Ministry for Primary Industries
Manatū Ahu Matua

Review of Risk Management Actions by Food Standards Scotland Relating to the *Escherichia coli* O157 PT 21/28 Raw Cow's Milk Cheese Recall in 2016

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Disclaimer

The Ministry for Primary Industries' conclusions presented in this report are based on a review of the documents provided by Food Standards Scotland to MPI in relation to the suspected *E. coli* 0157 outbreak in July 2016.

While every effort has been made to ensure the information in this publication is accurate, the Ministry for Primary Industries does not accept any responsibility or liability for error of fact, omission, interpretation or opinion that may be present, nor for the consequences of any decisions based on this information.

1. Executive Summary

A suspected foodborne outbreak of *E. coli* 0157 was reported to Food Standards Scotland (FSS) by Health Protection Scotland (HPS) on 21 July 2016. The outbreak was confirmed through epidemiological analysis, the comparison of phage type and MLVA profiling of the clinical *E. coli* 0157 PT21/28 isolates, and food chain investigation.

As a result, two batches of Errington Cheese Limited (ECL) unpasteurised Dunsyre Blue cow's milk cheese were implicated as the common source of the outbreak, and these were voluntarily recalled by ECL.

Concurrently, investigations undertaken by the competent authority, South Lanarkshire Council (SLC), indicated that the company's food safety management system was inadequate to control hazards associated with the production of cheese from raw milk. While the outbreak strain was not detected in a range of ECL cheeses and the raw cow's milk supply used to produce Dunsyre Blue, a number of different Shiga toxin-producing *E. coli* (STEC) and *stx*-negative *E. coli* 0157 strains were isolated from samples of raw cow's milk and unpasteurised cow's and sheep's milk cheeses produced by the company.

In light of mounting evidence that questioned the safety of ECL products, the Incident Management Team (IMT) extended the recall to all raw milk cheeses produced by ECL on 14 September 2016.

The Ministry for Primary Industries (MPI) has been asked by FSS, under the 2015 Cooperative Arrangement between MPI and the Central Food Authorities of the United Kingdom and Northern Ireland, to evaluate the risk management decisions on recall of product that were taken in relation to this food safety incident. The reviewers have been presented with extensive and systematic documentation.

The evaluation was based on international good practice, New Zealand regulatory requirements and expectations that would be applied in a similar scenario, and MPI's specialist scientific expertise.

The reviewers focused on the risk management decisions relating to the recall of cheeses, using the epidemiological and microbiological evidence associated with human cases and product testing, together with the an evaluation of the adequacy of control measures that were in place at ECL at the time of food incident.

The reviewers find the risk management decisions made and actions taken by the Competent Authority's SLC and FSS are reasonable and proportionate in regard to protecting public health.

2. Background

2.1. Events leading to the recall of product

A suspected foodborne outbreak of *E. coli* 0157 was reported to Food Standards Scotland (FSS) by Health Protection Scotland (HPS) on 21 July 2016. The outbreak was confirmed through epidemiological analysis, food chain investigation and comparison of the phage type of the *E. coli* 0157 PT21/28 isolates from human clinical cases as submitted to the national Scottish *E. coli* Reference Laboratory (SERL).

The outbreak affected 26 people (18 female, eight male) and comprised two phases. The initial phase involved 20 cases infected with the outbreak strain. The second phase involved an adult case, and a further five cases (three primary and two secondary cases) linked to a single childcare setting. Excluding the childcare setting cases, 15 of the 21 (71%) cases were known to have consumed Errington Cheese Limited (ECL) unpasteurised cow's milk cheese called Dunsyre Blue. A further two cases had eaten blue cheese purchased from a retailer that included Dunsyre Blue on a cheese platter or in a salad, and one further case had attended an event at which Dunsyre Blue was served. Seventeen of the 26 cases required hospitalisation, and a 3 year old child, who had eaten a blue cheese of unknown origin, died.

Two batches of Dunsyre Blue cheese were initially implicated. Cheese from one batch was no longer available for testing, hence the presence or absence of the outbreak strain could not be determined. The other batch was tested and returned a negative result for the outbreak strain. Nevertheless, epidemiological analysis strongly supported Dunsyre Blue as being the source of the outbreak. ECL voluntarily recalled the specific batches of Dunsyre Blue cheese that were linked to the outbreak on 8 September 2016.

Concurrently, investigations undertaken by the competent authority, the South Lanarkshire Council (SLC), identified deficiencies in the company's food safety management system (FSMS) for raw milk cheeses, and these deficiencies led to a judgement by SLC and FSS that the system was incapable of minimising, at best eliminating, hazards likely to be associated with the production of cheese from raw milk.

A number of different Shiga toxin-producing *E. coli* (STEC) and *stx*-negative *E. coli* 0157 strains were isolated from samples of raw cow's milk and a range of unpasteurised cow's and sheep's milk cheeses produced by the company. In contrast, the outbreak strain was not detected from the raw milk cheeses nor from the raw cow's milk used to produce Dunsyre Blue cheese.

The concurrent investigations also identified that the testing regime employed by ECL to verify the microbiological quality of the incoming milk (included checks for *Enterobacteriaceae*) did not provide evidence of process control and trend analysis, and there was no evidence of testing to assess the presence of STEC or generic *E. coli*.

In light of mounting evidence from 9 September 2016 that questioned the safety of ECL products as a whole, the Incident Management Team (IMT)[1] met on 14 September 2016

[1] The The IMT was chaired by Health Protection Scotland and consisted of representatives from National Services Scotland (NSS), Food Standards Scotland (FSS), South Lanarkshire Council (SLC), Scottish Enteric Reference Laboratory (SERL), Edinburgh Scientific Services, Glasgow Scientific Services, Public Health England (PHE), Food Standards Agency (FSA), NHS Dumfries & Galloway, NHS Fife, NHS Grampian, NHS Greater Glasgow & Clyde, NHS Lanarkshire, NHS Lothian, NHS Tayside, Aberdeen City Council, Aberdeenshire Council,

and requested ECL to voluntarily recall all cheeses produced by the company. ECL failed to respond in the requested time frame, and the IMT immediately issued a Food Alert for Action (FAFA) on the evening of 14 September 2016 requiring an immediate recall of raw milk cheeses manufactured by ECL. The FAFA was updated on 15 September 2016 and 9 November 2016 as additional human cases were notified and market place information came to light.

2.2. Competent Authority

SLC is the competent authority for ECL and was ultimately responsible for compliance and enforcement actions taken against the business. FSS has a statutory responsibility to ensure official controls are undertaken in accordance with EU law and its role in the incident was to support SLC through the provision of risk assessment and advice on risk management actions taken to ensure unsafe product was not placed on the market. FSS was also responsible for co-ordinating traceability investigations, ensuring consistent action was taken by enforcement authorities Scotland wide, and informing the public of product recalls and alerts.

2.3. Risk management decisions by FSS

FSS based its risk management decisions on three sources of scientific evidence:

i) epidemiological and food chain links between Dunsyre Blue cheese and the outbreak of *E. coli* 0157 PT21/28;
ii) deficiencies in ECL's food safety management system, and;
iii) detection of *E. coli* 0157 or STEC strains in a range of cheeses produced by ECL during the period before the recall.

ECL and its technical advisors have challenged these decisions because the outbreak strain was not identified in any cheeses produced by the company, and they further contended that certain *E. coli* 0157 and STEC strains identified in products were not pathogenic as they either lacked *stx* and/or *eae* genes or were not commonly associated with human illness.

