportive provided adequate safety measures were incorporated into accepting 'equivalent' processes.
- The microbiological safety assessment of hard raw milk cheeses concluded that the risk of foodborne illness associated with the consumption of hard cheeses (less than 39% moisture content) made from raw milk was comparable to that of pasteurised milk products.
- The microbiological safety assessment regarding semi-hard cheese noted that the risks of foodborne illness associated with their consumption when made from raw milk was not insignificant. The applicant has indicated that three of these cheeses are always able to be sourced from thermised milk and hence would comply with the current provisions of Australian and New Zealand regulations.
- The preferred option is to accept the application and allow those hard Swiss cheeses manufactured with the use of fresh milk which has not been pasteurised or thermised, and whose manufacturing protocol ensures an equivalent level of public health and safety to that of cheeses currently permitted.
- The full assessment recommends that the Code be amended in accordance with the preferred option, pursuant to section 12 of the *Australia New Zealand Food Authority Act 1991*. This should be done as a matter of urgency due to trade considerations, as a decision to accept the application is equivalent to admitting that a trade barrier is being maintained.
- The applicant should be advised that, provided they are sourced from thermised milk products, the semi-hard cheeses Appenzeller, Tilsiter and Vacherin Fribourgeois will be acceptable for import in that they already comply with current requirements.
- One semi-hard cheese Tete de Moine, is made exclusively from raw milk. This cheese shall not be permitted for import at this time on the basis that the process of manufacture does not provide an equivalent level of safety to cheeses made in accordance with H9. The matter of the manufacture of semi-hard cheeses may be reconsidered following the review of H9 and the establishment of the Food Safety Standards (Part 3 of the Code).
- It is proposed that due to the urgency of this application, and in order to expedite resumption of trade, a limited consultation period of three weeks is undertaken for the second period of public comment.

## BACKGROUND

For the purpose of this report, raw milk and unpasteurised milk are used interchangeably and are defined as milk that has not been subjected to a heat treatment designed to control pathogenic microorganisms.

An application was received by the Authority on 24 March 1998 from the Swiss Federal Veterinary Office to amend the AFSC to restore market access for Swiss hard and semi-hard cheeses made from unpasteurised milk. The application is made on behalf of the manufacturers and exporters of Swiss Emmentaler, Swiss Gruyere, Swiss Sbrinz, Swiss Tilsiter, Swiss Appenzeller, Swiss Vacherin Fribourgeois, and Tete de Moine.

There is a well established history, in excess of 30 years, of the importation into Australia of Swiss hard and semi-hard cheeses made from raw milk with no evidence of adverse public health and safety incidents. In 1994, the then National Food Authority (NFA) advised the Australian Quarantine and Inspection Service (AQIS) that a range of Swiss hard and semi-hard cheeses manufactured from raw milk did not represent a risk to public health and safety by virtue of the heat treatment given to the milk and the long maturation period for the cheeses. In October 1997, imports of Swiss cheeses were suspended by AQIS following a review of quarantine requirements. This drew attention to the fact that these cheeses were made from raw milk and did not comply with the technical requirements of the Code. Subsequently, this application was submitted to the Authority requesting recognition of the equivalence of Swiss hard and semi-hard cheese making practices to those currently permitted in Australia in terms of public health and safety, and to allow trade to be resumed.

The applicant claims that the process of manufacturing Swiss hard and semi-hard cheeses is, in effect, equivalent to pasteurisation or thermisation of the raw milk and holding period for cheese. The submission states that "there is scientific evidence that the combination of heating temperatures of milk, continual heating of the curd and the rapid acidification by the added starter cultures as well as the intense brining and the long ripening period (90 - 360 days) inactivates microorganisms potentially pathogenic to man and animal".

A consequence of approval of this application would be that trade may be resumed in Swiss cheeses that are made from unpasteurised milk, based on the demonstration that the manufacturing processes provide equivalent protection of public safety, as that afforded by pasteurisation or thermisation currently permitted in Standard H9.

## **OBJECTIVE**

The objective, in addressing the issue of permitting raw milk cheeses, would be to determine whether the manufacturing protocols and controls implemented by the Swiss authorities afford an equivalent level of protection of public health and safety to current Australian Standards in order that trade in these products may be resumed.

