



Final Report – Cost benefit analysis of molecular method for detection or confirmation of Shiga toxin producing *Escherichia coli*

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Executive Summary

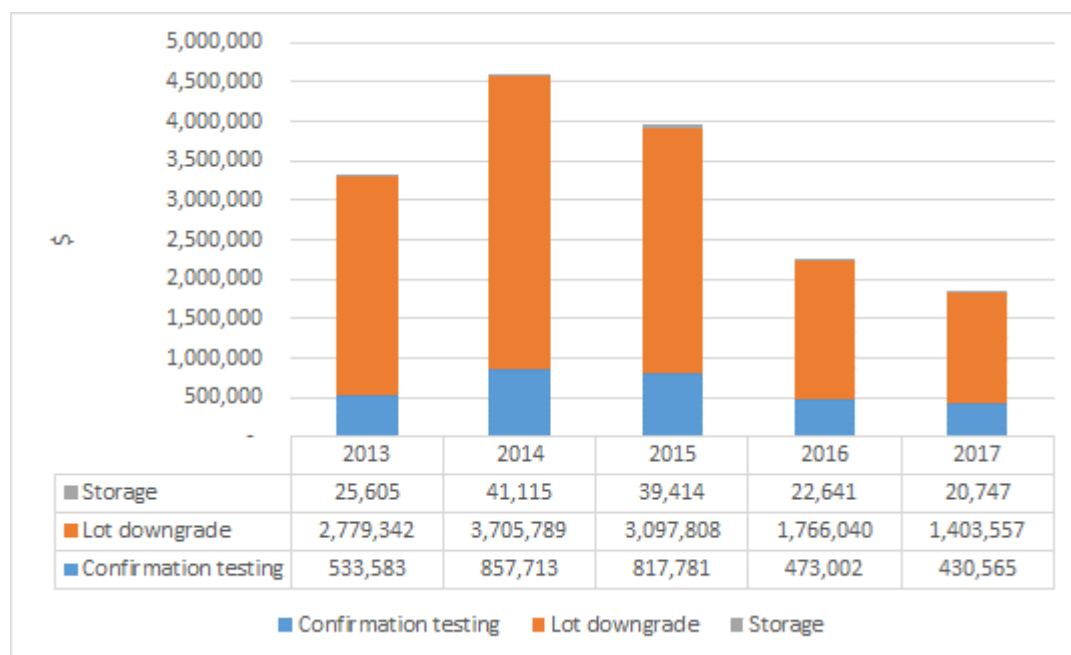
There is an agreement between the Australian and US governments that require testing for *Escherichia coli* O157:H7 in all lots of manufacturing beef exported to the USA, and by extension also to Canada (North America). There are six other serotypes of Shiga toxin-producing *E. coli* (STEC - O26, O45, O103, O111, O121 and O145) that are subject to regulation in the USA and many Australian exporters choose to test their product for these 'big 6' STEC. If product is found to contain these strains then they are treated in the same way as product containing O157. Both the US and Canada undertake port-of-entry testing. Other major export markets (including Japan, South Korea and European Union) also undertake port-of-entry testing for differing lists of STEC strains, with some Australian beef abattoirs undertaking routine O157:H7 testing of lots destined for these markets.

The current confirmatory test method used in Australia is a culture isolation method (FSIS-MLG 5B.05). However, a molecular method developed by Neogen, called NeoSeek, has also been approved for STEC confirmation testing by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) and provides a potential opportunity for reducing costs and/or improving product assurance.

The **average annual cost** (2013-2017) of STECs for the Australian beef industry, apart from mandatory and pre-emptive STEC screening (pre-confirmation testing), is **\$3.2 million** (Figure 1), with:

- The **majority of the cost (80%) from confirmed positive lots being downgraded** in value
- Confirmation testing 19% of the cost with associated storage costs less than 1%
- 90% of the total cost for manufacturing beef being exported to North America (US and Canada).