3. MPI Review

The Ministry for Primary Industries (MPI) has been asked by FSS, under the 2015 Cooperative Arrangement between MPI and the Central Food Authorities of the United Kingdom and Northern Ireland, to evaluate the risk management decisions on recall of product that were taken in relation to this food safety incident. In responding to this request, MPI's evaluation is based on a review of documents provided by FSS.

3.1. Terms of Reference provided by FSS

1. Review the evidence and information that was available to FSS [and provided to MPI] and provide comment on the strength of the key strands of evidence used to support risk management decisions, giving particular regard to the following:
    i) Epidemiological associations between cases and the implicated product;

Angus Council, Dumfries & Galloway Council, Dundee City Council, East Ayrshire Council, Edinburgh City Council, Fife Council, Glasgow City Council, North Ayrshire Council, Perth & Kinross Council, and the Scottish Government (Observer).

ii) Evidence for the deficiencies in the company's HACCP [risk management plan];
iii) Microbiological testing results:
- *E. coli* 0157 culture positive results in the absence of stx gene confirmation;
- the identification of presumptive positive results by PCR (detection of stx genes in samples);
- evidence relating to the pathogenicity of strains from whole genome sequencing data.

2. Does MPI support the way that the evidence was used to underpin the risk management decisions taken? Consideration should be given to the following:
   - Did the risk assessment identify the relevant evidence or were there any gaps in the evidence used to inform the risk assessment?
   - Did the risk assessment use appropriate methodologies?
   - Did the risk assessment weigh up/analyse the evidence appropriately to determine the risk and also the uncertainty?
   - Were the conclusions from the risk assessment set out in an appropriate way for the use of risk managers?
   - Did the evidence support the risk management action taken?

3. In light of all of the evidence that was available, and the relevant regulations and policy that FSS is required to follow in such circumstances, does MPI consider it to have been appropriate for FSS to take action on 14 September 2016 to instigate a recall of all cheeses produced by ECL which were on the market at that time? In particular, MPI opinion is sought on the following:
   - Did the risk management decision identify all the appropriate sources of information upon which to inform the decision?
   - Did the risk management decision take account of all of this information?
   - Did the risk management decision correctly interpret the information on which it was based?
   - Was the risk management decision in line with the relevant regulations and policy?

4. Based on all of the information provided, how would MPI have approached risk management in relation to this incident? Would MPI have reached the same decisions if it had the same information available to it, and was applying the same policies and regulation? If not, please highlight where different decisions would have been made and the reasons for this.

4. MPI Review

1. Review the evidence and information that was available to FSS and provide comment on the strength of the key strands of evidence used to support risk management decisions, giving particular regard to the following:

i) Epidemiological associations between cases and the implicated product;

The molecular epidemiological evidence of a common source outbreak of an unusual strain of *E. coli* O157:H7 PT21/28 is strong with all human isolates having the same MLVA pattern and differing by less than five SNPs.

The initial epidemiological evidence that the outbreak source was Dunsyre Blue cheese strengthened as the investigation progressed. Initially, 70% of cases recalled consuming Dunsyre Blue cheese, and 85% recalled eating blue cheese.

Further investigation of sales records and menus at food outlets indicated that the majority of the 23 cases not associated with the childcare facility had either eaten Dunsyre Blue cheese, eaten blue cheese from a platter on which Dunsyre Blue cheese was provided (no other common cheese) or eaten other foods (salads) in which Dunsyre Blue cheese was an ingredient. Onset of illness was in most cases within the 2-8 day incubation period for STEC illness.

Odds-ratio analysis and Baysian modelling against normal population statistics and other outbreaks were appropriate, and strongly indicated that Dunsyre Blue cheese was the source of the outbreak.

The reviewers consider the epidemiological association between the non-childcare facility cases and Dunsyre Blue cheese is very strong.

MPI and Massey University has recently published a report that addresses the issues of using epidemiological evidence when definitive microbiological test result evidence is not available during investigations of foodborne illness outbreaks and sporadic cases.

http://www.foodsafety.govt.nz/elibrary/industry/405017-Epi-Evidence-Report-and-SIS-Final.htm

ii) Evidence for the deficiencies in the company's HACCP [risk management plan]*;*

The ECL documented HACCP-based Food Safety Management System (FSMS) provided to the reviewers, was judged as inadequate to minimise the risk of food-borne STEC illness through a raw milk cheese pathway.

Cattle and sheep are recognized primary reservoirs of STECs, and illness/outbreaks of STEC illness attributed to the consumption of raw drinking milk and soft raw milk cheese are well documented in the literature, both for the United Kingdom and internationally.

According to the documents provided by FSS, the UK Specialist Cheesemakers Association (SCA) Assured Code of Practice (ACOP), [not provided by FSS nor available to the reviewers] specifically recommends testing of raw milk for *E. coli* (as an indicator) and STECs, and raw milk cheeses for *E. coli* O157 and other STEC strains. There is no evidence that ECL were aware of these guidelines, although Annex 10 of FSS raw milk risk assessment v3.0 includes a table from ECL referring to the SCA-ACOP with respect to farm grazing risk analysis and prerequisite controls.

Regulation (EC) No. 2073/2005 also states "In (The Scientific Committee on Veterinary Measures relating to Public Health [SCVPH]) opinion it concluded that applying an end-product microbiological standard for VTEC O157 is unlikely to deliver meaningful reductions in the associated risk for the consumers. … The SCVPH identified the following food categories where VTEC represents a hazard to public health: … raw milk and raw milk products…"

While ECL had identified a number of pathogens, including *E. coli* O157:H7, as potential hazards, it is surprising that with such readily available guidance ECL considered the risk of *E. coli* O157 to be low throughout the primary production phase and processing phase of the operation.

The reviewers have not seen any documented hazard analysis that outlines the evidence leading to this conclusion, and FSS states that "ECL had not undertaken any technical assessment or sampling to enable them to demonstrate the extent to which STEC or *E. coli* O157 that may have been introduced via the raw milk supply, would have been capable of surviving and growing throughout the production and maturation process for their cheese." There is also no explanation as to why a knowledgeable reviewer had not identified or questioned this conclusion during the FSMS approval process.

The documentation provided by ECL suggests that the remainder of the HACCP [risk management] plan was based on a conclusion of low risk, and therefore, devoid of any specific mention of controls and monitoring programmes for STECs. This meant that STECs were able to enter the cheese, potentially grow, but then not be subjected to an intervention step(s) that had been validated as minimising the risk of food-borne transmission. As a ready-to-eat product not usually subjected to an additional antimicrobial treatment, e.g. cooking, the risk to human health was not negligible.

The SAC-ACOP also specifies a limit for the aerobic plate count (APC) of <10,000cfu/ml in milk. The ECL microbiological monitoring programme specifies that the milk for its raw milk cheeses should not exceed the EU criterion of <100,000cfu/ml. Milk tested by ECL prior to the outbreak complied with the EU requirement on all occasions but exceeded the SAC-ACOP guidelines 33% of the time. The SCA-ACOP recommends remedial action in such situations, e.g. supplier checks/dairy hygiene checks/repeat testing. Again, there is no indication that ECL were aware of the SCA guideline, or if they were, reacted to the non-compliances.

The reviewers are not aware of practices in the Scottish artisan cheese-making industry at that time, and consequently cannot determine if the ECL FSMS is representative of common practice.

