



INFORMATION SHEET 2011/02 April 2011

Reassessment of the Silver Fern Farms Limited-Dargaville (ME125) HACCP plan to determine the likelihood of *E.coli* O157:H7 being a hazard

United States Federal Register Notice (67 FR 62325) 9 CFR, Part 417 Docket Number 00-022N dated 7 October 2002, titled "*E. coli* O157:H7 Contamination of Beef Products" requires all establishments to reassess their HACCP plans with respect to control of *E. coli* O157:H7 based on new information that *E. coli* O157:H7 is more prevalent in the U.S. than previously thought.

Silver Fern Farms Dargaville ME 125 originally reassessed its HACCP Plan in April 2003 to determine whether or not *E. coli* O157:H7 is a hazard that is reasonably likely to occur in beef exported to the United States or supplied to any other market.

This letter outlines reassessment of the HACCP Plan relevant to this site from April 2003 until April 2011.

This assessment confirmed *E. coli* O157:H7 is not a hazard reasonably likely to occur in beef meat from premises ME 125.

Our premises ME 125 has participated in the national monitoring programme for *E. coli* O157:H7 for premises exporting beef to the United States since June 1998. The current programme has been accepted by the FSIS as equivalent to US monitoring programmes. Twelve cartons (@27.2kg) of beef are randomly selected each day from each premise. A composite N60 sample is collected from multiple locations within the selected cartons, and composited (375g) for analysis. All analyses are carried out in laboratories approved and audited by the New Zealand government, and are certified to ISO Guide 17025. Analytical methods meet the requirements of FSIS Directive 10010.1, and include enrichment, screening with AOAC approved BioControl Assurance GDS kits, and isolation using immunomagnetic separation (IMS) procedures.

Plant *E coli* 0157 H7 Data

Since the commencement of *E coli* O157:H7 sampling in June 1998, until April 2011 there have been 24,708 cartons tested using the above outlined programme. Over that timeframe there have been 8 composite samples of 12 cartons at screen, tested positive for *E. coli* O157:H7. These were confirmed by electrophoresis at the ESR in Wellington. While the isolations in themselves are significant due to their rarity, we do not believe they are an indicator of inadequate plant performance for the following reasons:

1. ME 125 was operating in accordance with the New Zealand regulatory requirements for slaughter and dressing (IS5) and boning / refrigeration (IS6). It has also complied with all US requirements.
2. Of the 24,708 cartons of boneless manufacturing beef tested for E. coli 0157:H7 to date at ME 125, 0.38% has provided a positive result.

New Zealand, and therefore Silver Fern Farms Ltd Dargaville has always used IMS procedures for analyses of E coli 0157:H7 from meat and meat products which FSIS introduced as a “new” method only in September 1999.

On the basis of this data using a direct arithmetic calculation on finding 8 positives within this sample size, the proportion rate at Dargaville is <0.032%.

However in order to determine the true statistical significance of the results obtained, a comparison was made with the “USDA Table of Probabilities for use in Exploratory Sampling”.

At a prevalence of 0.01%, 29,956 samples may be required to detect a single positive at the 95% confidence level. Given the sample size from Dargaville i.e. 24,708 cartons, then at the 95% confidence level the expected prevalence is statistically between 0.01 and 0.02%.

Further analysis of the data was undertaken by using a confidence level spreadsheet below originally designed by AgResearch.

Confidence Intervals: By Neil Cox, AgResearch, Hamilton (modified by Roger Cook 12/5/00)					
Required				95% Confidence Limits	
signif level	Total	Num +ve	Proportion	Lower	Upper
0.05	24708	0	0.000%	0.0000%	0.015%
0.05	24708	1	0.004%	0.0001%	0.023%
0.05	24708	2	0.008%	0.0010%	0.029%
0.05	24708	3	0.012%	0.0025%	0.035%
0.05	24708	4	0.016%	0.0044%	0.041%
0.05	24708	5	0.020%	0.0066%	0.047%
0.05	24708	6	0.024%	0.0089%	0.053%
0.05	24708	7	0.028%	0.0114%	0.058%
0.05	24708	8	0.032%	0.0140%	0.064%

This spreadsheet confirms that by having found 8 positive samples from 24,078 cartons tested, confidence limits at 95% are between 0.0140 and 0.064%. This is a low prevalence.

Once the plant was notified that there were presumptive positive results, all manufacturing product destined for grinding from the affected days production was immediately retained, and the New Zealand Ministry of Agriculture and Forestry (MAF) notified.

A review was undertaken of all HACCP and associated processing records from the affected day's production, with no faulty elements identified that could have contributed to an increased incidence of faecal or ingesta contamination due to unhygienic processing.

The records that were reviewed included Boning Room Compliance Check Sheets, Slaughter Floor GMP Sheets, Pre-trim records, Slaughter Floor Compliance Check sheets, Contamination records (AsureQuality), CCP records, ZFT records, Training records of sampler. The records confirmed that the overall plant hygiene performance was meeting the New Zealand and US requirements.

As part of the process for Dargaville ensuring ongoing system integrity, the HACCP plan is subjected to a full annual review by a suitably qualified person, as well as being subjected to ongoing verification from independent government veterinary officials.

National Microbiological Database

New Zealand has in place a world leading national microbiological verification programme called the National Microbiological Database (NMD). In recognition of such in the New Zealand meat hygiene assurance programme, the USDA-FSIS have deemed the NMD programme to be equivalent to the *E. coli* and *Salmonella* testing requirements of the *US Pathogen Reduction /HACCP Final Rule*.

Accumulation by MAF of the data from all premises has allowed development of national performance targets, monitoring of national performance and individual premises on an ongoing basis, and provision of scientific data to support design of HACCP plans.

The NMD national profile demonstrates that under New Zealand's processing conditions and regulatory controls, contamination with generic *E. coli* is low, and detection of *Salmonella* is rare.

Dargaville has been following the NMD programme since it's inception in 1996, and has consistently performed well within the National profiles

Since the commencement of NMD in 1996, samples have been taken from carcasses, primal cuts and bulk manufacturing meat for Salmonella analysis and there have been **no positive detection's**.

In order to comply with the US HACCP legislation, the Dargaville HACCP plan was originally recognised as valid on 23 December 1998. Silver Fern Farms Ltd believes that the HACCP Plan is an integral part of the company systems delivering an acceptable level of food safety protection. The process is dynamic and under ongoing review.

The importance of mesophilic pathogens of enteric origin is highlighted in the raw material and hazard ID section of the HACCP Plan, where biological hazards associated with faecal and ingesta material from the gastrointestinal tract and hide are identified. These hazards also form a significant part of the hazard analysis and CCP determination process.

HACCP Implementation

Silver Fern Farms Ltd Dargaville operates a meat hygiene system that is consistent with the requirements of the Animal Products Act (1999). The slaughter and dressing standards are consistent with the requirements described in Industry Standard 5: Slaughter and Dressing. This is complemented by a validated HACCP plan that focuses on controlling pathogens of enteric origin.

The focus of every processing step in the slaughtering operation is designed as an intervention measure to minimise contamination getting on the product.