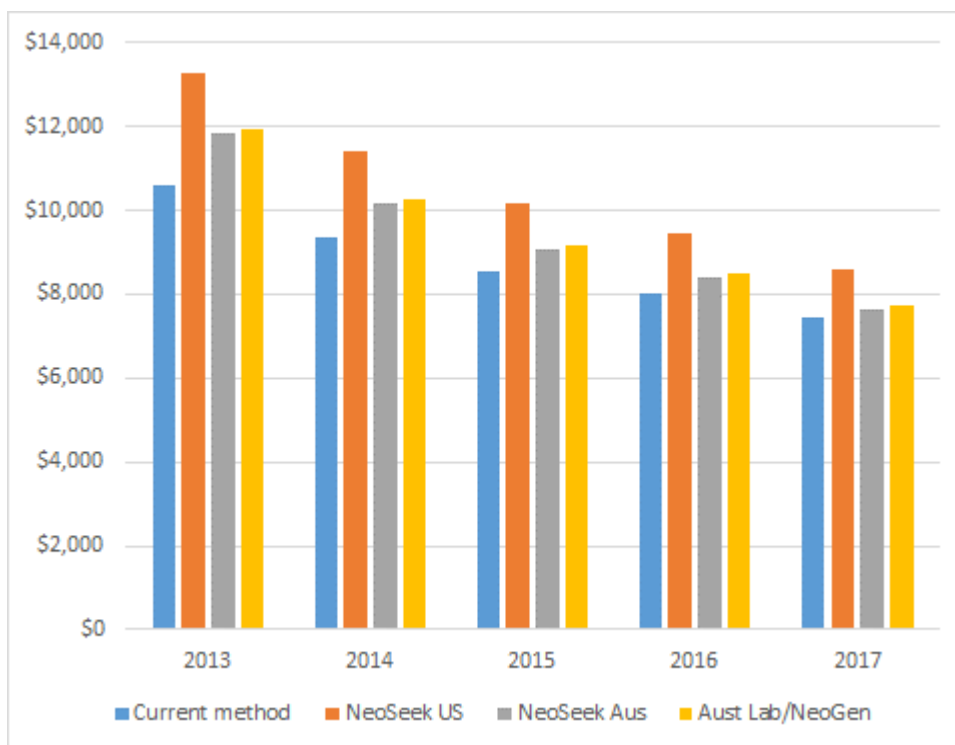
Figure 1: Cost of STEC for Australian beef industry



The **current confirmation test method** for all 7 STECs **has served the Australian industry well** in regards to no STEC-positive lots being found through North American port of entry testing over the past five years. If Australia adopted the NeoSeek confirmation test method:

- The **confirmation testing costs** would **decrease**
- There would be **increased costs through more downgraded lots** (estimated to be 33-48%, as a result of more confirmed positives)
- **Overall** the costs would **increase by 7-21%** (Figure 2), equating to **\$203,366-\$596,587/annum**.

Figure 2: Total cost (testing cost, storage cost, lot downgrade cost) per confirmation test for current method and three potential NeoSeek test method options



FSIS are looking to shift from the current culture based method (FSIS-MLGB.05) to a molecular method (e.g. NeoSeek) and **it is thought that within five years US port of entry confirmation testing will have shifted to a molecular method**. The New Zealand bobby calf and veal industry have recently moved to NeoSeek to guarantee market assurance and future proof their product.

The recommendations for the Australian industry (including MLA, AMPC, beef abattoirs, DAWR, commercial laboratories, CSIRO) are as follows:

- Continue to reduce STEC prevalence through adoption of best practice holistic carcass management and specific antimicrobial interventions.
- In the short term, continue with current screening and confirmation methods and don't transition to NeoSeek method.

- Work closely with FSIS to know when FSIS will shift from current method to molecular method and plan timeframe for shifting Australia's test method accordingly.
- Leverage and collaborate with FSIS transition process and the NeoSeek method, being used by NZ, as much as possible.
- Examine the opportunity, feasibility and requirement for Australian laboratory to undertake part (i.e. front end of testing) or all of molecular method 1-2 years prior to anticipated FSIS shift. This would involve dialogue between DAWR, MLA, Australian commercial laboratories, NeoGen and CSIRO. This would include adapting molecular method to have suitable specificity and sensitivity for Australian STEC strains.

Contents

Executive Summary	2
Contents	5
1 Introduction	6
1.1 Background	6
2 Objectives	6
3 Methodology	8
3.1 Industry consultation	8
3.2 Costs related to STECs	8
3.3 Comparison of current confirmation test method with Neoseek	9
4 Results & Discussion	12
4.1 Whole of industry costs related to STECs	12
4.2 All 7 STEC testing – current and NeoSeek	13
4.3 Comparison of costs for individual abattoirs	20
4.4 Potential benefits of reduced risk or increased assurance with NeoSeek	20
4.5 Regulatory and laboratory considerations	21
4.6 Handling of lots that are confirmed positive	22
5 Summary and recommendations	22
6 Appendix	24
6.1 List of Tables	24
6.2 List of figures	24

1 Introduction

1.1 Background

There is an agreement between the Australian and US governments that require testing for *Escherichia coli* O157:H7 in all lots of manufacturing beef exported to the USA, and by extension also to Canada (North America). There are six other serotypes of Shiga toxin-producing *E. coli* (STEC - O26, O45, O103, O111, O121 and O145) that are subject to regulation in the USA and many Australian exporters choose to test their product for these 'big 6' STEC. If product is found to contain these strains then they are treated in the same way as product containing O157. Both the US and Canada undertake port-of-entry testing. Other major export markets (including Japan, South Korea and European Union) also undertake port-of-entry testing for differing lists of STEC strains, with some Australian beef abattoirs undertaking routine O157:H7 testing of lots destined for these markets.