The reviewers note that under New Zealand law, a business manufacturing similar foods as ECL is required to have a documented risk-based programme (Risk Management Programme under the Animal Products Act 1999, or a custom Food Control Programme under the Food Act 2014). These require comprehensive descriptions of the hazard analysis; the process and identified critical control points; published validation studies or in-house validation studies that show that STECs are controlled/eliminated in their process through application of CCPs; CCP parameters and microbiological monitoring programmes and critical limits; non-compliance corrective actions and follow up activities; and verification and internal audit activities.

Comprehensive guidance for validation of risk management programmes is available to manufacturers (Appendix 1).

In the New Zealand context, it is highly unlikely that a programme similar to the ECL FSMS would be approved by MPI. Production and sale of soft raw milk cheese would be not be possible until the programme was revised to cover the requirements outlined in the previous paragraph, evaluated by a competent expert, and approved by MPI.

iii) Microbiological testing results:

The following section describes the epidemiological analysis of the microbiological test results. *E. coli* O157:H7 PT21/28 was not detected in any foods investigated during the outbreak investigation. However, cheese from all suspected batches was not available for testing, doubts were later raised as to the batches associated with the outbreak, and the strain has not been detected from any other human cases or food around the time of, or subsequent to, the outbreak.

In the New Zealand context, it is not necessary to have microbiological analysis confirmation to confirm a source of an outbreak. Epidemiological analysis and food investigation findings can provide an acceptable level of evidence to make a robust risk management decision about the source.

Despite not detecting *E. coli* O157:H7 PT21/28 in any foods, the molecular epidemiological evidence i.e. isolates having the same MLVA pattern and differing by less than five SNPs, of a common source outbreak from Dunsyre Blue cheese due to this organism is strong.

The documents provided accurately represent international understanding on characterisation of STECs in terms of their diversity, pathogenicity and molecular determinants. In doing so, however, the documents also highlight that STEC characterisation is in a transitional phase from traditional culture/serotype based methodologies to molecular systems. Thus, some uncertainty exists, and there is the potential for confusion in manufacturers developing food safety management systems and laboratories testing for STECs in support of assurances from such systems.

Adding to the potential for confusion were the now discontinued proposed EU guidelines for when STEC are detected in foods, and the development of UK guidelines which were in the consultation phase immediately before the outbreak. FSS acknowledges that individual manufacturers may not have been aware of the draft guidelines, or, if so, not understood the science and implications.

Nevertheless, Scottish manufacturers and food safety management system developers should have been aware of the potential risk of STECs, even if just *E. coli* O157:H7, in soft raw milk cheeses, even if addressed as simply identifying the inability of such processes to prevent the growth of, or inactivate, *E. coli* as a genus.

- *E. coli 0157 culture positive results in the absence of stx gene confirmation;*

There is much debate as to whether *stx*-negative *E. coli* O157:H7 can induce cellular damage and cause disease in humans. In support of the potential, *stx*-negative strains have been isolated from the stools of human cases, albeit usually with uncomplicated diarrhoea. Core genome phylogenetic analysis has shown that *stx*-negative isolates cluster together with *stx*-positive STEC isolates suggesting that *stx*-negative isolates have either lost the *stx* phage or

are a progenitor of STEC O157:H7/NM. It is not known if loss of the *stx*-encoding bacteriophage occurs during infection or when culturing the *stx*-negative strains.

Given that soft raw milk cheeses can support the growth of STECs, are ready-to-eat, and are not usually subjected to an additional antimicrobial treatment, it is prudent to regard the presence of *stx*-negative strains in the raw milk and raw cheese products as a hazard of concern.

In the New Zealand context, the presence of *stx*-negative strains indicates an absence of adequate process control, and therefore requires corrective actions by the manufacturer.

In contrast, the reviewers do not consider the presence of *stx*-negative or *stx*-positive strains to be predeterminants of a hazard of concern in raw materials for products that will be subjected to a validated antimicrobial treatment, e.g. pasteurization or cooking during processing or by the consumer.

- *the identification of presumptive positive results by PCR (detection of stx genes in samples);*

Defining a food sample as "presumptive positive" through detection of *stx* genes in an enrichment broth is consistent with international practice. Decisions on subsequent procedures for confirmation depend on the level of protection required which itself depends on any regulatory requirements, subsequent antimicrobial processing of the food, the severity of the illness, and the availability of robust analytical procedures. The results achieved will then be weighted in terms of strength of evidence.

Generally, the strongest evidence would be an STEC isolate from the sample confirmed to contain *stx* gene(s) and an attachment gene such as *eae* or *aggR*. This evidence would strengthen further if the *stx* gene was shown to be stx_{2a} (consistently associated with HUS and even in *eae*-negative strains) followed by stx_{1a} and stx_{2c}.

However, isolation of STECs from food samples is difficult with an absence of selective media for serotypes other than O157, and current differential media for non-O157 STECs are subjective, inconsistent and unreliable. Use of immunomagnetic separation to select for specific serotypes prior to differential plating improves isolation, but immunomagnetic beads and media are not available for all serotypes; usually just the serotypes of greatest regulatory interest in the United States and Europe (e.g. O26, O45, O103, O104, O111, O121, O145, and O157). Even then, confirmation rates have been reported as low as 36% whereas use of new molecular methods such as NeoSeek® increase confirmation rates to 81%.

In light of the difficulties with isolation of STECs from foods, the reviewers consider the weight of evidence applied by FSS to presumptive positives (that were not able to be confirmed) as appropriate for high risk products that will not be subjected to a validated antimicrobial treatment, e.g. cooking, during processing or by the consumer.

- *evidence relating to the pathogenicity of strains from whole genome sequencing data.*

The reviewers knowledge on the association of *stx* subtypes with infection is extensive, but still with many data gaps and uncertainties. There are at least 10 known *stx* subtypes, not all implicated in human disease, with stx_{2a} the most consistently associated with HUS, even in some *eae*-negative strains. stx_{1a}, stx_{2c} and stx_{2d} have also been implicated, albeit not as definitively or conclusively, in bloody diarrhoea and HUS. The disease outcome of STEC with stx_{2d} depends on the type of *stx* phage it carries, the site in the bacterial genome where the phage had inserted, and the combination of other genes present.

Our existing knowledge of STEC virulence, therefore, enables the potential of a STEC strain to cause severe clinical disease in humans to be assessed on virulence gene content, independent of its serotype. New technologies such as whole genome sequencing enable investigators to identify *stx* genes, insertion sites and gene combinations.

Thus, it is not prudent to regard any STEC strain as being non-pathogenic or not posing a health risk, as all STEC strains likely have the potential to cause diarrhoea and to have the potential to cause diarrhoea in highly susceptible individuals.

The reviewers consider the weight of evidence applied by FSS for the pathogenicity of strains from whole genome sequencing data, and statements of uncertainty, to be appropriate for high risk products that will not be subjected to a validated antimicrobial treatment, e.g. cooking, during processing or by the consumer.

2. *Does MPI support the way that the evidence was used to underpin the risk management decisions taken? Consideration should be given to the following:*

Two major risk management decisions involving recall of product were made by the IMT during the outbreak and subsequent investigations. Firstly, the decision on 28 July 2016 to recall batches of Dunsyre Blue cheese associated with the outbreak of human STEC illness. Secondly, the decision on 14 September 2016 to recall all ECL products from the market place as a result of identification of serious deficiencies in ECL's food safety management system and the detection of STECs in raw materials and cheese products.