Specific operations within the HACCP plan, have been designed to control and minimise the incidence of faecal and ingesta material onto product, they include:

- Washing of cattle in the stockyards
- Washing of anal area post stun and before shackling
- Oesophageal clipping/tying to eliminate ingesta leakage
- Bagging and applying band to control faecal leakage during bunging operation
- Trimming of any identified faecal contamination immediately when it is identified at each operation.
- Sterilisation of knives and equipment between carcasses.
- Highly trained operators.
- Strategically located trimming steps
- Rapid product cooling by implementing validated refrigeration management processes
- Application of a Zero Faecal Tolerance programme to effectively monitor and control faecal contamination during the slaughter and dressing operations

Monitoring of all the operations/procedures outlined above are undertaken throughout the processing day to ensure that they remain effective.

A key component of the HACCP Plan which enhances the Zero Faecal Tolerance Programme is the incorporation into the HACCP Plan of a System CCP consisting of PM Inspection / Detain Trimming / Reinspection. The System CCP is designed to control Faecal/ingesta contamination which may contribute to mesophilic pathogens occurring on product.

To enhance the performance of the ZFT CCP pre-trim has been designated a control point. A pre boning inspection is performed on all carcasses prior to the start of any cutting or boning, to ensure the removal of any visible contamination that might still be present on carcasses after leaving the slaughterfloor.

Monitoring of the System CCP is undertaken repeatedly throughout the day, with verification of all records regarding monitoring frequency, critical limit adherence, and any relevant corrective actions undertaken daily.

Conclusion

Silver Fern Farms Ltd Dargaville contends that the IMS-based methods used in the *E coli 0157:H7* monitoring are sufficiently contemporary and sensitive to enable detection of *E coli 0157:H7* when presented at a level that is unacceptable to the United States.

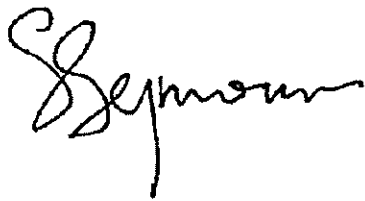
The evidence presented suggests that *E coli 0157:H7* is reasonably unlikely to occur in beef exported to the United States or any other market from Silver Fern Farms Ltd Dargaville, and the results of the ongoing monitoring programme verify this suggestion. Results from the National Microbiological Database clearly indicate that contamination of meat and meat products with faecal material, hence faecal pathogens such as Salmonella and *E. coli 0157:H7*, is minimal without the use of decontamination procedures.

Only product that is compliant with the HACCP requirements and tested negative for *E.coli* O157:H7 is shipped to the United States. This attestation is made to demonstrate that beef supplied to customers in the US from **Silver Fern Farms – Dargaville (ME 125)** meets the requirements of FSIS Notice “*E. coli* O157:H7 Contamination of Beef Products”, 9 CFR Part 417, 7

October 2002 and provides the evidence that *E. coli* O157:H7 is reasonably unlikely to occur in this product.

Silver Fern Farms Ltd will continue to undertake daily verification of the effectiveness of the HACCP Plan especially with regards to targeting *E. coli* O157:H7 as the organism of concern. Should there be any adverse change in the *E. coli* O157:H7 status, Silver Fern Farms Ltd Dargaville will immediately respond in terms of reviewing our systems and requiring further reassessment of our HACCP plans.

Sincerely

A handwritten signature in black ink, appearing to read 'Seymour', with a stylized, cursive script.

Shannon Seymour
North Island Manager Technical and Quality
12th April 2011



INFORMATION SHEET 2011/03 April 2011

Reassessment of the Silver Fern Farms Limited-Hawera (ME9) HACCP plan to determine the likelihood of *E.coli* O157:H7 being a hazard

United States Federal Register Notice (67 FR 62325) 9 CFR, Part 417 Docket Number 00-022N dated 7 October 2002, titled "*E. coli* O157:H7 Contamination of Beef Products" requires all establishments to reassess their HACCP plans with respect to control of *E. coli* O157:H7 based on new information that *E. coli* O157:H7 is more prevalent in the U.S. than previously thought.

Silver Fern Farms Ltd Hawera ME 9 originally reassessed its HACCP Plan in April 2003 to determine whether or not *E. coli* O157:H7 is a hazard that is reasonably likely to occur in beef exported to the United States or any other markets

This letter outlines reassessment of the HACCP Plan relevant to this site from April 2003 until April 2011.

This assessment confirmed *E. coli* O157:H7 is not a hazard reasonably likely to occur in beef meat from premises ME 9.

Our premises ME 9 has participated in the national monitoring programme for *E. coli* O157:H7 for premises exporting beef to the United States since June 1998. The current programme has been accepted by the FSIS as equivalent to US monitoring programmes. Twelve cartons (@27.2kg) of beef are randomly selected each day from each FSIS premise. A composite N60 sample is collected from multiple locations within the selected cartons, and composited (375g) for analysis. All analyses are carried out in laboratories approved and audited by the New Zealand government, and are certified to ISO Guide 17025. Analytical methods meet the requirements of FSIS Directive 10010.1, and include enrichment, screening with AOAC approved BioControl Assurance GDS kits, and isolation using immunomagnetic separation (IMS) procedures.

Plant *E. coli* O157:H7 Data

Since the commencement of *E. coli* O157:H7 sampling in June 1998, until April 2011 there have been 24,376 cartons tested using the above outlined programme.

Over that timeframe there have been 3 composite samples, one of 5 cartons and two of 12 at screen, tested positive for *E. coli* O157:H7. These were confirmed by electrophoresis at ESR in Wellington. While the isolations are significant due to their rarity, we do not believe they are an indicator of inadequate plant performance for the following reasons:

1. ME 9 was operating in accordance with the New Zealand regulatory requirements for slaughter and dressing (IS-5) and boning /refrigeration (IS-6). It has also complied with all US requirements.
2. Of the 24,376 cartons of boneless manufacturing beef tested for E coli 0157:H7 to date at ME 9, approx 0.12% has provided a positive result.

New Zealand, and therefore Silver Fern Farms Ltd Hawera has always used IMS procedures for analyses of E coli O157:H7 from meat and meat products which FSIS introduced as a "new" method only in September 1999.

On the basis of this data using a direct arithmetic calculation on finding 3 positives with this sample size, the proportion rate at Hawera is 0.012%.

However in order to determine the true statistical significance of the results obtained, a comparison was made with the "USDA Table of Probabilities for use in Exploratory Sampling".

At a prevalence of 0.01%, 29,956 samples would be required to detect a single positive at the 95% confidence level. Given the sample size from Hawera i.e. 24,376 cartons, then at the 95% confidence level the expected prevalence is statistically between 0.01 and 0.02%.

Further analysis of the data was undertaken by using a confidence level spreadsheet below originally designed by AgResearch.

**Confidence Intervals: By Neil Cox, AgResearch, Hamilton
(modified by Roger Cook 12/5/00)**

Required signif.level	Total	Num +ve	Proportion	95% Confidence Limits	
				Lower	Upper
0.05	24376	0	0.000%	0.0000%	0.015%
0.05	24376	1	0.004%	0.0001%	0.023%
0.05	24376	2	0.008%	0.0010%	0.030%
0.05	24376	3	0.012%	0.0025%	0.036%

This spreadsheet confirms that by having found three positive samples from 24,376 cartons tested, confidence limits at 95% is between 0.0025%-0.036%. This is an extremely low prevalence.

Upon notification of the presumptive positive results, all manufacturing product destined for grinding from the affected days production was immediately retained, and the New Zealand Ministry of Agriculture and Forestry (MAF) notified.

