

# Reassessment of the Top 7 STEC and HACCP Plan for Silver Fern Farms Limited- Hawera (ME9) for adult cattle

## August 2023

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United States regulation (9 CFR 417) regards a hazard that occurs and is not controlled by a CCP as being an unforeseen hazard. United States regulation requires the corrective actions to include a reassessment of the hazard analysis whenever an unforeseen hazard occurs. This document is a reassessment of the HACCP plan and Top 7 STEC (O157:H7, O26, O45, O103, O111, O121 and O145) prevalence to determine whether Top 7 STEC is a hazard considered likely to occur at Silver Fern Farms Limited Hawera.

**Silver Fern Farms Ltd Hawera** originally reassessed its HACCP Plan in April 2003 to determine whether or not Top 7 STECs are a hazard that is reasonably likely to occur in beef exported to the United States. This letter outlines reassessment of the HACCP Plan relevant for this site from then until August 2023.

This assessment confirmed the Top 7 are not a hazard reasonably likely to occur in beef meat from premises ME9.

Our facility ME9 participates in the national monitoring programme for STEC's for premises exporting beef to the United States (*E.coli* O157:H7 since June 1998, and the additional six other serogroups since June 2012). 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 listed 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 STEC prevalence Data

Since the commencement of *E.coli* O157:H7 sampling in June 1998, until August 2023 there have been 57,496 cartons tested using the above outlined programme.

Over that timeframe there have been 14 composite samples (one of 5 cartons and thirteen of 12) cartons at screen, tested positive for *Shiga Toxin-producing E.coli*. 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. ME9 was operating in accordance with the New Zealand regulatory requirements for slaughter and dressing (Code of Practice 5) and boning /refrigeration (Code of Practice 9). It has also complied with all US requirements.
2. Of the 57,496 cartons of boneless manufacturing beef tested to date at ME9, approx 0.28% have provided a positive result.

On the basis of this data using a direct arithmetic calculation on finding 14 positives within this sample size, the proportion rate at Hawera is 0.024%.

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 ME9 i.e. 57,496 cartons, then at the 95% confidence level the expected prevalence is statistically less than 0.01%.

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	57496	0	0.000%	0.000%	0.006%
0.05	57496	1	0.002%	0.000%	0.010%
0.05	57496	2	0.003%	0.000%	0.013%
0.05	57496	3	0.005%	0.001%	0.015%
0.05	57496	4	0.007%	0.002%	0.018%
0.05	57496	5	0.009%	0.003%	0.020%
0.05	57496	6	0.010%	0.004%	0.023%
0.05	57496	7	0.012%	0.005%	0.025%
0.05	57496	7	0.012%	0.005%	0.025%
0.05	57496	8	0.014%	0.006%	0.027%
0.05	57496	9	0.016%	0.007%	0.030%
0.05	57496	10	0.017%	0.008%	0.032%
0.05	57496	11	0.019%	0.010%	0.034%
0.05	57496	12	0.021%	0.011%	0.036%
0.05	57496	13	0.023%	0.012%	0.039%
0.05	57496	14	0.024%	0.013%	0.041%

This spreadsheet confirms that by having found 14 positive samples from 57,496 cartons tested, confidence limits at 95% is between 0.013%-0.041%. This is an extremely low prevalence.

**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 NZ MPI 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.

ME9 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 ME9 HACCP plan was originally recognised as valid on 5<sup>th</sup> 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.

ME9 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 slaughter and dressing (Code of Practice 5). 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.
- Use of steam vacuum on targeted regions of the carcass according to good operational practices
- 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.

## **Product Disposition, Corrective and Preventative Action**

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 for Primary Industries (NZMPI) 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 Process Control Sheets, Slaughter Floor Process Control Sheets, Pre trim control point records, Contamination records (AsureQuality), CCP Records, ZFT records and Training records of Samplers. The records confirmed that the overall plant hygiene performance was meeting the New Zealand and US requirements.

As part of the process for ME9 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.

## **Conclusion**

Silver Fern Farms Ltd – Hawera (ME9) contends that the analytical methods used in the monitoring programme are sufficiently contemporary and sensitive to enable detection of Top 7 STEC's when presented at a level that is unacceptable to the United States.

The evidence presented suggests that Top 7 STEC's are reasonably unlikely to occur in beef exported to the United States. ME9, 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 Top 7 STEC's are minimal without the use of carcass interventions.

Only product that is compliant with the HACCP requirements and tested negative for Top 7 are shipped to the United States. This attestation is made to demonstrate that beef supplied to customers in the US from **Silver Fern Farms – Hawera (ME9)** meets the requirements of FSIS Notice "E. coli O157:H7 Contamination of Beef Products", 9 CFR Part 417, 7 October 2002 and US Department of Agriculture Food Safety Inspection Service proposed rule "Shiga Toxin-Producing Escherichia coli in Certain Raw Beef Products" (Federal Register Volume 76, Number 182, September 20, 2011) and provides the evidence that Top 7 STEC's are 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 Top 7 STEC's as the organisms of concern. Should there be any adverse change in the *E.coli*, ME9 will immediately respond in terms of reviewing our systems and requiring further reassessment of our HACCP plan.

This reassessment letter is on-going and valid through until the end of August 2024.

Sincerely

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

Shannon Love  
**Market Access Manager**  
**Silver Fern Farms Ltd**  
15<sup>th</sup> August 2023