The current practice of the Australian beef industry has resulted in a low prevalence of STECs in Australian manufacturing beef lots, which has decreased since 2013 (Figure 5 and Figure 6). This has been due, in part, to the successful holistic management of beef carcasses, from handling of livestock pre-slaughter all the way to delivery of product to destination market.

Due to the STEC screening and confirmation testing program in place, there have been no port-of-entry rejections of STEC in Australian product or subsequent rejections, from any export markets in the past few years. The current testing procedure involves a screening test. Any samples that are positive from this test (potential positives) are submitted to a secondary confirmatory testing (which occurs in two stages).

The current confirmatory test method used in Australia is a culture isolation method (FSIS-MLG 5B.05). However, a molecular method developed by Neogen, called NeoSeek, has also been approved for STEC confirmation testing by the United States Department of Agriculture's Food Safety and Inspection Service (FSIS) and provides a potential opportunity for reducing costs and/or improving product assurance.

2 Objectives

The objectives of the project were as follows:

1. Utilisation of information supplied by MLA to undertake a desktop costing of
 - current testing
 - current product markdowns/rejections as a result of current positive tests
 - potential impact of new testing system on testing costs, positive test rates, product markdowns, product rejections, and market access.
2. Industry consultation to determine opportunities, barriers and strategies for working collaboratively with the Australian meat industry, and relevant regulatory bodies, in rolling out and implementing the new test.
3. Development and supply of Excel model to MLA, to allow MLA to undertake future modelling based on multiple scenarios
4. Cost benefit analysis of the spray chiller intervention system using ClO₂ or peroxyacetic acid.

Objective 4 was achieved in the project Milestone 1 report¹.

¹ V.MFS.0424 – Milestone 1 Report: Cost benefit analysis of spray chilling intervention

3 Methodology

3.1 Industry consultation

The process of data and information collection, as well as current and potential operational considerations and opportunities, was undertaken by communicating with:

- MLA
- CSIRO
- Department of Agriculture and Water Resources (DAWR)
- Five abattoirs
- Two major Australian beef processing companies
- Major commercial provider of STEC confirmation testing
- Major New Zealand beef processing company
- Ministry of Primary Industries (MPI) NZ.

3.2 Costs related to STECs

The three major areas of cost considered in this report are the testing of potential positives (confirmation testing), the downgrade of lots that are confirmed positive and the costs associated with storage of product whilst awaiting results of confirmation testing.

In brief the process for STEC testing is as follows:

- For manufacturing beef being sent to US or Canada, testing of each lot (350 or 700 cartons) are tested for all 7 STECs using a screening test method (BAX [Hygiena] or Assurance GDS [BioControl]). If this test gives a positive (potential positive) then sample is submitted for a confirmation test (all 7 STECs).
- For manufacturing beef sent to other export markets (which are predominantly Japan and Korea), testing of the majority of lots (not mandatory) are tested for O157:H7 using screening test method. If this test gives a positive (potential positive) then sample is submitted for a confirmation test (O157:H7 only).
- If any lots are confirmed positive for any STEC (O157:H7 or any of other 6) then they are heat treated and sold to a market in which price is approximately 50% of non-heat treated product.

The ratio of prevalence for O157:H7 and non-O157 STECs is similar (Figure 5).

The source numbers used for the calculation of STEC costs are based on 2013-2017 STEC testing data from DAWR (included screening test #, confirmation test #, confirmed positive # for both O157:H7 and non- O157:H7 STECs) and values summarised in Table 1.