A review was undertaken of all HACCP and associated processing records from the affected day's production, with no faulty elements identified that could have contributed to an increased incidence of faecal or ingesta contamination due to unhygienic processing

The records that were reviewed included Boning Room Compliance Check Sheets, Slaughter Floor GMP Sheets, Pretrim records, Slaughter Floor Compliance Check sheets, Contamination records (AsureQuality), CCP Records, ZFT records, Training records of Sampler. The records confirmed that the overall plant hygiene performance was meeting the New Zealand and US requirements.

As part of the process for Hawera ensuring ongoing system integrity, the HACCP plan is subjected to a full annual review by a suitably qualified person, as well as being subjected to ongoing verification from independent government veterinary officials.

National Microbiological Database

New Zealand has in place a world leading national microbiological verification programme called the National Microbiological Database (NMD). In recognition of such in the New Zealand meat hygiene assurance programme, the USDA-FSIS have deemed the NMD programme to be equivalent to the *E. coli* and *Salmonella* testing requirements of the *US Pathogen Reduction /HACCP Final Rule*.

Accumulation by MAF of the data from all premises has allowed development of national performance targets, monitoring of national performance and individual premises on an ongoing basis, and provision of scientific data to support design of HACCP plans.

The NMD national profile demonstrates that under New Zealand's processing conditions and regulatory controls, contamination with generic *E. coli* is low, and detection of *Salmonella* is rare.

Hawera has been following the NMD programme since it's inception in 1996, and has consistently performed well within the National profiles. Since the commencement of NMD in 1996, samples have been taken from carcasses, primal cuts and bulk manufacturing meat for *Salmonella* analysis and there have been **no positive detection's**.

HACCP Implementation

In order to comply with the US HACCP legislation, the Hawera HACCP plan was originally recognised as valid on 5th November 1998. Silver Fern Farms Ltd believes that the HACCP Plan is an integral part of the company systems delivering an acceptable level of food safety protection. The process is dynamic and under ongoing review.

The importance of mesophilic pathogens of enteric origin is highlighted in the raw material and hazard ID section of the HACCP Plan, where biological hazards associated with faecal and ingesta material from the gastrointestinal tract and hide are identified. These hazards also form a significant part of the hazard analysis and CCP determination process.

Silver Fern Farms Ltd Hawera operates a meat hygiene system that is consistent with the requirements of the Animal Products Act (1999). The slaughter and dressing standards are consistent with the requirements described in Industry Standard 5: Slaughter and Dressing. This is complemented by a validated HACCP plan that focuses on controlling pathogens of enteric origin.

The focus of every processing step in the slaughtering operation is designed as an intervention measure to minimise contamination getting on the product.

Specific operations within the HACCP plan, have been designed to control and minimise the incidence of faecal material onto product, they include:

- Washing of cattle in the stockyards
- Washing of anal area post stun and before shackling
- Oesophageal clipping/tying to eliminate ingesta leakage

- Bagging and applying band to control faecal leakage during bunging operation
- Trimming of any identified faecal contamination immediately when it is identified at each operation.
- Sterilisation of knives and equipment between carcasses.
- Highly trained operators.
- Strategically located trimming steps
- Application of a Zero Faecal Tolerance programme to effectively monitor and control faecal contamination during the slaughter and dressing operations
- Rapid product cooling by implementing validated refrigeration management processes

Monitoring of all the operations/procedures outlined above are undertaken throughout the processing day to ensure that they remain effective.

A key component of the HACCP Plan which enhances the Zero Faecal Tolerance Programme is the incorporation into the HACCP Plan of a System CCP consisting of PM Inspection / Detain Trimming / Reinspection. The System CCP is designed to control faecal/ingesta contamination which may contribute to mesophilic pathogens occurring on product.

To enhance the performance of the ZFT CCP pre-trim has been designated a control point. A pre-boning inspection is performed on all carcasses prior to the start of any cutting or boning, to ensure the removal of any visible contamination that might still be present on carcasses after leaving the slaughterfloor.

Monitoring of the System CCP is undertaken repeatedly throughout the day, with verification of all records regarding monitoring frequency, critical limit adherence, and any relevant corrective actions undertaken daily.

Conclusion

Silver Fern Farms Ltd Hawera contends that the IMS-based methods used in the *E. coli* 0157:H7 monitoring are sufficiently contemporary and sensitive to enable detection of *E. coli* 0157:H7 when presented at a level that is unacceptable to the United States.

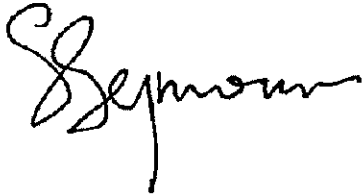
The evidence presented suggests that *E. coli* 0157:H7 is reasonably unlikely to occur in beef exported to the United States or other markets from Silver Fern Farms Ltd Hawera, and the results of the ongoing monitoring programme verify this suggestion. Results from the National Microbiological Database clearly indicate that contamination of meat and meat products with faecal material, hence faecal pathogens such as Salmonella and *E. coli* 0157:H7, is minimal without the use of decontamination procedures.

Only product that is compliant with the HACCP requirements and tested negative for *E. coli* 0157:H7 is shipped to the United States. This attestation is made to demonstrate that beef supplied to customers in the US from **Silver Fern Farms – Hawera (ME 9)** meets the requirements of FSIS Notice “*E. coli* 0157:H7 Contamination of Beef Products”, 9 CFR Part 417, 7 October 2002 and provides the evidence that *E. coli* 0157:H7 is reasonably unlikely to occur in this product.

Silver Fern Farms Ltd will continue to undertake daily verification of the effectiveness of the HACCP Plan especially with regards to targeting *E. coli* 0157:H7 as the organism of concern.

Should there be any adverse change in the E. coli 0157:H7 status, Silver Fern Farms Ltd Hawera will immediately respond in terms of reviewing our systems and requiring further reassessment of our HACCP plan.

Sincerely

A handwritten signature in black ink, appearing to read 'Shannon Seymour', written in a cursive style.

Shannon Seymour
North Island Manager Technical and Quality
12th April 2011



INFORMATION SHEET 2011/04 April 2011

Reassessment of the Silver Fern Farms Limited-Pacific (ME52) HACCP plan to determine the likelihood of *E. coli* O157:H7 being a hazard

United States Federal Register Notice (67 FR 62325) 9 CFR, Part 417 Docket Number 00-022N dated 7 October 2002, titled "*E. coli* O157:H7 Contamination of Beef Products" requires all establishments to reassess their HACCP plans with respect to control of *E. coli* O157:H7 based on new information that *E. coli* O157:H7 is more prevalent in the U.S. than previously thought.

Silver Fern Farms Ltd Pacific ME 52 originally reassessed its HACCP Plan in April 2003 to determine whether or not *E. coli* O157:H7 is a hazard that is reasonably likely to occur in beef exported to the United States or any other markets.

This letter outlines reassessment of the HACCP Plan relevant to this site from April 2003 until April 2011.

This assessment confirmed *E. coli* O157:H7 is not a hazard reasonably likely to occur in beef meat from premises ME 52.

Our premises ME 52 has participated in the national monitoring programme for *E. coli* O157:H7 for premises exporting beef to the United States since June 1998. The current programme has been accepted by the FSIS as equivalent to US monitoring programmes. Twelve cartons (@27.2kg) of beef are randomly selected each day from each FSIS premise. A composite sample N60 is collected from multiple locations within the selected cartons, and composited (375g) for analysis. All analyses are carried out in laboratories approved and audited by the New Zealand government, and are certified to ISO Guide 17025. Analytical methods meet the requirements of FSIS Directive 10010.1, and include enrichment, screening with AOAC approved BioControl Assurance GDS kits, and isolation using immunomagnetic separation (IMS) procedures.