## **RELEVANT PROVISIONS**

Standard H9 - Cheese and Cheese Products states that milk and milk products used for cheese production shall be either pasteurised or undergo equivalent treatment which results in a phosphatase activity of 10 mg/kg or less, or be subjected to a minimum heat treatment at a temperature of 62°C for a period of not less than 15 seconds and a holding period of 90 days for cheese. An excerpt of these provisions is at Attachment 4.

New Zealand has similar requirements to current Australian regulations for the heat treatment of milk used in the manufacture of cheese. An excerpt of these provisions is at Attachment 5.

## **OVERSEAS REGULATIONS**

There are no Codex requirements for the heat treatment of milk for cheesemaking. However, a "Proposed Draft Code of Hygienic Practice for Milk and Milk Products" is in the process of being developed. It is foreseen that this Code will apply to all products derived from milk including raw milk cheeses. This Code of practice has been controversial since the Delegates of some countries (USA, Australia and Canada) claim that the safety of raw milk, no matter how carefully produced and the safety of soft ripened cheeses subsequently made from that raw milk, cannot be sufficiently assured on a consistent basis without pasteurisation or some equivalent safeguard. Representatives from other countries, including France and the Netherlands, support the inclusion of an annex which deals with the production of raw milk cheeses.

The proposed "Code of Hygienic Practice" will be based on stipulating that the products should be subject to a combination of control measures, from raw material production to the point of consumption, which are shown to achieve the appropriate level of public health protection (Decisions of the Codex Committee on Food Hygiene, Washington D.C. 24 October 1997).

The European Union law on milk and milk products, adopted by EU ministers in June 1992, contains provisions for cheese made from unpasteurised milk, concurrently with specific health and hygiene regulations. EU regulations specify limits for pathogenic and indicator micro-organisms in cheese and other raw milk products.

In October 1995, the United States Food and Drug Administration issued a statement on its position on the trade of raw milk products. It stated "it is our position that unpasteurised milk and products manufactured from unpasteurised milk (with few exceptions) present an unacceptable risk to the public health, therefore the interstate trade of these products within the United States is prohibited". This prohibition does not apply to imported products.

Health Canada has recently withdrawn its proposed amendment that would have required that all cheese be made from pasteurised milk or be processed so as to have assurance of safety equivalent to pasteurisation. Canada permits the use of raw milk in cheesemaking.

## **REGULATORY OPTIONS including alternatives to regulation**

### **Option 1**

Maintain the *status quo* and do not permit the sale of cheese manufactured from raw milk.

### **Option 2**

Allow the sale of those cheeses that have been manufactured from raw milk where the manufacturing practices are found upon a case-by-case scrutiny by ANZFA to provide a fully equivalent protection of public health and safety to current food standards and have been entered into a schedule in Standard H9 specifying those products and processes where full equivalence has been established.

### **Option 3**

Non-regulatory provisions such as self-regulation and co-regulation through codes of practice are not considered feasible or adequate as they are not enforceable and a failure to comply could have fatal consequences.

## **PUBLIC CONSULTATION**

This application has undergone a period of Public Consultation pursuant to s14 of the Australia New Zealand Food Authority Act 1991. Public comment was for a period of six weeks from 13 May 1998 until 24 June 1998 following Preliminary Assessment of the application. Thirteen written submissions were received and a full summary these comments is at Attachment 3.

### **Assessment of Issues Raised in Public Submissions**

- There would be an inconsistency in accepting A357 after the ANZFA decision made on A270;

*Application A270 - Cheeses Made From Fresh Milk That Has Not Been Pasteurised Or Subjected To Another Heat Treatment.*

The Authority previously rejected an application (A270) from the Australian Specialist Cheesemaker's Association, requesting a variation to the Food Standards Code to permit the use of fresh milk that has not been pasteurised or subjected to another heat treatment prior to cheesemaking, in the making of both hard dry, and soft moist specialty cheeses. The applicant also requested that the Authority develop a Code of Practice, incorporating the principles of a Hazard Analysis Critical Control Point (HACCP) based system for cheeses made from raw milk as the risk to public health by consumption of raw milk cheeses could be significantly reduced through the implementation this type of system. The application was rejected on the grounds that the applicant did not demonstrate adequate process controls to ensure that public health would be effectively protected.

Further, neither the Australian Specialist Cheesemakers Association nor any other body that the Authority was aware of, was in a position to develop and implement such a Code. The Swiss are able to demonstrate hazard identification and process control sufficient to address the concern regarding public health and safety and are able to provide a level of protection equivalent to that afforded by a process which includes pasteurisation. Only those cheeses determined to be safe by the risk assessment and certified in accordance with Swiss manufacturing protocol would be accepted. Therefore, an approval for the sale of raw milk cheese will only apply for other manufacturers where a similar level of public health and safety protection can be demonstrated.