The reviewers judge the appropriateness of these decisions by comparing the incident to a similar incident if it occurred in New Zealand. If foodborne illness is caused by a pathogen which i) exceeds the specified limit in the Australia New Zealand Food Standards Code (the Food Standards Code) or ii) for which a microbiological limit is not described in the Food Standards Code, but is considered to be of concern, MPI would require the associated food business operator (FBO) to complete a risk assessment within a specified timeframe and determine whether or not a recall is necessary to protect public health. This approach is taken as it is the FBO's obligation to manage any risks identified.

Guidance for development by FBOs of recall plans and the performance of recall risk assessments is provided by MPI (Appendix 2).

Following this assessment and in the situations listed above, the FBO usually identifies the need to undertake a recall. This maybe either be a consumer level or trade level recall, a decision largely dependent on the status of the product in the food chain.

Where the FBO declines to carry out a recall and warranted MPI officers, with input from technical experts, are of the view that a recall is required, MPI can issue a "Direction to Recall" (Appendix 2). A Privileged Statement can also be issued by the Director General to warn the public of the presence of unsafe product in the marketplace. These measures can also be used if the Director General is no longer confident that the manufacturer is meeting its obligation to produce safe and suitable food.

A "Notice of Direction" can also be utilised, and would usually involve a direction to cease processing and selling of product.

- *Did the risk assessment identify the relevant evidence or were there any gaps in the evidence used to inform the risk assessment?*

The reviewers conclude that the risk assessment activities reported in the three versions of the risk assessment report, and summarised in full in the final IMT report, are consistent with New Zealand expectations, and are appropriate in terms of strength of evidence and timeliness.

While the three early assessments did not discuss the possible use of case-control studies and odds-ratio analysis when evaluating the epidemiological link to Dunsyre Blue cheese, the justification for not carrying out a case-control study and the odds-ratio/Bayesian analyses as described in the final IMT report is reasonable.

The reviewers understand that ECL was unable to provide time-course studies that would have allowed FSS to better understand changes in the microbiological profile of STECs throughout the manufacturing process. Use of predictive microbiological modelling and international expert knowledge and opinion was not described in the risk assessment reports and would have added to the strength of evidence.

The reviewers note that FSS employed in its initial assessment activities Combase predictive modelling using the pH and water activity values from testing undertaken by South Lanarkshire Council. However, the data available was only from two cheeses sampled beyond the end of maturation and, in the absence of records from ECL's manufacturing process, the modelling required FSS to make assumptions on temperature control throughout the manufacturing process. FSS did not have sufficient confidence to formally include the modelling outputs in the risk assessment.

Nevertheless, the conclusions reached by FSS with respect to likely STEC growth and survival during manufacture of the Dunsyre Blue cheese in the absence of predictive modelling, were, in the reviewers opinion, fully justified.

Gaps in evidence and the uncertainties were well described in the documentation provided to MPI.

- *Did the risk assessment use appropriate methodologies?*

The risk assessment methodologies reported are consistent with international guidelines (e.g. Codex) and expectations, and in general did not differ from those employed in New Zealand for investigation of foodborne illness outbreaks.

- *Did the risk assessment weigh up/analyse the evidence appropriately to determine the risk and also the uncertainty?*

The risk assessment documents provided describe an appropriate process of collection, analysis, weighting and determination of uncertainty around the available evidence in terms of determination of conclusions on hygienic processing and possible risk to human health.

- *Were the conclusions from the risk assessment set out in an appropriate way for the use of risk managers?*

The reviewers found the risk assessment documents easy to follow in terms of description of the evidence, analysis and conclusions reached. Weighting of the available evidence and documentation of uncertainty inherent in the evidence, or due to data gaps, were appropriately described and communicated.

- *Did the evidence support the risk management action taken?*

The reviewers consider the evidence supports the risk management actions taken by FSS both in respect of the recalls associated with the epidemiological link between the cases and Dunsyre Blue Cheese, and the subsequent recalls due to deficiencies in ECL's food safety management system.

As previously stated, it is unlikely that ECL would have gained approval to produce a soft raw milk cheese in New Zealand given the lack of documentation in the risk management plan on hazard analysis, and identification of CCPs and validation of control measures for STEC (and other hazards). Similarly, discovery of such a process in New Zealand would likely result in a recall of products and review of the manufacturer's processing approvals under the Animal Products Act 1999 and Food Act 2014.

3. *In light of all of the evidence that was available, and the relevant regulations and policy that FSS is required to follow in such circumstances, does MPI consider it to have been appropriate for FSS to take action on 14 September 2016 to instigate a recall of all cheeses produced by ECL which were on the market at that time? In particular, MPI opinion is sought on the following:*

Investigations undertaken by the competent authority, SLC, prior to 14 September 2016 identified deficiencies in the company's HACCP-based food safety management system that fully supported a judgement of inadequacy. A number of STECs and *stx*-negative *E. coli* 0157 strains were isolated from samples of raw cow's milk from the sole supplier to ECL, and unpasteurised cow's and sheep's milk cheeses produced by the company.

On 14 September 2016, with mounting evidence that questioned the past and on-going safety of ECL products, the IMT on advice from SLC decided to request of ECL a voluntary recall of all cheeses produced by ECL that were within date and on sale. With no response from ECL, FSS issued a food alert for action (FAFA) recalling all batches, and issued a further FAFA on 15 September 2016.

Subsequent to issue of the FAFA, attempts by SLC to swab the plant were thwarted by ECL until 5 October 2016. Samples of cow's milk from the sole supplier to ECL, and cow and

ewe's milk[2] cheeses produced by ECL were shown to contain a variety of STECs and stx-negative *E. coli* O157 strains.

Legal communications with local authorities were initiated by ECL representatives on 16 September with respect to their compliance with the Food Safety Act, and continued until 13 October when ECL advised FSS of instigation of a legal review against the FAFA, and a request to suspend the FAFA advice to local authorities to destroy product. While the recall remained in place, the advice to local authorities to destroy product was suspended by FSS on 19 October 2016.

Additional legal communications occurred between FSS and SCL, and/or ECL from 19 October 2016 through February 2017 regarding:

- The epidemiological evidence linking ECL to the original outbreak for *E. coli* O157:H7 illness;
- Requirements for revalidation of ECL's HACCP plan;
- Requirements of HACCP and how failure of an effective HACCP plan means that food does not meet food safety requirements;
- ECL challenge of the product detention notices;
- ECL requests to produce and market Dunsyre soft cheese labelled as a "Raw material to be cooked"
- ECL request, and SLC approval, to produce and market semi-hard Corra Linn cheeses despite the FAFA still being in place. The product sold to the UK tested positive for stx1/2, and was detained by the FSA;
- Question of authority to guarantee that cheese is produced in line with the Food Hygiene Regs 2006.

<u>New Zealand requirements for manufacture of raw milk products</u>

A raw milk product is defined as a processed dairy product that (a) has not received a pathogen elimination step (5-log reduction in the number of pathogens of human health significance); and (b) in which as a result of its nature and the manner in which it is processed, may allow the survival of pathogens, but in the case of pathogens specified in the food safety criteria, will not support their growth or allow their survival, to levels that exceed those specified in the food safety criteria.

Manufacturers of raw milk products in New Zealand must have either a registered HACCP-based risk management programme (RMP) under the Animal Products Act 1999 or a customized Food Control Programme (FCP) under the Food Act 2014.