Plant *E. coli* O157 H7 Data

Since the commencement of *E. coli* O157:H7 sampling in June 1998, until April 2010 there have been 23,863 cartons tested using the above outlined programme.

Over that timeframe there has been 2 composite samples (one of 5 cartons and one of 12) at screen tested positive for *E. coli* O157:H7. This was confirmed by electrophoresis at the ESR in Wellington. While the isolations are significant due to their rarity, we do not believe they are an indicator of inadequate plant performance for the following reasons:

1. ME 52 was operating in accordance with the New Zealand regulatory requirements for slaughter and dressing (IS-5) and boning /refrigeration (IS-6). It has also complied with all US requirements.
2. Of the 23,863 cartons of boneless manufacturing beef tested for E coli O157:H7 to date at ME 52, approx 0.07% has provided a positive result.

New Zealand, and therefore Silver Fern Farms Ltd Pacific has always used IMS procedures for analyses of E coli O157:H7 from meat and meat products which FSIS introduced as a "new" method in September 1999.

On the basis of this data using a direct arithmetic calculation on finding 2 positives with this sample size, the proportion rate at Pacific is <0.01%.

However in order to determine the true statistical significance of the results obtained, a comparison was made with the "USDA Table of Probabilities for use in Exploratory Sampling".

At a prevalence of 0.01%, 29,956 samples would be required to detect a single positive at the 95% confidence level. Given the sample size from Pacific i.e. 23,863 cartons, then at the 95% confidence level the expected prevalence is statistically between 0.01 and 0.02%.

Further analysis of the data was undertaken by using a confidence level spreadsheet below originally designed by AgResearch.

**Confidence Intervals: By Neil Cox, AgResearch, Hamilton
(modified by Roger Cook 12/5/00)**

Required signif.level	Total	Num +ve	Proportion	95% Confidence Limits	
				Lower	Upper
0.05	23863	0	0.000%	0.0000%	0.015%
0.05	23863	1	0.004%	0.0001%	0.023%
0.05	23863	2	0.008%	0.0010%	0.030%

This spreadsheet confirms that by having found two positive samples from 23,863 cartons tested, confidence limits at 95% is between 0.0010%-0.030%. This is an extremely low prevalence.

Upon notification of the presumptive positive results, all manufacturing product destined for grinding from both days production was immediately retained, with the New Zealand Ministry of Agriculture and Forestry (MAF) notified.

A review was undertaken of all HACCP and associated processing records from the affected day's production, with no faulty elements identified that could have contributed to an increased incidence of faecal contamination due to unhygienic processing

The records that were reviewed included Boning Room Compliance Check Sheets, Slaughter Floor GMP Sheets, Pretrim records, Slaughter Floor Compliance Check sheets, Contamination records (AsureQuality), CCP Records, ZFT records, Training records of Sampler. The records confirmed that the overall plant hygiene performance was meeting the New Zealand and US requirements.

As part of the process for Pacific ensuring ongoing system integrity, the HACCP plan is subjected to a full annual review by a suitably qualified person, as well as being subjected to ongoing verification from independent government veterinary officials.

National Microbiological Database

New Zealand has in place a world leading national microbiological verification programme called the National Microbiological Database (NMD). In recognition of such in the New Zealand meat hygiene assurance programme, the USDA-FSIS have deemed the NMD programme to be equivalent to the *E. coli* and *Salmonella* testing requirements of the *US Pathogen Reduction /HACCP Final Rule*.

Accumulation by MAF of the data from all premises has allowed development of national performance targets, monitoring of national performance and individual premises on an ongoing basis, and provision of scientific data to support design of HACCP plans.

The NMD national profile demonstrates that under New Zealand's processing conditions and regulatory controls, contamination with generic *E. coli* is low, and detection of *Salmonella* is rare.

Pacific has been following the NMD programme since its inception in 1996, and has consistently performed well within the National profiles.

Since the commencement of NMD in 1996, samples have been taken from carcasses, primal cuts and bulk manufacturing meat for *Salmonella* analysis and there have been **no positive detections**.

HACCP Implementation

In order to comply with the US HACCP legislation, the Pacific HACCP plan was originally recognised as valid on 23 December 1998. Silver Fern Farms Ltd believes that the HACCP Plan is an integral part of the company systems delivering an acceptable level of food safety protection. The process is dynamic and under ongoing review.

The importance of mesophilic pathogens of enteric origin is highlighted in the raw material and hazard ID section of the HACCP Plan, where biological hazards associated with faecal and ingesta material from the gastrointestinal tract and hide are identified. These hazards also form a significant part of the hazard analysis and CCP determination process.

Silver Fern Farms Ltd Pacific operates a meat hygiene system that is consistent with the requirements of the Animal Products Act (1999). The slaughter and dressing standards are consistent with the requirements described in Industry Standard 5: Slaughter and Dressing. This is complemented by a validated HACCP plan that focuses on controlling pathogens of enteric origin.

The focus of every processing step in the slaughtering operation is designed as an intervention measure to minimise contamination getting on the product.

Specific operations within the HACCP plan, have been designed to control and minimise the incidence of faecal material onto product, they include:

- Washing of cattle in the stockyards
- Washing of anal area post stun and before shackling
- Oesophageal clipping/tying to eliminate ingesta leakage
- Bagging and applying band to control faecal leakage during bunging operation
- Trimming of any identified faecal contamination immediately when it is identified at each operation.
- Sterilisation of knives and equipment between carcasses.
- Highly trained operators.

- Strategically located trimming steps
- Application of a Zero Faecal Tolerance programme to effectively monitor and control faecal contamination during the slaughter and dressing operations
- Rapid product cooling by implementing validated refrigeration management processes

Monitoring of all the operations/procedures outlined above are undertaken throughout the processing day to ensure that they remain effective.

A key component of the HACCP Plan which enhances the Zero Faecal Tolerance Programme is the incorporation into the HACCP Plan of a System CCP consisting of PM Inspection / Detain Trimming / Reinspection. The System CCP is designed to control Faecal/ingesta contamination which may contribute to mesophilic pathogens occurring on product.

To enhance the performance of the ZFT CCP pre-trim has been designated a control point. A pre-boning inspection is performed on all carcasses prior to the start of any cutting or boning to ensure the removal of any visible contamination that might still be present on carcasses after leaving the slaughterfloor.

Monitoring of the System CCP is undertaken repeatedly throughout the day, with verification of all records regarding monitoring frequency, critical limit adherence, and any relevant corrective actions undertaken daily.

Conclusion

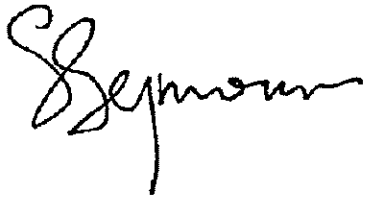
Silver Fern Farms Ltd Pacific contends that the IMS-based methods used in the *E coli 0157:H7* monitoring are sufficiently contemporary and sensitive to enable detection of *E coli 0157:H7* when presented at a level that is unacceptable to the United States.

The evidence presented suggests that *E coli 0157:H7* is reasonably unlikely to occur in beef exported to the United States or other markets from Silver Fern Farms Ltd Pacific, and the results of the ongoing monitoring programme verify this suggestion. Results from the National Microbiological Database clearly indicate that contamination of meat and meat products with faecal material, hence faecal pathogens such as Salmonella and *E. coli 0157:H7*, is minimal without the use of decontamination procedures.