- There is no alternative to pasteurisation as a Critical Control Point (CCP);

While pasteurisation is well regarded as a highly effective means of ensuring the microbiological safety of milk and products derived therefrom, it is by no means a guarantee of product safety in itself. It must be combined with other points of hazard identification and suitable manufacturing processes. It is correct to state that raw milk cheese has been implicated in foodborne illness outbreaks, however, it is relevant to point out that cheeses made from pasteurised milk subject to further processing, such as Cheddar, have also been implicated in foodborne illness. This has occurred due to pasteurisation failures and post-production contamination and indicates the importance of a HACCP based production plan taking into account all critical control points in order to ensure adequate protection, than in reliance on one point only. The Swiss manufacturers have demonstrated the efficacy of their protocol in ensuring a product of equivalent safety as those products which are already permitted in Australia. Indeed, the Code already accepts this principle by allowing milk to be thermised.

- The decision to allow cheese to be sold which has been made from raw milk will not only compromise public health and safety, but will also affect the good name of Australia and New Zealand in international and domestic market places;

ANZFA's primary objective in the setting of food standards is the protection of public health and safety. No food product would be allowed for sale on the market if found to be unsafe in terms of human health. If manufacturers in Australia and New Zealand are able to demonstrate equivalent safety measures in production systems then this will only serve to enhance international status.

- Concern that allowing this process allows other manufacturers to follow suit when they may not have equivalent safe processes.

It is illegal to sell food which is not safe or fit for consumption. The products which are the subject of this application have been assessed as being safe and the provisions for this will be reflected in the draft amendment. Standards are developed to ensure that unsafe practices or products do not appear in the market. All manufacturers will have to comply with the requirements of the Code. Any manufacturer wishing to sell

raw milk cheese products may do so provided that they are able to demonstrate that their manufacturing process(es) ensures an equivalent level of protection to public health and safety, as currently provided for in the Code.

## MICROBIOLOGICAL RISK ASSESSMENT

The application is made on behalf of the manufacturers and exporters of Swiss Emmentaler, Swiss Gruyère, Swiss Sbrinz, Swiss Tilsiter (green and red label), Swiss Appenzeller, Swiss Vacherin Fribourgeois, and Tete de Moine. Protocols were also provided for the manufacture of another hard cheese, Raclette.

A microbiological risk assessment of the manufacturing protocol provided by the Swiss Federal Veterinary Office (the applicant) has been undertaken. The risk of human foodborne disease associated with the consumption of Swiss cheeses made from raw milk was assessed. In particular the potential for disease caused by exposure to pathogenic micro-organisms *Escherichia coli*, *Salmonella* species, *Staphylococcus aureus*, *Listeria monocytogenes* and *Campylobacter jejuni/coli* was considered.

Swiss Tilsiter (green label) is manufactured using pasteurised milk, as is Raclette and as these cheeses already comply with the requirements of Standard H9 and NZFR they are not required to be further assessed.

The hard and very-hard cheeses Swiss Emmentaler, Swiss Sbrinz and Swiss Gruyère made from raw milk (in accordance with manufacturing protocol set out in Swiss Federal Government Ordinances) have been evaluated as posing no greater threat to public health and safety than that posed by cheeses made from pasteurised or thermised milk, based on microbiological parameters. These cheeses are stored for very long periods (for at least 90 and up to 360 days) and hence the environment in the product is not conducive to the survival or proliferation of pathogenic micro-organisms.

The semi-hard cheeses Swiss Tilsiter (red label), Swiss Appenzeller, and Swiss Vacherin Fribourgeois are manufactured alternatively from raw or thermised milk. Concerns were raised with about the risk of foodborne infection from *E.coli* particularly in view of increasing incidence of the emerging pathogenic strains, such as enterohaemorrhagic *E.coli*.(EHEC).

The applicant has indicated that those semi-hard cheeses (manufactured in accordance with manufacturing protocol assessed) are able to be always sourced from thermised milk. These would meet the existing requirements of Standard H9 and the NZFR.