Processing under an RMP must be compliant with the standard requirements for milk production and processing described in:

- The Animal Products (Dairy Processing Specifications) Notice 2006
- The Animal Products (Dairy) Approved Criteria (DPC1, DPC2, DPC3 & DPC4)
- NZCP1: Design and operation of farm dairies

Additional requirements are described in the Animal Products (Raw Milk Products Specifications) Notice 2009, and the Code of Practice: Additional Measures for Raw Milk

[2] Ewe's milk for cheeses produced by ECL was from ECL's own farm. Ewe's milk was not tested for STECs as the ewes were dry at the time of the investigation.

Products, March 2010. These additional requirements apply to both RMPs under the Animal Products Act 1999 and FCPs under the Food Act 2014.

Specifically, the Notice and Code describe requirements for:

- Animal identification
- Animal health
- Feed (such that is not a vector for pathogens)
- Milking area hygiene
- Teat hygiene and milk stripping (abnormality checks)
- Milk refrigeration (<7°C)
- Separation from milk for pasteurization
- Microbiological monitoring programme including, but not limited to, APC and *E. coli*
- Milk transportation (<8°C)

- Developing a HACCP Plan following the steps set out in DPC1: Approved criteria for general dairy processing. This applies the Codex HACCP Principles and includes identification of the pathogens of significance.
- Environmental pathogen management plan
- Operator defined process measures (ODPM) that describe
    - process steps, including inputs and outputs, acceptable operational (process) tolerance criteria for each measure (e.g. minimum and/or maximum temperature and time, minimum pH or titratable acidity, acceptable range for salt and moisture percentage.
    - manner in which the process measures will be monitored
    - actions to be taken should measures fail to be applied as intended.
- Programme validation to demonstrate that the process will produce a raw milk product that consistently meets microbiological limits and food safety criteria, using
    - predictive mathematical model
    - challenge study
    - reliable information from other manufacturers, scientific literature, operator experience
    - a validation protocol to confirm suitability, where supporting information indicates that the intrinsic nature of the process and product will result in a product that consistently meets microbiological requirements.
- Product microbiological monitoring programme including, but not limited to, *Salmonella*, *Listeria*, coagulase-positive staphylococci and their toxin, and *E. coli*.

For raw milk products, there will typically not be specific microbiological criteria defined, and the combination of ODPMs applied are considered to serve as a CCP. Failure to apply an ODPM is treated as a CCP failure, with affected products deemed non-conforming.

While the Food Act 2014 does not specify requirements for safe production of raw milk cheeses, the manufacturer is required to demonstrate that their products do not pose a risk to human health. As such, an evaluator of an FCP for raw milk cheeses would expect to see a documented risk-based programme with the elements described above for an RMP.

MPI specifies a maximum permissible level for *E. coli* in all cheese, with a published three-class microbiological criterion of n=5, c=1, m=10/g, M=100/g. The rationale for the limit is that testing heat treated product for *E. coli* indicates whether or not suitable hygiene

standards have been maintained post-pasteurisation, Similarly, testing raw milk cheese gives confidence that, despite any increase that can be expected to occur due to concentration during cheese-making, the process and/or cheese characteristics should result in sufficient reduction of the pathogen of concern.

Testing for STECs is not required for raw milk or raw milk products. MPI considers the prevalence and counts of STECs, not just *E. coli* O157:H7, to be so low and the distribution to be uneven in a food, that the probability of detection would be low from a sampling plan that would be commercially practical. While it is likely that only 1:100,000 *E. coli* would be *E. coli* O157:H7; the ratio perhaps a little lower for the non-O157 STECs, and this would make detection difficult, it cannot be ruled out that all the *E. coli* present are STECs. In addition, MPI considers the current procedures for detection, confirmation and determination of likely pathogenicity of STECs to not be sufficiently robust, although that is improving with molecular initiatives.

While testing for STECs is not required, during the hazard analysis phase of development of their RMP for production of raw milk cheeses, processors would be expected to consider STECs to be a pathogen of concern given their very low infectious dose and severe illness. MPI specifically states that cheeses made from raw (unpasteurised) milk can contain harmful bacteria. Raw milk from any animal can have STECs, *Listeria* and *Campylobacter,* and lists foodborne outbreaks attributed to the consumption of raw milk.

However, for historic reasons, it is common in New Zealand for HACCP plans within RMPs to identify *E. coli* as a microbiological criterion rather than STECs as a specific hazard of concern.

These requirements are also set within a regulatory approach that acknowledges the importance of consumer understanding of the product. New Zealand consumers have access to information that describes the dangers of raw-milk cheeses, at-risk population groups, labelling and handling requirements to reduce the risks[3].

MPI expects that the RMP will validate that the process will not support STEC growth or allow their survival (Appendix 3). Soft raw-milk cheese processes are described as the least likely to inactivate STECs and, hence, most likely to carry harmful bacteria. To this end, it is unlikely that a raw milk soft cheese such as Dunsyre Blue would be approved for manufacture in New Zealand. The raw milk cheese products that have been approved for manufacture in New Zealand are Cheddar, Red Leicester, and Gouda-style cheese.

- *Did the risk management decision identify all the appropriate sources of information upon which to inform the decision?*

The reviewers are not aware of all sources of information available in Scotland, the UK and wider EU. However, the sources of information identified in the documents provided by FSS are similar to those in New Zealand and appear appropriate to inform the decisions with respect to (a) recalls associated with the epidemiological link between the cases and Dunsyre Blue cheese, and (b) the subsequent recall on 14 September 2016 due to deficiencies in ECL's food safety management system.

[3] https://www.mpi.govt.nz/food-safety/food-safety-for-consumers/is-it-safe-to-eat/raw-milk-cheese/

As noted above, evidential use of predictive microbiological modelling and international expert knowledge and opinion to better understand growth and survival of STECs through the manufacturing process may have added to the strength of evidence, but is unlikely to have changed the risk assessment conclusions and risk management decision.

- *Did the risk management decision take account of all of this information?*

The documented risk assessment and risk management decision with respect to the FAFA on 14 September 2016 is judged to have appropriately used evidence from the information sources identified.

Robust reasons have been documented where contrary data has been discounted or information has been provided but not used. Transparency and openness are stated operating tenants of FSS and the IMT.

- *Did the risk management decision correctly interpret the information on which it was based?*

Interpretation of the information presented to risk managers to inform their decision making on 14 September 2016 is judged to be reasonable and proportionate. It is consistent with international guidelines and practices.

- *Was the risk management decision in line with the relevant regulations and policy?*

The reviewers consider that the risk management decisions made at various times throughout the incident response with respect to food safety management systems were fully in line with the EU regulations and policy, risk-based international guidelines such as those from Codex, and New Zealand regulatory practice.

4. *Based on all of the information provided, how would MPI have approached risk management in relation to this incident? Would MPI have reached the same decisions if it had the same information available to it, and was applying the same policies and regulation? If not, please highlight where different decisions would have been made and the reasons for this.*

The reviewers consider that MPI would generally have approached risk management of a food safety incident with these characteristics in a similar manner.

Notwithstanding this, two differences stand-out. Firstly, it is usual for the MPI Response Team, the equivalent of the IMT, to meet daily, if not twice daily, during the initial response period. This ensures that all decision-making risk managers, risk assessors and risk communicators from across the various central and local government department are fully informed at all times, and risk management decisions can be made without undue delay.