Only product that is compliant with the HACCP requirements and tested negative for *E.coli* O157:H7 is shipped to the United States. This attestation is made to demonstrate that beef supplied to customers in the US from **Silver Fern Farms – Pacific (ME 52)** meets the requirements of FSIS Notice “*E. coli* O157:H7 Contamination of Beef Products”, 9 CFR Part 417, 7 October 2002 and provides the evidence that *E. coli* O157:H7 is reasonably unlikely to occur in this product.

Silver Fern Farms Ltd will continue to undertake daily verification of the effectiveness of the HACCP Plan especially with regards to targeting *E coli 0157:H7* as the organism of concern. Should there be any adverse change in the *E. coli 0157:H7* status, Silver Fern Farms Ltd Pacific will immediately respond in terms of reviewing our systems and requiring further reassessment of our HACCP plans.

Sincerely

A handwritten signature in black ink, appearing to read 'Shannon Seymour'. The signature is fluid and cursive, with the first letter 'S' being particularly large and stylized.

Shannon Seymour
North Island Manager Technical and Quality
12th April 2011



INFORMATION SHEET 2011/05 April 2011

Reassessment of the Silver Fern Farms Limited-Te Aroha (ME84) HACCP plan to determine the likelihood of *E. coli* O157:H7 being a hazard

United States Federal Register Notice (67 FR 62325) 9 CFR, Part 417 Docket Number 00-022N dated 7 October 2002, titled "*E. coli* O157:H7 Contamination of Beef Products" requires all establishments to reassess their HACCP plans with respect to control of *E. coli* O157:H7 based on new information that *E. coli* O157:H7 is more prevalent in the U.S. than previously thought.

Silver Fern Farms Ltd Te Aroha ME 84 originally reassessed its HACCP Plan in April 2003 to determine whether or not *E. coli* O157:H7 is a hazard that is reasonably likely to occur in beef exported to the United States or any other markets.

This letter outlines reassessment of the HACCP Plan relevant to this site from April 2003 until April 2011.

This assessment confirmed *E. coli* O157:H7 is not a hazard reasonably likely to occur in beef meat from premises ME 84.

Our premises ME 84 has participated in the national monitoring programme for *E. coli* O157:H7 for premises exporting beef to the United States since June 1998. The current programme has been accepted by the FSIS as equivalent to US monitoring programmes. Twelve cartons (@27.2kg) of beef are randomly selected each day from each FSIS premise. A composite N60 sample is collected from multiple locations within the selected cartons, and composited (375g) for analysis. All analyses are carried out in laboratories approved and audited by the New Zealand government, and are certified to ISO Guide 17025. Analytical methods meet the requirements of FSIS Directive 10010.1, and include enrichment, screening with AOAC approved BioControl Assurance GDS kits, and isolation using immunomagnetic separation (IMS) procedures.

Plant *E. coli* O157 H7 Data

Since the commencement of *E. coli* O157:H7 sampling in June 1998, until April 2011 there have been 23,184 cartons tested using the above outlined programme.

Over that timeframe there have been 6 composite samples (two of 5 cartons and four of 12) tested positive at screen for *E. coli* O157:H7. This was confirmed by electrophoresis at the ESR in Wellington. While the isolations are significant due to their rarity, we do not believe they are significant as an indicator of inadequate plant performance for the following reasons:

1. ME 84 was operating in accordance with the New Zealand regulatory requirements for slaughter and dressing (IS-5) and boning /refrigeration (IS-6). It has also complied with all US requirements.
2. Of the 23,184 cartons of boneless manufacturing beef tested for E coli O157:H7 to date at ME84, only approx. 0..25% has provided a positive result.

New Zealand, and therefore Silver Fern Farms Ltd Te Aroha has always used IMS procedures for analyses of E coli O157:H7 from meat and meat products which FSIS introduced as a “new” method in September 1999.

On the basis of this data using a direct arithmetic calculation on finding 6 positives with this sample size, the proportion rate at Te Aroha is approx. 0.026%.

However in order to determine the true statistical significance of the results obtained, a comparison was made with the “USDA Table of Probabilities for use in Exploratory Sampling”.

At a prevalence of 0.01%, 29,956 samples would be required to detect a single positive at the 95% confidence level. Given the sample size from Te Aroha i.e. 23,184 cartons, then at the 95% confidence level the expected prevalence is statistically between 0.01 and 0.02%.

Further analysis of the data was undertaken by using a confidence level spreadsheet below originally designed by AgResearch.

**Confidence Intervals: By Neil Cox, AgResearch, Hamilton
(modified by Roger Cook 12/5/00)**

Required signif level	Total	Num +ve	Proportion	95% Confidence Limits	
				Lower	Upper
0.05	23184	0	0.000%	0.0000%	0.016%
0.05	23184	1	0.004%	0.0001%	0.024%
0.05	23184	2	0.009%	0.0010%	0.031%
0.05	23184	3	0.013%	0.0027%	0.038%
0.05	23184	4	0.017%	0.0047%	0.044%
0.05	23184	5	0.022%	0.0070%	0.050%
0.05	23184	6	0.026%	0.0095%	0.056%

This spreadsheet confirms that by having found six positive samples from 23,184 cartons tested, confidence limits at 95% are between 0.0095%-0.056%. This is an extremely low prevalence.

Upon notification of the presumptive positive results, all manufacturing product destined for grinding from the affected days production was immediately retained, and the New Zealand Ministry of Agriculture and Forestry (MAF) notified.

A review was undertaken of all HACCP and associated processing records from the affected days production, with no faulty elements identified that could have contributed to an increased incidence of faecal and ingesta contamination due to unhygienic processing

The records that were reviewed included Boning Room Compliance Check Sheets, Slaughter Floor GMP Sheets, Pretrim records, Slaughter Floor Compliance Check sheets, Contamination records (AsureQuality), CCP Records, Pre-trim CP records, ZFT records, Training records of the Sampler. The records confirmed that the overall plant hygiene performance was meeting the New Zealand and US requirements.

As part of the process for ensuring ongoing system integrity, the HACCP plan is subjected to a full annual review by a suitably qualified person, as well as being subjected to ongoing verification from independent government veterinary officials.

National Microbiological Database

New Zealand has in place a world leading national microbiological verification programme called the National Microbiological Database (NMD). In recognition of such in the New Zealand meat hygiene assurance programme, the USDA-FSIS have deemed the NMD programme to be equivalent to the *E. coli* and *Salmonella* testing requirements of the *US Pathogen Reduction /HACCP Final Rule*.

Accumulation by MAF of the data from all premises has allowed development of national performance targets, monitoring of national performance and individual premises on an ongoing basis, and provision of scientific data to support design of HACCP plans.

The NMD national profile demonstrates that under New Zealand's processing conditions and regulatory controls, contamination with generic *E. coli* is low, and detection of *Salmonella* is rare.

Te Aroha has been following the NMD programme since its inception in 1996, and has consistently performed well within the National profiles.

Since the commencement of NMD in 1996, samples have been taken from carcasses, primal cuts and bulk manufacturing meat for *Salmonella* analysis and there has been one positive detection on 30th January 2009. This is considered to be a rare event, and not indicative of a systemic issue. A comprehensive review of processing records was undertaken, and product restricted from *Salmonella*-sensitive markets.