One semi-hard cheese (Tete de Moine) is always made from raw milk. The risk assessment raises concerns about the potential for foodborne illness arising from contamination by *E.coli* (including EHECs) and *Salmonella* spp. The Swiss regulations require all cheese products (from pasteurised milk or otherwise) to be

free of *Listeria* spp and Salmonellids in 25g of cheese products. Products found not to comply with these regulations cannot be sold or exported for human consumption. The manufacturing protocol and survey data assert that *E.coli* levels do not exceed 10 CFU/g. However, to require compliance with 10 CFU/g would be onerous and, given level of imports of this product, would not be justified. It is proposed not to allow this product to be imported at this time.

Currently, a review of the standards related to stored dairy products is underway with a view to develop joint standards for Australia and New Zealand. ANZFA will re-examine semi-hard cheeses and raw milk in the context of domestic and imported cheese once the new standard and the Food Safety Standards (Part 3 of the Code) are in place.

## **OTHER ISSUES**

### *Mycobacterium bovis*

This is the causative agent of bovine tuberculosis, and may be present in products containing or made from raw milk which is harvested from animals carrying the bacterium. In the past a significant number of human tuberculosis infections were caused by this pathogen. Some countries permitting the manufacture of cheese from raw milk require 2-3 months of storage before sale of the cheese. This practice minimises the probability of survival of the tubercle bacilli. There is no known reported cheese borne disease outbreak involving *Mycobacterium*. In the Western world, including Australia, improvements in the health of animals and on the farm sanitation together with the widespread use of pasteurisation have virtually eliminated these bacteria from milk that reaches the consumer.

All countries which are signatories to the Treaty establishing the European Economic Community (EC) are subject to the requirements for the marketing of raw milk, heat-treated milk and milk-based products. The EC stipulates that raw milk (prior to any processing) must originate from herds which are officially tuberculosis and brucellosis free, in addition to compliance with stringent ordinances pertaining to Hygienic Practices.

Switzerland is not a member of the EU, however, as a trading partner they must meet the requirements of the EU criteria. The Swiss herd management system minimises the risk of animals carrying the organism, and the long maturation period of the cheeses would not support the growth or survival of this organism. These measures ensure that no affected product would appear on the market.

### *Small niche-market product*

The export product accounts for a total annual cheese import of approximately 80 tonnes. Of this about 300 kgs consists of semi-hard cheese, with the remainder being hard or very hard cheese. Therefore the risk of consuming contaminated semi-hard cheese is low.



It could be further argued that these products are a niche-market product, sold in specialty delicatessen and cheese shops, with consumers, usually of European background with an awareness of the product, actively seeking out a raw milk cheese. Nonetheless, the risk is greater, than currently permitted, for semi-hard raw milk cheeses. It is prudent at this time to limit semi-hard cheeses to thermised milk products.

### *Fast-tracking provisions*

During Preliminary Assessment comment was sought on whether omitting a round of comment would be supported. This was proposed due to the urgency of the application and to expedite the resumption of trade in the event that the application was accepted. There are three options for expediting a recommendation:

- In matters of minor complexity, the Authority may omit a round of comment under Section 36 of the Act. However, it is considered that the matter under assessment in this application does not constitute an issue of minor importance or complexity;
- Secondly, the Authority may omit a round of comment under s37 of the Act if it considers that a recommendation should be made to the Council as a matter of urgency. This may be warranted due to the highly sensitive nature of the trade implications raised by this application. This would mean that no comment could be sought on drafting; however under s.37 where inquiry is omitted this must occur after the standard is gazetted.
- Finally, there is the option of a conducting a limited consultation period of three weeks in order to seek comment on the proposed drafting for this application. This option would meet in full the requirements of the Code without significantly delaying resolution of this matter. This would be combined with a mailout to appropriate groups and individuals to facilitate comprehensive comment.

The third option is the most appropriate as it allows comment to be made on drafting while still reducing the amount of time to complete the application process.

## **REGULATORY IMPACT ANALYSIS**

### **Option 1**

Maintain the *status quo* and do not permit sale of cheese manufactured from raw milk that have been manufactured according to strict protocols which ensure that they are safe for human consumption.

### **Advantages/benefits**

### *Industry*

- No competition in the market from cheese manufactured from raw milk

### *Consumers*

- No benefit.

### *Government*

- No benefit.

## **Disadvantages/costs**

This option maintains the regulatory status quo which prohibits the sale of cheese manufactured from raw milk. Despite this prohibition, Swiss cheeses made from raw milk have been imported over the last three decades. These were assessed as being safe for consumption, in 1994 by the then NFA. Option 1 would prevent Swiss cheese from being imported into Australia.