Secondly, because of this structure, assuming access to the same information in the same or shorter timeframe, it is probable that MPI would have put in place a Notice of Direction to prevent further processing and sale followed by withdrawal of approval for ECL to process at an earlier opportunity than did the IMT, FSS and SCL. When there is strong evidence that a food product/process has resulted in illness and may pose a continuing risk to human health,

the onus is on the manufacturer to immediately react to remove the threat to consumers and for MPI to ensure this occurs. The manufacturer must then provide proof that its process has regained or is in control such that its products are no longer a risk to the consumer before resuming processing. The scope of the recall is precautionary and will include all likely affected product. The scope of the recall will be reduced if the manufacturer provides evidence as to why other batches or product types should not be included in the recall.

Under New Zealand law, it is highly unlikely that ECL would have gained approval to produce a soft raw milk cheese without a documented risk-based programme (Risk Management Programme under the Animal Products Act 1999, or a Custom Food Control Programme Programme under the Food Act 2014) that included comprehensive descriptions of:

(a) a robust hazard analysis;
(b) process flow including requirements for raw materials and time course studies for parameters essential for control of STECs;
(c) published validation studies or in-house validation studies that show that STECs are controlled/eliminated in their process through application of CCPs;
(d) CCP parameters and microbiological monitoring programmes and critical limits;
(e) non-compliance actions and follow up activities, and
(f) internal audit activities.

MPI has the final regulatory approval function for such high-risk processes.

5. Conclusion of the review

The reviewers have been presented with extensive and systematic documentation on the public health incident in question.

Our evaluation is based on international good practice, New Zealand regulatory requirements and expectations that would be applied in a similar scenario, and our specialist scientific expertise.

We have focused on the risk management decisions relating to the recall of cheeses, using the epidemiological and microbiological evidence associated with human cases and product testing, together with the an evaluation of the adequacy of control measures that were in place at ECL at the time of food incident.

The reviewers find the risk management decisions made and actions taken by the Competent Authority's SLC and FSS are reasonable and proportionate in regard to protecting public health.

6. Appendices

Appendix 1: Guidance documents for validation of risk management programmes

The MPI Risk Management Programme (RMP) Manual[4] describes in sections 4.3 - 4.5 the general requirements for operators to validate that their RMP is effective; i.e. to provide evidence that demonstrates that when the RMP is implemented as documented, the criteria defining the product's fitness for intended purpose, and particularly the regulatory limits and operator-defined limits are consistently met.

A draft amendment to the RMP Manual[5] is currently undergoing public consultation (closed on 8 March 2018) and includes additional guidance on validation (section 5.2 replaces 4.2). This includes a flowchart, additional detail about how to develop a validation protocol and the suggested content of a validation report.

Manufacturers validating a Custom Food Control Plan (FCP) under the Food Act 2014 are referred to the validation requirements in the RMP Manaual.

Validation will generally involve product testing and/or the measurement of process parameters. Where available, historical data may be used to show that a process is consistently able to meet the criteria (e.g. microbiological databases, final product testing results). Operators lacking in-house expertise are recommended to use external competent persons to undertake validation and to prepare any validation reports, and should consider:

- any hazards that may already be controlled by the supplier when establishing incoming hazard levels
- the use of calibrated equipment when any critical measurements are taken
- statistical sampling of each batch for a number of batches, including inputs as well as final product
- the use of challenge tests, where appropriate, and
- enhanced sampling if there is high variability within the operation to ensure that the process design is capable of dealing with all variables likely to be encountered.

Many resources (listed below) are available to operators to inform the validation process, either when demonstrating the appropriateness of a limit or when collecting evidence to demonstrate that a limit will be met. Many of these are generic, such as the 2016 MPI requirements for the direct sale of raw drinking milk to consumers, but provide additional guidance to raw cheese manufacturers on effective pathogen management, including on-farm measures, outline control measures and microbiological limits that MPI currently considers to be appropriate, and the actions to be taken by a manufacturer in the event of unfavourable environmental monitoring results.

[4] http://www.mpi.govt.nz/dmsdocument/183-risk-management-programme-manual-for-animal-product-processing
[5] http://www.mpi.govt.nz/dmsdocument/26308-draft-guidance-document-risk-management-programme-manual-for-animal-product-processing

Resources include:

- New Zealand standards and codes of practice
  - *Animal Products (Raw Milk Products Specifications) Notice 2009*[6]
  - *Code of Practice: Additional Measures for Raw Milk Products, March 2010*[7]
  - *Raw milk products advisory (2013) for import of raw milk products, currently limited to the EU and Switzerland*[8]
  - *Animal Products Notice: Raw Milk for Sale to Consumers (2016)*[9]

- New Zealand generic validation and guidance documents
  - *What is Validation?*[10]
  - *How to determine the shelf life of food*[11]
  - *MPI Operational Guideline: Dairy HACCP Plans (2003)*[12]
  - *Draft Pathogen Management Plan Guidance (2006)*[13]

- FSANZ standards (Australia only) and guidelines
  - *MPI Code of Practice: Additional Measures for Raw Milk Products, March 2010*
  - *FSANZ Guide to the requirements for raw milk cheese in Standard 4.2.4 – Primary Production and Processing Standard for Dairy Products (at Approval) – Proposal P1022 Primary Production & Processing Requirements for Raw Milk Cheese*[14]
    - *Food Standards (Proposal P1022 – Primary Production and Processing Requirements for Raw Milk Products) Variation*[15]
    - *Food Standards (Proposal P1007 – Primary Production & Processing Requirements for Raw Milk Products) Variation*[16]
  - *Supporting document 1 - Guide to the requirements for raw milk cheese in Standard 4.2.4*[17]
  - *Supporting document 2 Guide to the validation of raw milk cheese (at Approval) – Proposal P1022 Primary Production & Processing Requirements for Raw Milk Products*[18]
  - *Supporting document 3 Scientific information for the assessment of raw milk products – Cheeses (at Approval) – Proposal P1022 Primary Production & Processing Requirements for Raw Milk Products*[19]
  - *Question and answers about changes made through Proposal P1022*[20]

- Local and domestic industry codes of practice (usually members only), validation studies and historical knowledge on performance of control measures
  - New Zealand Specialist Cheesemakers Association (www.nzsca.org.nz) Code of Practice
  - UK Specialist Cheesemakers Association (www.specialistcheesemakers.co.uk) Code of Practice. Note that two of the three registered New Zealand manufacturers of raw milk cheese are members.

[6] http://www.mpi.govt.nz/dmsdocument/1005-animal-products-raw-milk-products-specifications-notice-2009
[7] http://www.mpi.govt.nz/dmsdocument/23074-code-of-practice-additional-measures-for-raw-milk-products-march-2010
[8] https://www.mpi.govt.nz/dmsdocument/2975-raw-milk-products-advisory
[9] https://www.mpi.govt.nz/dmsdocument/11473-animal-products-notice-raw-milk-for-sale-to-consumers-regulated-control-scheme
[10] http://www.mpi.govt.nz/dmsdocument/23059-what-is-validation
[11] http://www.foodsafety.govt.nz/elibrary/industry/determine-shelf-life-of-food/
[12] https://www.mpi.govt.nz/dmsdocument/20096-operational-guideline-dairy-haccp-plans
[13] http://www.foodsafety.govt.nz/elibrary/industry/Pathogen_Management-Sets_Requirements.pdf
[14] https://www.foodstandards.gov.au/code/proposals/Documents/P1022-Raw-milk-prods-AppR-SD1.pdf
[15] https://www.legislation.gov.au/Details/F2015L00198
[16] https://www.legislation.gov.au/Details/F2012L01339
[17] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1022primary5627.aspx
[18] http://www.foodstandards.gov.au/code/proposals/Documents/P1022-Raw-milk-prods-AppR-SD2.pdf
[19] http://www.foodstandards.gov.au/code/proposals/Documents/P1022-Raw-milk-prods-AppR-SD3.pdf
[20] http://www.foodstandards.govt.nz/code/proposals/documents/P1007%20PPPS%20for%20raw%20milk%201AR%20SD3%20Cheese%20Risk%20Assessment.pdf

- Peer-reviewed scientific literature
- Mathematical and predictive microbiological modelling programmes
- Challenge testing
- MPI and FSANZ publications (see below)

The following project reports published on the MPI and FSANZ websites are valuable resources for developers of RMP's to assure the safety of raw drinking milk, and domestic and imported raw milk cheeses in New Zealand.