HACCP Implementation

In order to comply with the US HACCP legislation, the Te Aroha HACCP plan was originally recognised as valid on 2 December 1998. Silver Fern Farms Ltd believes that the HACCP Plan is an integral part of the company systems delivering an acceptable level of food safety protection. The process is dynamic and under ongoing review.

The importance of mesophilic pathogens of enteric origin is highlighted in the raw material and hazard ID section of the HACCP Plan, where biological hazards associated with faecal and ingesta material from the gastrointestinal tract and hide are identified. These hazards also form a significant part of the hazard analysis and CCP determination process.

Silver Fern Farms Ltd Te Aroha operates a meat hygiene system that is consistent with the requirements of the Animal Products Act (1999). The slaughter and dressing standards are consistent with the requirements described in Industry Standard 5: Slaughter and Dressing. This is complemented by a validated HACCP plan that focuses on controlling pathogens of enteric origin.

The focus of every processing step in the slaughtering operation is designed as an intervention measure to minimise contamination getting on the product.

Specific operations within the HACCP plan, have been designed to control and minimise the incidence of faecal material onto product, they include:

- Washing of cattle in the stockyards
- Washing of anal area post stun and before shackling
- Oesophageal clipping/tying to eliminate ingesta leakage
- Bagging and applying band to control faecal leakage during bunging operation
- Trimming of any identified faecal contamination immediately when it is identified at each operation.
- Sterilisation of knives and equipment between carcasses.
- Highly trained operators.
- Strategically located trimming steps
- Application of a Zero Faecal Tolerance programme to effectively monitor and control faecal contamination during the slaughter and dressing operations
- Rapid product cooling by implementing validated refrigeration management processes

Monitoring of all the operations/procedures outlined above are undertaken throughout the processing day to ensure that they remain effective.

A key component of the HACCP Plan which enhances the Zero Faecal Tolerance Programme is the incorporation into the HACCP Plan of a System CCP consisting of PM Inspection / Detain Trimming / Reinspection. The System CCP is designed to control faecal/ingesta contamination which may contribute to mesophilic pathogens occurring on product

To enhance the performance of the ZFT CCP pre-trim has been designated a control point. A pre-boning inspection is performed on all carcasses prior to the start of any cutting or boning, to ensure the removal of any visible contamination that might still be present on carcasses after leaving the slaughterfloor.

Monitoring of the System CCP is undertaken repeatedly throughout the day, with verification of all records regarding monitoring frequency, critical limit adherence, and any relevant corrective actions undertaken daily.

Conclusion

Silver Fern Farms Ltd Te Aroha contends that the IMS-based methods used in the *E coli 0157:H7* monitoring are sufficiently contemporary and sensitive to enable detection of *E coli 0157:H7* when presented at a level that is unacceptable to the United States.

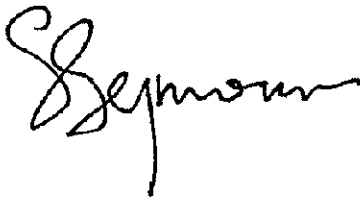
The evidence presented suggests that *E coli 0157:H7* is reasonably unlikely to occur in beef exported to the United States or other markets from Silver Fern Farms Ltd Te Aroha, and the results of the ongoing monitoring programme verify this suggestion. Results from the National Microbiological Database clearly indicate that contamination of meat and meat products with faecal material, hence faecal pathogens such as Salmonella and *E. coli 0157:H7*, is minimal without the use of decontamination procedures.

Only product that is compliant with the HACCP requirements and tested negative for *E.coli* O157:H7 is shipped to the United States. This attestation is made to demonstrate that beef

supplied to customers in the US from **Silver Fern Farms – Te Aroha (ME 84)** meets the requirements of FSIS Notice “*E. coli* O157:H7 Contamination of Beef Products”, 9 CFR Part 417, 7 October 2002 and provides the evidence that *E. coli* O157:H7 is reasonably unlikely to occur in this product.

Silver Fern Farms Ltd will continue to undertake daily verification of the effectiveness of the HACCP Plan especially with regards to targeting *E. coli* O157 H7 as the organism of concern. Should there be any adverse change in the *E. coli* O157 H7 status, Silver Fern Farms Ltd Te Aroha will immediately respond in terms of reviewing our systems and requiring further reassessment of our HACCP plans.

Sincerely

A handwritten signature in black ink, appearing to read 'Shannon Seymour', written in a cursive style.

Shannon Seymour
North Island Manager Technical and Quality
12th April 2011



INFORMATION SHEET 2011/007 June 2011

Reassessment of the Silver Fern Farms - Pareora (ME 34) HACCP plan to determine the likelihood of *E. coli* O157:H7 being a hazard

The HACCP plan for beef produced at Silver Fern Farms - Pareora (ME 34) has been reassessed to determine whether or not *E. coli* O157:H7 is a hazard that is reasonably likely to occur in beef exported to the United States.

The outcome of this reassessment is that *E. coli* O157:H7 is not a hazard reasonably likely to occur in beef meat produced at ME 34.

The USDA-FSIS has deemed the New Zealand HACCP programme to be equivalent to that of the *US Pathogen Reduction/HACCP Final Rule*. The Silver Fern Farms – Pareora (ME 34) HACCP plan follows this programme, which incorporates a number of supporting systems (Pre-requisite Programmes). For example, temperature controls are maintained to prevent any growth of *E. coli* O157:H7 should it occur. Effective, early meat chilling to less than +7°C is applied to all chilled product with vacuum packed chilled product being maintained in the range +1°C to -1.5°C. Frozen product is reduced to -12°C and maintained at or below this temperature.

The HACCP Plan is an integral part of the plant Risk Management Programme which has been independently validated and registered by the New Zealand Food Safety Authority. This HACCP Plan focuses on the controlling of pathogens of enteric origin and many of the processing steps in the slaughtering operation are intervention steps to reduce, eliminate or control the contamination of the carcass with faecal matter and *E. coli* O157:H7. These steps include:

- ◆ Stock washing prior to slaughter to prevent hide to carcass contamination
- ◆ 100% ante-mortem veterinary inspection by the NZFSA Verification Authority
- ◆ Washing of anal area post stunning, as required, to prevent faecal contamination
- ◆ Clipping of oesophagus to eliminate ingesta leakage
- ◆ Bagging during bunning to control faecal leakage
- ◆ Sterilisation of knives and implements between carcasses to reduce cross contamination
- ◆ Specific trimming at designated locations to remove visible contamination
- ◆ Application of a Zero Faecal Tolerance programme to effectively monitor and control faecal contamination during the slaughter and dressing operations

Silver Fern Farms - Pareora (ME 34) has participated in the national monitoring programme for *E. coli* O157:H7 for premises exporting beef to the United States since June 1998. The current programme has been accepted by the FSIS as equivalent to US monitoring programmes. Twelve cartons (@ 27.2kg) of beef are randomly selected each day from each FSIS premise. A composite N60 sample is collected from multiple locations within the selected cartons, and composited (375g) for analysis. All analyses are carried out in laboratories approved and audited by the New Zealand government, Laboratory Approval Scheme and accredited to NZS ISO/IEC 17025:2005. Analytical methods meet the requirements of FSIS Directive 10010.1, and include enrichment, screening with AOAC approved PCR, ELISA and VIA kits, and isolation using immunomagnetic separation (IMS) procedures.