### *Industry*

- This option disadvantages Australian importers of Swiss cheese manufactured from raw milk;
- Accepting this option (effectively banning the product) could result in trade retaliation from Switzerland. The import market for Swiss raw milk cheese in Australia was worth approximately AUD\$1 000 000, and accounted for 70 - 80 tons of cheese, until suspension of imports in 1997. Retaliation by the Swiss could cost the Australian economy at least this much in exports to Switzerland.

### *Consumers*

- Limited consumer choice.

### *Government*

- Damage to an otherwise good bilateral relationship between Australia and Switzerland and possible WTO action by Switzerland, which might result in other WTO members joining such action, against Australia. Accepting this option is in direct contradiction of a former assessment in 1994 by the NFA, that these Swiss cheeses were manufactured according to processes which ensured that they were safe for human consumption. The findings of this application support the former findings, which leaves no defence to any accusations that ANZFA would be maintaining an unnecessary barrier to trade.

## **Option 2**

Amend the Food Standards Code to allow the sale of cheeses that have been manufactured from raw milk, where the manufacturing practices are found on a case-by-case scrutiny to provide an equivalent level of protection of public health and safety to that set in the current food standards for cheese.

## **Advantages/benefits**

### *Industry*

- Importers will retain this sector of their trade;
- Removes threat of trade retaliation by Swiss;
- Sets a benchmark for domestic specialty cheesemakers and thereby promotes innovation (providing domestic producers are able to develop suitable protocols and management systems in order to establish a comparative product);
- Sets a benchmark for other countries who wish to export similar cheeses to Australia.

### *Consumers*

- Consumers will be able to choose raw milk cheese products in the marketplace that they have been assessed as safe for human consumption;
- Some of these products may be regarded as being traditionally important.

### *Government*

- Australia and New Zealand will be able to comply with its WTO obligations under the SPS Agreement. Both countries have an obligation to accept SPS measure of other Members as equivalent where the exporting Member has objectively demonstrated that the SPS measure achieves Australia and New Zealand's appropriate level of protection;
- Implement the NFA decision passed in 1994 that these cheeses were subject to safe production methods through an appropriate regulatory response.

## **Disadvantages/costs**

### *Industry*

- No perceived costs. There has been a long history of these products in the Australian market prior to 1997; this option will restore the situation;
- Domestic speciality cheesemakers may incur costs in developing suitable protocols and management systems in order to establish a comparative product.

### *Consumers*

- No perceived costs.

### *Government*

- The cost of the amended regulation would not be expected to be greater than those incurred under the current provisions;
- Imports would be controlled by imported food inspection program and subject to certification by Swiss Authorities;
- The cost of assessing applications from other exporting countries of cheese manufactured from raw milk and domestic speciality cheesemakers that wish to sell such cheeses in Australia.

## **ANZFA Section 10 Objectives**

### ***1) Protection of public health and safety***

There are significant public health and safety issues concerning the consumption of raw milk in cheese produced without an effective HACCP based system. Consumption of raw milk cheeses, particularly, soft and semi-soft ripened cheeses, can present a significant public health risk. Many outbreaks in the literature are associated with soft or fresh type cheeses. However, the Swiss industry protocol have demonstrated, that the critical control points which are applied to their raw milk cheesemaking process, for hard cheeses (Gruyère, Emmental and Sbrinz) , are at least as effective as the currently acceptable heat treatment steps in the control of human pathogens.

The conclusions regarding semi hard cheeses will result in these only being supplied to the market when made from thermised milk. Semi-hard cheeses made from thermised milk already comply with Australian and New Zealand requirements.

One semi-hard cheese Tete de Moine will not be accepted at this stage, as it is unable to be manufactured from thermised or pasteurised milk.

### ***2) Adequate consumer information***

The cheeses that are the subject of this application pose no greater risk than any other foods when prepared and stored appropriately. Currently, the existing market for these specialty cheese varieties is a niche market with a knowledge of the product. The Swiss products are already labelled as being made from raw milk, to appeal to the consumer that is seeking these out.

### ***3) Promotion of fair trading in food***

While the existence of niche markets for specialty raw milk cheeses should not be denied, this should not be at the expense of increased risk to public health and safety risks. The preferred option is to recognise the Swiss product as equivalent in the first instance. If local or other international manufacturers can demonstrate processes which provide an equivalent level of public health and safety as those of current regulations they could be considered in the Review of Food Standards or in a future application.