- A systematic review of the human disease evidence associated with the consumption of raw milk and raw milk cheeses.[21]

- An assessment of available information on raw milk cheeses and human disease 2000–2010.[22]

- Evaluation of the microbial safety of raw milk cheeses.[23]

- Publications on the effect of processing on the survival of bacterial pathogens in raw milk products.[24]

- Challenge testing of microbiological safety of raw milk cheeses.[25]

- Estimating the risk to New Zealand consumers from the consumption of Roquefort cheese (confidential - restricted circulation)

- Risk profile: *Listeria monocytogenes* in low-moisture cheeses.[26]

- Risk Profile: *Listeria monocytogenes* in soft cheeses.[27]

- Risk profile: *Bacillus cereus* in dairy products.[28]

- Assessment of the microbiological risks associated with the consumption of raw milk.[29]

- An assessment of the effects of pasteurisation on claimed nutrition and health benefits of raw milk.[30]

- Estimating bacterial pathogen levels in New Zealand bulk tank milk.[31]

- Microbiology of raw milk in New Zealand.[32]

- Risk profile: *Listeria monocytogenes* in raw milk.[33]

[21] http://www.mpi.govt.nz/dmsdocument/22309-a-systematic-review-of-the-human-disease-evidence-associated-with-the-consumption-of-raw-milk-and-raw-milk-cheeses
[22] http://www.mpi.govt.nz/dmsdocument/20612-an-assessment-of-available-information-on-raw-milk-cheeses-and-human-disease-20002010
[23] http://www.mpi.govt.nz/dmsdocument/12945-evaluation-of-the-microbial-safety-of-raw-milk-cheeses
[24] http://www.mpi.govt.nz/dmsdocument/3766-publications-on-the-effect-of-processing-on-the-survival-of-bacterial-pathogens-in-raw-milk-products
[25] http://www.mpi.govt.nz/dmsdocument/20621-challenge-testing-of-microbiological-safety-of-raw-milk-cheeses
[26] http://www.mpi.govt.nz/dmsdocument/20627-risk-profile-listeria-monocytogenes-in-low-moisture-cheeses
[27] http://www.mpi.govt.nz/dmsdocument/25856-risk-profile-listeria-monocytogenes-in-soft-cheeses
[28] http://www.mpi.govt.nz/dmsdocument/14149-risk-profile-bacillus-cereus-in-dairy-products
[29] http://www.mpi.govt.nz/dmsdocument/1118-assessment-of-the-microbiological-risks-associated-with-the-consumption-of-raw-milk
[30] http://www.mpi.govt.nz/dmsdocument/1119-an-assessment-of-the-effects-of-pasteurisation-on-claimed-nutrition-and-health-benefits-of-raw-milk
[31] https://www.ncbi.nlm.nih.gov/pubmed/27296424
[32] https://www.ncbi.nlm.nih.gov/pubmed/22663980

- Risk profile: *Campylobacter jejuni/coli* in raw milk.[34]

- Risk profile: Shiga toxin-producing *Escherichia coli* in raw milk.[35]

- Evaluation of methods for detection of coagulase-positive *Staphylocccus* and staphylococcal toxin in milk and cheese.[36]

- Pasteurization of milk: The heat inactivation kinetics of milk-borne dairy pathogens under commercial-type conditions of turbulent flow.[37]

- Pasteurisation of dairy products: Times, temperatures, and evidence for control of pathogens.[38]

- FSANZ microbiological risk assessment of raw milk cheese.[39]

[33] http://www.mpi.govt.nz/dmsdocument/1122-risk-profile-listeria-monocytogenes-in-raw-milk
[34] http://www.mpi.govt.nz/dmsdocument/1120-risk-profile-campylobacter-jejunicoli-in-raw-milk
[35] http://www.mpi.govt.nz/dmsdocument/1121-risk-profile-shiga-toxin-producing-escherichia-coli-in-raw-milk
[36] http://www.mpi.govt.nz/dmsdocument/25871-evaluation-of-methods-for-detection-of-coagulase-positive-staphylocccus-and-staphylococcal-toxin-in-milk-and-cheese
[37] http://www.journalofdairyscience.org/article/S0022-0302(11)00673-4/references
[38] http://www.mpi.govt.nz/dmsdocument/25877-pasteurisation-of-dairy-products-times-temperatures-and-evidence-for-control-of-pathogens
[39] http://www.foodstandards.govt.nz/code/proposals/documents/P1007%20PPPS%20for%20raw%20milk%201AR%20SD3%20Cheese%20Risk%20Assessment.pdf

Appendix 2: Guidance and support for food business recall risk assessments

A food business operator (FBO) that is associated with foodborne illness, and whose product, when tested for pathogens;

(i) exceeds the specified limit in the Australia New Zealand Food Standards Code (the Food Standards Code) or
(ii) is considered to be of concern when a microbiological limit is not described in the Food Standards Code,

is required by MPI to complete a risk assessment within a specified timeframe and determine whether or not a recall is necessary to protect public health.

Where appropriate, FBO's are required to have in place a food recall plan that describes the process for determining whether or not a recall is required.

The development of recall plans is supported by the 2015 MPI Recall Guidance Material[40] (currently being updated) that includes information on how to undertake a food recall risk assessment. The guide provides a hazard/risk analysis form for FBO's to use to collate information required for the risk assessment.

MPI has statutory powers under the Food Act 2014/ Animal Products Act 1999 to require an FBO to provide information to inform a recall risk assessment, should the FBO refuse to provide it.

Warranted MPI officers, and necessary technical experts, review the completed recall hazard/risk analysis form (or equivalent information) and risk assessment. Should MPI not agree with an FBO's conclusion that the risk is low and a recall is not required, MPI will inform the FBO of the reasons and MPI's risk conclusion.

If the FBO still does not take steps to recall the product, MPI will do so using powers under the Food Act 2014 and Animal Products Act 1999 (Sections 284 and 85, respectively) by issuing a "Direction to Recall". The Director General of MPI may at the same time as a recall is in effect issue a "Privileged Statement" to inform and protect the public, but this is only issued if the FBO isn't cooperative or the recall is incomplete.

[40] https://www.mpi.govt.nz/food-safety/food-recalls/developing-your-food-recall-plan/

Appendix 3: Application of microbiological criterion for *E. coli* in soft unpasteurised cheeses.

New Zealand regulations under the *Animal Products Act 1999* for production of cheeses are defined in *Animal Products DPC1: Approved Criteria for General Dairy Processing (DPC1)* and describe a production limit of 100 cfu/g for *E. coli* in all dairy products intended for the general population. The *Australia New Zealand Food Standards Code* standard 1.6.1 and the associated Schedule 27 also apply to foods intended for sale, and this has a limit for *E. coli* in cheese (raw or pasteurised, domestic or imported) of n=5, c=1 m=10/g, M=100/g.