Between the period 25 March 2002 (new facility start up) and 30 May 2011, 4196 samples of manufacturing beef have been tested for the presence of *E. coli* O157:H7 with no *E. coli* O157:H7 being detected. These results indicate that there is a 95% probability that less than 0.08% of product is likely to contain *E. coli* O157:H7, i.e. it is a hazard not reasonably likely to occur.

Only product that is compliant with the HACCP requirements and tested negative for *E. coli* O157:H7 is shipped to the United States. This attestation is made to demonstrate that beef supplied to customers in the US from **Silver Fern Farms - Pareora (ME 34)** meets the requirements of FSIS Notice "*E. coli* O157:H7 Contamination of Beef Products", 9 CFR Part 417, 7 October 2002 and provides the evidence that *E. coli* O157:H7 is reasonably unlikely to occur in this product.

A handwritten signature in black ink, appearing to read "M B Bull".

M B Bull

South Island Manager Technical & Quality

20 June 2011



INFORMATION SHEET 2011/006 June 2011

Reassessment of the Silver Fern Farms - Belfast (ME 15) HACCP plan to determine the likelihood of *E. coli* O157:H7 being a hazard

The HACCP plan for beef produced at **Silver Fern Farms - Belfast (ME 15)** has been reassessed to determine whether or not *E. coli* O157:H7 is a hazard that is reasonably likely to occur in beef exported to the United States.

The outcome of this reassessment is that *E. coli* O157:H7 is not a hazard reasonably likely to occur in beef meat produced at ME 15.

The USDA-FSIS has deemed the New Zealand HACCP programme to be equivalent to that of the *US Pathogen Reduction/HACCP Final Rule*. The premises (ME 15) HACCP plan follows this programme, which incorporates a number of supporting systems (Pre-requisite Programmes). For example, temperature controls are maintained to prevent any growth of *E. coli* O157:H7 should it occur. Effective, early meat chilling to less than +7°C is applied to all chilled product with vacuum packed chilled product being maintained in the range +1°C to -1.5°C. Frozen product is reduced to -12°C and maintained at or below this temperature.

The HACCP Plan is an integral part of the plant Risk Management Programme which has been independently validated and registered by the New Zealand Food Safety Authority. This HACCP Plan focuses on the controlling of pathogens of enteric origin and many of the processing steps in the slaughtering operation are intervention steps to reduce, eliminate or control the contamination of the carcass with faecal matter and *E. coli* O157:H7. These steps include:

- ◆ Stock washing prior to slaughter to prevent hide to carcass contamination
- ◆ 100% ante-mortem veterinary inspection by the NZFSA Verification Authority
- ◆ Washing of anal area post stunning, as required, to prevent faecal contamination
- ◆ Clipping of oesophagus to eliminate ingesta leakage
- ◆ Bagging during bunning to control faecal leakage
- ◆ Sterilisation of knives and implements between carcasses to reduce cross contamination
- ◆ Specific trimming at designated locations to remove visible contamination
- ◆ Application of a Zero Faecal Tolerance programme to effectively monitor and control faecal contamination during the slaughter and dressing operations

Silver Fern Farms - Belfast (ME 15) has participated in the national monitoring programme for *E. coli* O157:H7 for premises exporting beef to the United States since June 1998. The current programme has been accepted by the FSIS as equivalent to US monitoring programmes. Twelve cartons (@ 27.2kg) of beef are randomly selected each day from each FSIS premise. A composite N60 sample is collected from multiple locations within the selected cartons, and composited (375 g) for analysis. All analyses are carried out in laboratories approved and audited by the New Zealand government, Laboratory Approval Scheme and accredited to NZS ISO/IEC 17025:2005. Analytical methods meet the requirements of FSIS Directive 10010.1, and include enrichment, screening with AOAC approved PCR, ELISA and VIA kits, and isolation using immunomagnetic separation (IMS) procedures.



Between the period 15 July 1998 and 31 May 2011, 18,990 samples of manufacturing beef have been tested for the presence of *E. coli* O157:H7 with no *E. coli* O157:H7 being detected. These results indicate that there is a 95% probability that less than 0.02% of product is likely to contain *E. coli* O157:H7 i.e. it is a hazard not reasonably likely to occur.

Upon notification of the presumptive positive results all manufacturing product from the affected day's production was immediately retained and the New Zealand Food Safety Authority notified. A review of all HACCP and associated processing records from the affected day's production was undertaken, in which no faulty elements that could have contributed to an increased incidence of faecal or ingesta contamination were identified.

Only product that is compliant with the HACCP requirements and tested negative for *E. coli* O157:H7 is shipped to the United States. This attestation is made to demonstrate that beef supplied to customers in the US from **Silver Fern Farms - Belfast (ME 15)** meets the requirements of FSIS Notice "*E. coli* O157:H7 Contamination of Beef Products", 9 CFR Part 417, 7 October 2002 and provides the evidence that *E. coli* O157:H7 is reasonably unlikely to occur in this product.

A handwritten signature in black ink, appearing to read "M B Bull".

M B Bull

South Island Manager Technical & Quality

20 June 2011



INFORMATION SHEET 2011/09 June 2011

Reassessment of the Silver Fern Farms Limited-Finegand (ME26) HACCP plan to determine the likelihood of *E.coli* O157:H7 being a hazard

United States Federal Register Notice (67 FR 62325) 9 CFR, Part 417 Docket Number 00-022N dated 7 October 2002, titled "*E. coli* O157:H7 Contamination of Beef Products" requires all establishments to reassess their HACCP plans with respect to control of *E. coli* O157:H7 based on new information that *E. coli* O157:H7 is more prevalent in the U.S. than previously thought.

Silver Fern Farms Ltd Finegand ME26 originally reassessed its HACCP Plan in April 2003 to determine whether or not *E. coli* O157:H7 is a hazard that is reasonably likely to occur in beef exported to the United States or any other markets

This letter outlines reassessment of the HACCP Plan relevant to this site from April 2003 until June 2011.

This assessment confirmed *E. coli* O157:H7 is not a hazard reasonably likely to occur in beef meat from premises ME26.

Our premises ME26 has participated in the national monitoring programme for *E. coli* O157:H7 for premises exporting beef to the United States since June 1998. The current programme has been accepted by the FSIS as equivalent to US monitoring programmes. Twelve cartons (@27.2kg) of beef are randomly selected each day from each FSIS premise. A composite N60 sample is collected from multiple locations within the selected cartons, and composited (375g) for analysis. All analyses are carried out in laboratories approved and audited by the New Zealand government, and are certified to ISO Guide 17025. Analytical methods meet the requirements of FSIS Directive 10010.1, and include enrichment, screening with AOAC approved BioControl Assurance GDS kits, and isolation using immunomagnetic separation (IMS) procedures.

Plant *E. coli* O157 H7 Data

Since the commencement of *E. coli* O157:H7 sampling in June 1998, until April 2011 there have been 24,376 cartons tested using the above outlined programme.

Over that timeframe there have been 3 composite samples, one of 5 cartons and two of 12 at screen, tested positive for *E. coli* O157:H7. These were confirmed by electrophoresis at ESR in Wellington. While the isolations are significant due to their rarity, we do not believe they are an indicator of inadequate plant performance for the following reasons:

1. ME26 was operating in accordance with the New Zealand regulatory requirements for slaughter and dressing (IS-5) and boning /refrigeration (IS-6). It has also complied with all US requirements.
2. Of the 12,941 cartons of boneless manufacturing beef tested for E coli O157:H7 to date at ME26, approx 0.09% has provided a positive result.