### ***4) Promotion of trade and commerce in the food industry***

The permission to use unpasteurised milk in cheesemaking, through the use of a comprehensive Hazard Analysis Critical Control Point (HACCP) based management program, may positively influence the consumer perception of dairy products.

### ***5) Promotion of consistency with international standards***

The permission to manufacture a wide range of raw milk cheeses would not achieve harmonisation between Australia and New Zealand through this application, until such a time as the Review of Food Standards addresses these provisions.

While there are no consistent international standards in the use of raw milk in cheesemaking, Australia as a signatory to the SPS agreement under its WTO obligations cannot restrict international trade, if it can be demonstrated that products have an equivalent and acceptable level of safety.

## **OTHER RELEVANT MATTERS**

- Review of H9 - Cheese and Cheese Products is in progress and will re-examine the issue of raw milk cheese in terms of public health and safety.
- It is foreseen that the future Hygiene standards, and requirements for food manufacturers to have appropriate HACCP based Food Safety Plans, will eventually supersede prescriptive standards developed to address this application.
- A Review of Microbiological Standards, for inclusion in a Joint Food Standards Code is currently in progress.

## **CONCLUSIONS**

- Option 2 is the preferred option and should be accepted in order to amend the Code to allow the import of Swiss raw milk cheeses.
- Accepting this application is based on more than just assessment of the product. The manufacturers have demonstrated compliance with a system of adequate process controls providing an equivalent level of public health and safety to that of current provisions. The critical criteria are safety assessment of the manufacturing protocols combined with the knowledge that a competent authority (the Swiss Federal Veterinary Office) are overseeing the management of these protocols;
- The microbiological risk assessment has shown that the safety of the hard cheeses is equivalent to that provided under current regulations; the semi-hard cheeses present some concerns, if made from raw milk, but these are addressed by requiring these products to be sourced from thermised milk;
- One semi-hard cheese, Tete de Moine will not be permitted at this time as it is made exclusively from raw milk and the risk assessment concludes that the risk is greater than that presently accepted under the current Standard H9.
- Issues raised in public submissions do not alter the conclusions of the RIS or the microbiological risk assessment;
- The draft variation to Standard H9 should come into force at time of gazettal.

## WORLD TRADE ORGANISATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter does need to be advised to the WTO as a SPS Notification because it results in a regulatory provision less stringent than other countries currently allow.

### Attachments to the Report:

1. Draft Variation to the Australian *Food Standards Code*
2. Explanatory Notes
3. Public Comment Received
4. Relevant Provisions - Australia
5. Relevant Provisions - New Zealand

**DRAFT VARIATION TO THE AUSTRALIAN FOOD STANDARDS CODE****A357 - SWISS RAW MILK CHEESES****PROPOSED DRAFT VARIATION TO THE AUSTRALIAN FOOD STANDARDS CODE:**

To commence: On gazettal

*Standard H9 of the Food Standards Code is varied by:-*

(a) *omitting ‘;or’ from clause (1)(d)(i); and*

(b) *inserting after paragraph (1)(d)(ii): -*

*; or*

(iii) *if they are specified in Column 1 of the Table to this subclause, be produced and processed using a method that:*

*ensures that the cheese produced achieves an equivalent level of safety protection as cheese prepared from milk or milk products that have been heat treated in accordance with (1)(d)(i); and*

*is set out in legislation or documentation listed in Column 2 of the Table to this subclause.*

**TABLE TO SUBCLAUSE (1)(d)**

<b>Column 1</b> <b>Milk and milk products</b>	<b>Column 2</b> <b>Legislation or documentation</b>
Milk and milk products used to produce Gruyere, Sbrinz or Emmental cheese only	The <u>Ordinance on Quality Assurance in the Dairy Industry</u> of the Swiss Federal Council of 18 October 1995

**Editorial note:**

Legislation or documentation will only be listed in the Table to subclause (1)(d) if it incorporates or provides for methods which provide a level of safety protection equivalent to that provided by a process that includes treatment of the milk or milk product in accordance with paragraph (1)(d)(i), and has adequate hazard identification and process controls.