New Zealand's *Animal Products (Raw Milk Products Specifications) Notice 2009* defines a raw milk product to be a processed dairy product in which, as a result of its nature and the manner in which it is processed, may allow the survival of pathogens, but in the case of pathogens specified in the food safety criteria, will not support their growth or allow their survival, to levels that exceed those specified in the food safety criteria.

The Notice does not include *E. coli* as a food safety criterion at the recommendation of the European Commission. While European Legislation, notably Commission Regulation 2073/2005, describes a limit for *E. coli* in cheeses made from heat treated milk (applied at the point the levels are expected to be at their highest), the limit does not apply to raw milk cheese.

Nevertheless, irrespective of the absence of *E. coli* as a food safety criterion in the Notice, the DPC1 and Food Standards Code limits apply throughout a raw milk cheese products shelf life. Consequently, raw milk cheese producers must still consider *E. coli* when developing their risk based management programmes, and must show that the cheese will consistently meet the *E. coli* micro limit throughout the products shelf life.

While neither the Notice nor the Food Standards Code specify microbiological limits for STECs, conditions that allow the growth of mesophilic *Listeria* and *Staphylococcus* will in most cases allow the growth of STECs. It is therefore highly unlikely that a soft raw milk cheese would qualify as a permitted raw milk product as it would likely support the growth of pathogens, and an unripened cheese would definitely not be permitted.

What level of *E. coli* in raw milk cheese is acceptable?

Internationally there is debate regarding acceptable levels of generic (non-toxigenic) *E. coli* in soft and semi-soft unpasteurised cheeses at the end product stage.

Proponents of removing *E. coli* limits, both international and New Zealand members of the UK Specialist Cheesemakers Association, suggest that significantly elevated *E. coli* levels are not associated with poor hygiene. They contend that the cheesemaking process facilitates growth of low levels of generic *E. coli* present in raw milk, but that detection of levels of up to 10,000 cfu/g in end product do not present a food safety risk as the strains "will be non-toxigenic" and the competing effect of microflora in the cheese prevents STEC growth.

MPI does not hold this view. MPI agrees that growth and/or concentration of mesophilic *E. coli* during cooking and curd production can occur; conditions that are required to support the growth of the starter culture.

However, observations to date indicate that elevated levels of *E. coli* at the end of maturation are more likely to be associated with:

- process hygiene and temperature control during transport (milk tank sanitation),
- process hygiene during manufacture (including the immediate environment), and
- starter activity and hitting acidity targets within the expected timeframes

In addition, any process that supports the growth of generic *E. coli* will support the growth of STECs. While it is likely that only a small proportion of the *E. coli* present are STECs, it cannot be ruled out that all the *E. coli* present in the raw milk are STECs.

Estimates of dose-response (infectious dose) have been made for STEC O157:H7 based on food concentration of the pathogen and patient consumption data from outbreaks. It is thought that exposure to less than 100 cells of STEC O157:H7 is sufficient to cause infection. Exposure estimates of as low as 2-45 cells have been reported from outbreaks, and STECs have been detected in raw milk cheeses at 5-10 CFU/g. The probability of infection on exposure to a single viable cell of STEC O157 is significant.

Therefore, given the potential for STEC to account for a proportion of the *E. coli* population of bacteria, New Zealand requires the maturation period and cheese characteristics to deliver a meaningful reduction of pathogens and *E. coli*. Because *Salmonella* and *L. monocytogenes* have to date not been found in New Zealand raw milk during the validation of raw milk products, there has been a greater emphasis on modelling the growth/die off characteristics of *E. coli* through the manufacturing process.

From a validation perspective, growth and concentration of *E. coli* to higher levels during cooking and curd formation then enables the die off of *E. coli* to be better tracked and confirmed through ripening/maturation. In addition, *E. coli* is considered to have a slower die off than other pathogens of concern which provides some level of confidence that a raw milk cheese that meets the *E. coli* limits will not pose a risk to public health.

The International Dairy Federation (IDF) supports testing for *E. coli* in raw milk cheese when implementing HACCP and verifying the safety of the finished cheese by demonstrating a decline in numbers during ageing (sampling and testing at the end of the ripening period)[41].

E. coli has historically been one of the primary indicator organisms for process hygiene, and as such, the limits applied are reasonably well accepted by industry for thermised and pasteurised cheese. Consequently, MPI is of the view that in the absence of robust scientific evidence to support removal of, or an increase in, the *E. coli* limit, a limit of 100 cfu/g should be applied to all types of cheese (e.g. soft or hard), regardless of whether it is pasteurised or unpasteurised.

Microbiological profile of raw milk on farm

Inherent in the validation process for raw milk cheeses is an MPI requirement that the raw milk be microbiologically tested on a per batch basis. This equates to a per make basis as the businesses are generally very small. The results indicate that levels in the raw milk are

[41] https://www.fil-idf.org/wp-content/uploads/2016/12/Escherichia-coli-as-indicators-in-cheese-processing.pdf

generally below 50 cfu/ml for *E. coli*, and that there is no correlation between the *E. coli* levels in raw milk and those in the matured cheese[42]. Unfortunately, the data does not allow an assessment of the likely levels in the mature cheese if levels in the raw milk in the farm bulk milk tank were to be significantly elevated (for instance >1,000 or 10,000 cfu/ml).

Dairy companies in New Zealand that take raw milk for pasteurised products test twice a month for Total coliforms as a hygiene indicator and apply financial penalties if the levels exceed 100 to 500 cfu/ml (note that limit applied varies between milk processing companies). Regular monitoring and the application of financial penalties has led to improved milk quality levels at the farm vat and a greater focus on contributing factors such as water quality, teat hygiene, milk cooling and hot water cleaning temperatures.

Elevated *E. coli* levels in matured cheese

E. coli levels at the end of maturation of raw milk cheeses occasionally exceed the stated Food Standards Code microbiological limits. In such cases, MPI has allowed further maturation to be undertaken, with the proviso that at the end of an extended period (typically 2 months) the levels meet the Food Standards Code limits. These exceptions typically occur during the cheesemaker's validation period and result in the minimum maturation period being extended within the programme.

In addition, extended microbiological monitoring is required to provide assurances that a safe raw milk cheese can be manufactured. Extended monitoring includes:

- Raw milk ex farm
- Raw milk at the start of manufacture
- Curd on the day of manufacture, and
- Product at 90 days

MPI does not permit manufacturers of heat treated cheeses to extend maturation, and any failure against the *E. coli* limits requires the cheese to be further processed with heat treatment (i.e. as processed cheese), downgraded to stock food, or destroyed.

Food Standards Code Review

Food Standards Code Standard 1.6.1 and the associated Schedule 27 are currently under review. Australia, not New Zealand, is considering removing *E. coli* as a food safety limit for cheeses made with heat treated milk, but applying a process hygiene limit for *E. coli* under the production standards. It is far from certain that any change will be agreed and adopted. If it is adopted, then it is possible that a two tiered approach would be taken under the production standards, with a lower threshold prompting remedial action and a second limit putting the product into the category of non-conforming/not for human consumption.

It is unclear what approach might be taken for raw milk cheeses and what limits might be applied. Needless to say, MPI remains comfortable with the current 100 cfu/g microbiological limit, and is yet to be convinced that higher limits such as 1,000 to 10,000 cfu/g in a matured cheese reflect good hygienic practice.

[42] Data available on request.