New Zealand, and therefore Silver Fern Farms Ltd Finegand has always used IMS procedures for analyses of E coli O157:H7 from meat and meat products which FSIS introduced as a "new" method only in September 1999.

On the basis of this data using a direct arithmetic calculation on finding 1 positive with this sample size, the proportion rate at Finegand is 0.008%.

However in order to determine the true statistical significance of the results obtained, a comparison was made with the "USDA Table of Probabilities for use in Exploratory Sampling".

At a prevalence of 0.01%, 29,956 samples would be required to detect a single positive at the 95% confidence level. Given the sample size from Finegand i.e. 12,941 cartons, then at the 95% confidence level the expected prevalence is statistically between 0.02 and 0.03%.

Further analysis of the data was undertaken by using a confidence level spreadsheet below originally designed by AgResearch.

**Confidence Intervals: By Neil Cox, AgResearch, Hamilton
(modified by Roger Cook 12/5/00)**

Required signif level	Total	Num +ve	Proportion	95% Confidence Limits	
				Lower	Upper
0.05	12941	0	0.000%	0.0000%	0.029%
0.05	12941	1	0.008%	0.0002%	0.043%

This spreadsheet confirms that by having found one positive sample from 12,941 cartons tested, confidence limits at 95% is between 0.0002%-0.043%. This is an extremely low prevalence.

Upon notification of the presumptive positive results, all manufacturing product destined for grinding from the affected days production was immediately retained, and the New Zealand Ministry of Agriculture and Forestry (MAF) notified.

A review was undertaken of all HACCP and associated processing records from the affected day's production, with no faulty elements identified that could have contributed to an increased incidence of faecal or ingesta contamination due to unhygienic processing

The records that were reviewed included Boning Room Compliance Check Sheets, Slaughter Floor GMP Sheets, Pretrim records, Slaughter Floor Compliance Check sheets, Contamination records (ASUREQuality), CCP Records, ZFT records, Training records of Sampler. The records confirmed that the overall plant hygiene performance was meeting the New Zealand and US requirements.

As part of the process for Finegand ensuring ongoing system integrity, the HACCP plan is subjected to a full annual review by a suitably qualified person, as well as being subjected to ongoing verification from independent government veterinary officials.

National Microbiological Database

New Zealand has in place a world leading national microbiological verification programme called the National Microbiological Database (NMD). In recognition of such in the New Zealand meat hygiene assurance programme, the USDA-FSIS have deemed the NMD programme to be equivalent to the *E. coli* and *Salmonella* testing requirements of the *US Pathogen Reduction /HACCP Final Rule*.

Accumulation by MAF of the data from all premises has allowed development of national performance targets, monitoring of national performance and individual premises on an ongoing basis, and provision of scientific data to support design of HACCP plans.

The NMD national profile demonstrates that under New Zealand's processing conditions and regulatory controls, contamination with generic *E. coli* is low, and detection of *Salmonella* is rare.

Finegand has been following the NMD programme since its inception in 1996, and has consistently performed well within the National profiles.

Since the commencement of NMD in 1996, samples have been taken from carcasses, primal cuts and bulk manufacturing meat for *Salmonella* analysis and there have been **no positive detection's**.

HACCP Implementation

In order to comply with the US HACCP legislation, the Finegand HACCP plan was originally recognised as valid on 5th November 1998. Silver Fern Farms Ltd believes that the HACCP Plan is an integral part of the company systems delivering an acceptable level of food safety protection. The process is dynamic and under ongoing review.

The importance of mesophilic pathogens of enteric origin is highlighted in the raw material and hazard ID section of the HACCP Plan, where biological hazards associated with faecal and ingesta material from the gastrointestinal tract and hide are identified. These hazards also form a significant part of the hazard analysis and CCP determination process.

Silver Fern Farms Ltd Finegand operates a meat hygiene system that is consistent with the requirements of the Animal Products Act (1999). The slaughter and dressing standards are consistent with the requirements described in Industry Standard 5: Slaughter and Dressing. This is complemented by a validated HACCP plan that focuses on controlling pathogens of enteric origin.

The focus of every processing step in the slaughtering operation is designed as an intervention measure to minimise contamination getting on the product.

Specific operations within the HACCP plan, have been designed to control and minimise the incidence of faecal material onto product, they include:

- Washing of cattle in the stockyards
- Washing of anal area post stun and before shackling
- Oesophageal clipping/tying to eliminate ingesta leakage

- Bagging and applying band to control faecal leakage during bunging operation
- Trimming of any identified faecal contamination immediately when it is identified at each operation.
- Sterilisation of knives and equipment between carcasses.
- Highly trained operators.
- Strategically located trimming steps
- Application of a Zero Faecal Tolerance programme to effectively monitor and control faecal contamination during the slaughter and dressing operations
- Rapid product cooling by implementing validated refrigeration management processes

Monitoring of all the operations/procedures outlined above are undertaken throughout the processing day to ensure that they remain effective.

A key component of the HACCP Plan which enhances the Zero Faecal Tolerance Programme is the incorporation into the HACCP Plan of a System CCP consisting of PM Inspection / Detain Trimming / Reinspection. The System CCP is designed to control faecal/ingesta contamination which may contribute to mesophilic pathogens occurring on product.

To enhance the performance of the ZFT CCP pre-trim has been designated a control point. A pre-boning inspection is performed on all carcasses prior to the start of any cutting or boning, to ensure the removal of any visible contamination that might still be present on carcasses after leaving the slaughterfloor.

Monitoring of the System CCP is undertaken repeatedly throughout the day, with verification of all records regarding monitoring frequency, critical limit adherence, and any relevant corrective actions undertaken daily.

Conclusion

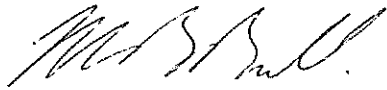
Silver Fern Farms Ltd Finegand contends that the IMS-based methods used in the *E. coli* O157:H7 monitoring are sufficiently contemporary and sensitive to enable detection of *E. coli* O157:H7 when presented at a level that is unacceptable to the United States.

The evidence presented suggests that *E. coli* O157:H7 is reasonably unlikely to occur in beef exported to the United States or other markets from Silver Fern Farms Ltd Finegand, and the results of the ongoing monitoring programme verify this suggestion. Results from the National Microbiological Database clearly indicate that contamination of meat and meat products with faecal material, hence faecal pathogens such as Salmonella and *E. coli* O157:H7, is minimal without the use of decontamination procedures.

Only product that is compliant with the HACCP requirements and tested negative for *E. coli* O157:H7 is shipped to the United States. This attestation is made to demonstrate that beef supplied to customers in the US from **Silver Fern Farms – Finegand (ME26)** meets the requirements of FSIS Notice “*E. coli* O157:H7 Contamination of Beef Products”, 9 CFR Part 417, 7 October 2002 and provides the evidence that *E. coli* O157:H7 is reasonably unlikely to occur in this product.

Silver Fern Farms Ltd will continue to undertake daily verification of the effectiveness of the HACCP Plan especially with regards to targeting *E. coli* O157:H7 as the organism of concern.

Should there be any adverse change in the E. coli 0157:H7 status, Silver Fern Farms Ltd Finegand will immediately respond in terms of reviewing our systems and requiring further reassessment of our HACCP plan.



M B Bull

South Island Manager Technical & Quality

20 June 2011