**EXPLANATORY NOTES**

*(document available separately upon request)*



## PUBLIC COMMENT RECEIVED

## A357 - SWISS RAW MILK CHEESES

<p><b>1. Simon Christen</b></p> <p>In favour of Option 2</p>	<ul style="list-style-type: none"> <li>• Comments on 30 years of free trade without any threat to public health;</li> <li>• States that Swiss should be exempted from the ruling passed on A270 (that is re: pasteurised milk);</li> <li>• If an alternative to pasteurisation is allowed then comminuted fermented meat products should also be exempted as they have a fairly similar argument.</li> </ul>
<p><b>2. Saunders Unsworth - Government and Public Relations Consultants</b></p> <p>In favour of Option 2</p>	<ul style="list-style-type: none"> <li>• Support Option 2; are concerned about the perpetuation of protectionist policies;</li> <li>• Support fasttracking of the application to restore market conditions to those that existed prior to Oct 97;</li> <li>• are concerned that safety is ensured and verifiable.</li> </ul>
<p><b>3. Queensland Health - Environmental Health Unit</b></p> <p>Oppose Option 2</p>	<ul style="list-style-type: none"> <li>• Do not support fasttracking of application;</li> <li>• Oppose Option 2 - permission to use unpasteurised milk in cheese-making;</li> <li>• note the conflict with A270 decision;</li> <li>• state that labelling cannot substitute for safety;</li> <li>• if safety is compromised then so will trade in Australia and New Zealand;</li> </ul>
<p><b>4. N.S.W. Milk (New South Wales Dairy Corporation)</b></p>	<ul style="list-style-type: none"> <li>• Questions efficacy of applying a heat treatment to the curd stage, in terms of pathogen elimination ability and also presence of heat stable toxins; Also concerned over the possibility that bacterial proliferation may occur during this process where pathogens have not been killed by an initial pasteurisation/thermisation step;</li> <li>• E.coli may survive harsh pH environments created by starter culture acidification (documented as surviving in pH 2). Pasteurisation can deal with this organism;</li> <li>• Refute the 30 years of safe import by giving example of Listeria outbreak - 122 cases involving a soft raw milk cheese</li> </ul>
<p><b>5. Ministry of Agriculture and Forestry, NZ</b></p>	<ul style="list-style-type: none"> <li>• Food safety objectives - suggest that a clear basis for determining equivalence is determined (in light of SPS Agreement);</li> <li>• It would not be appropriate to allow trade to resume on the basis of historical precedent, or on assertion of equivalence, when basis has not been established;</li> <li>• Do not consider labelling to be sufficient protection.</li> </ul>
<p><b>6. WA Health - Environmental Health Service</b></p>	<ul style="list-style-type: none"> <li>• Micro criteria should be sought in accordance with AS;</li> <li>• The same assessment made on fermented comminuted meat products applies to cheeses;</li> <li>• Micro criteria should demand absence of pathogens in 25g</li> </ul>

<p><b>7. Queensland Dairy Authority</b></p> <p>Support Option 1</p>	<ul style="list-style-type: none"> <li>• Asserts that there is a contradiction of the decision made on A270;</li> <li>• Some heat treatment is necessary to provide assurance of pathogen destruction;</li> <li>• No evidence is provided of 'equivalent' process;</li> <li>• Supports Option 1</li> </ul>
<p><b>8. Victorian Dairy Authority</b></p> <p>Support Option 1</p>	<ul style="list-style-type: none"> <li>• Do not support Option 2 (prefer Option 1), as pasteurisation is the major CCP in cheesemaking and the removal of this step renders the risk of foodborne illness from cheese unacceptably high. It would also adversely affect the Australian market;</li> <li>• If ANZFA goes with Option 2, this is in conflict with the decision on A270;</li> <li>• Quality of milk OS is unknown and this presents a great microbiological risk.</li> </ul>
<p><b>9. InforMed Systems Ltd</b></p> <p>Support Option 2</p>	<ul style="list-style-type: none"> <li>• Support outcome oriented standard - that is the removal of prescription of pasteurisation in order to maintain bacteriological safety of cheeses.</li> </ul>
<p><b>10. Albert Alferink, Cheese Vendor</b></p> <p>Support Option 2</p>	<ul style="list-style-type: none"> <li>• Supports the applicants objective.</li> </ul>
<p><b>11. Ministry of Health (NZ)</b></p>	<ul style="list-style-type: none"> <li>• Raw milk is not pathogen free, and it is impossible to ensure that it is, contamination can only be minimised not nil;</li> <li>• Pasteurisation affords the milk to be of known microbiological status, and as such is a major CCP. It forms part of a comprehensive food safety program;</li> <li>• There must be a replacement of critical control(s) if pasteurisation is omitted;</li> <li>• Cheese production - NZ has comprehensive FSP in place, recognising that pasteurisation is the biggest and best CCP in these plans;</li> <li>• Historic use does not guarantee micro safety. Use Garibaldi as an example of this, and emerging pathogens;</li> <li>• New standards cannot be exclusive to the Swiss, it must apply to manufacturers anywhere;</li> <li>• Buyer beware (labelling) does not assure consumer safety. Special labelling need not be required if equivalent safety is assured;</li> <li>• Pasteurisation is not the issue (!) the safety of the products is the issue, the standard should be outcome oriented (based on HACCP systems);</li> <li>• if using the terms hard or semi-hard cheese define them. if the standard addressed the control of hazards, descriptors are unnecessary;</li> <li>• ANZFA's preferred option is superficial! ANZFA needs to address the problem with HACCP model.</li> </ul>
<p><b>12. Dairy Authority of South Australia</b></p> <p>Oppose Option 2</p>	<ul style="list-style-type: none"> <li>• Do not support permission for raw milk cheese;</li> <li>• Asserts that there is need for caution not to allow the door to open for all cheeses to be made from raw milk and in particular emphasises the dangers associated with emerging pathogens.</li> </ul>

<p><b>13. New Zealand Dairy Board</b></p> <p>In favour of Option 2</p>	<ul style="list-style-type: none"> <li>• Support Option 2 as long as equivalence of safety can be assured and that appropriate consumer information can be provided. Note that this option is in keeping with approach of 3rd session of Codex Committee on Milk and Milk Products (Montevideo);</li> <li>• NZ consumers are used to pasteurised products and therefore will not expect that products will be made on raw milk. Hence adequate consumer education will need to take place;</li> <li>• Equivalence - should be recognised that no matter how good the HACCP system, pathogens will always be present in milk TB status should be provided, documentation of pH composition and ripening conditions should be provided. Raise concern that if TB is present that the cooking temps employed in cheese manufacture may not be sufficient to kill the organism;</li> <li>• HACCP - the best plan is only as good as the monitoring. NZ prescribe monitoring for Listeria in Critical Hygiene area (indicator of plant hygiene) as well as in final product. Should require results of Listeria monitoring in plant as well as absence in cheese.</li> </ul>
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**AUSTRALIAN FOOD STANDARDS CODE Standard H9 - Cheese and Cheese Products (excerpt)**

- (d) Milk and milk products used for cheese production shall -
- (i) be heat treated by being held at a temperature of not less than 72 °C for a period of not less than 15 seconds, or at a temperature and for a period equivalent thereto in phosphatase destruction; or
  - (ii) be subjected to a minimum heat treatment at a temperature of 62 °C for a period of not less than 15 seconds.
- (e) Milk and milk products used for cheese production shall be taken to have been adequately heat treated in accordance with paragraph (d)(i) of this clause if they do not exhibit a phosphatase activity in excess of that required to give a reading of 10 µg/mL of *p*-nitrophenol when tested by the current standard method in AS 2300, *Methods of Chemical and Physical Testing for the Dairying Industry*.
- (f) Cheese prepared from milk and milk products subjected to a minimum heat treatment in accordance with the provisions of paragraph (d)(ii) of this clause shall -
- (i) be labelled, in standard type of 3 mm, with the date of manufacture;
  - (ii) not be sold unless it has been stored at a temperature of not less than 2 °C for a period of 90 days from the date of manufacture of the cheese;
  - (iii) be free from *Listeria monocytogenes* in 25 g of the food when examined by the method prescribed by clause (22) of this Standard.

**NEW ZEALAND FOOD REGULATIONS for the requirements including heat treatment of milk used in cheese manufacture (excerpt).**

- (2) The milk or cream or mixture of milk and cream that is used in the manufacture of cheese -
- (a) Shall be subjected to pasteurisation or an equivalent heat treatment; or
  - (b) Shall be subjected to heat treatment at a temperature of not less than 62°C for a period of not less than 15 seconds; and
    - (i) The cheese shall be labelled with the date of commencement of manufacture; and
    - (ii) The cheese shall be stored prior to sale at a temperature of not less than 2°C for a period of not less than 90 days from the date of commencement of manufacture; and
    - (iii) The cheese shall contain not more than:
      - (aa) 100 *Escherichia coli* per gram; and
      - (bb) 100 *Staphylococcus aureus* (coagulase producing) per gram; and
    - (iv) A 50 g sample of the cheese shall be free from *Salmonella*.