Table 1: Australian beef industry information related to STEC costs

Parameter	Value	Source	Assumptions/comments
Average annual kgs sent to North America for manufacturing	256,496,618	MLA statistics download	
Average annual kgs sent to other export markets for manufacturing	131,578,794	MLA statistics download	
Average cattle slaughter in	8,091,195	DAWR	
Estimated % of trim sent to North America for manufacturing to total trim	34.7%		300kg HCW; 30% of HCW is trim. Volume sent to North America for manufacturing divided by estimated total trim produced from export plants.
Average price (\$/kg) of manufacturing beef sent to North America	5.21	MLA statistics download	
Estimated % of trim sent to other export countries for manufacturing to total trim	18.4%		300kg HCW; 30% of HCW is trim. Volume sent to other export markets for manufacturing divided by
% 350 carton lots to North America	84.0%		Based on number of all 7 STEC testing and volumes of manufacturing beef
% 700 carton lots to North America	16.0%		Based on number of all 7 STEC testing and volumes of manufacturing beef
Screening test cost (\$/test)	100	Commercial laboratory	
Confirmation testing cost - all 7	1900	Commercial laboratory	average price
Storage time required awaiting confirmation test - days	3.5	Commercial laboratory	2-5 days (average of 3) for test; 0-1 day to transport sample to laboratory (average of 0.5)
Storage cost whilst awaiting confirmation test results (\$/carton/day)	0.065	Abattoirs/processing companies	35% of industry have no storage cost due to their lot transport system; 65% of industry have storage cost of \$0.10
O157:H7 confirmation testing cost	300	Commercial laboratory	

3.3 Comparison of current confirmation test method with NeoSeek

Table 2 provides a comparison of the current all 7 STEC confirmation test (for potential positive lots produced for North American market) with the NeoSeek test method. Three NeoSeek scenarios are presented, one (abbreviated as 'NeoSeek US') based on system being used by New Zealand bobby calf and veal industry² and two potential future options where either the NeoSeek test is undertaken completely in Australia through NeoGen's GeneSeek Australasia facility (Gatton, Queensland; abbreviated as 'NeoSeek Australia') or the front end component of test is undertaken in non-NeoGen Australian laboratory and data sent to NeoGen for analysis (abbreviated as 'Aust Lab/NeoGen' in text). Other relevant information used in the calculations is detailed as follows:

- 'NeoSeek US' method calculated to have an extra 2.5 days (6-3.5) of storage for potential positives lots awaiting confirmation test result
 - 3.5 days (current method average – including test time and sample transport time)
 - NeoSeek method – 6 day average (4.5 day for transport of DNA sample to Nebraska + 1.5 [1-2] days for testing/results; 6 day average received from New Zealand beef processor)
- 'NeoSeek Australia'³ and 'Aust Lab/NeoGen' method calculated to save 2 days (3.5-1.5) of storage for potential positives lots awaiting confirmation test result

² For detailed description see pages 14-17 of V.MFS.0403 Seminar Report – STEC in manufacturing beef: Where have we been? Where should we be going? 5-6 June 2017.

³ <http://www.neogen.com/en/neogen-acquires-australian-animal-genomics-laboratory>

- 3.5 days (current method average – including test time and sample transport time)
- NeoSeek method – 1.5 days (including test time and sample transport time)
- Capital cost for NeoSeek front end to be setup in non-NeoGen Australian laboratory
 - \$500,000 – based on discussion with commercial laboratory and CSIRO
 - 10 year depreciation
 - 7% discount rate.
- Increased confirmed positives
 - MPI NZ undertook a trial involving culture vs NeoSeek comparison of spiked and “real” enrichment samples (~2,500 analyses) and saw 48% increase in confirmed positives with NeoSeek method.
 - CSIRO undertook a trial involving culture vs NeoSeek comparison (100 samples) and saw 33% increase (16/12) in confirmed positives with NeoSeek method.⁴

Table 2: Comparison of current confirmation test method and NeoSeek method

	Current method	NeoSeek US	NeoSeek Australia	Aust Lab/NeoGen	Source of information and assumptions
Method type	culture based isolation	non-culture; molecular	non-culture; molecular	non-culture; molecular	
Approved by FSIS	yes	yes	no	no	
Used by FSIS at port of entry	yes	no		no	
Test cost - \$AU/test	\$1,900	\$360	\$300	\$360	Current method - based on discussion with major commercial laboratory provider (average figure, there is a range). NeoSeek US - based on \$400 New Zealand, following discussion with New Zealand Ministry of Primary Industries (MPI). NeoSeek Australia reduced freight cost. Aust Lab/NeoGen - reduced freight cost but \$500,000 capital outlay for Australian laboratory will require a front end test cost similar to total test cost supplied by NeoGen.
Turnaround on results from laboratory receipt of sample - days	2-5 (average of 3)	1-2 (average 1.5)	1	1	Current method - based on discussion with major commercial laboratory provider (can have negative results by 2 or 3 days). NeoSeek - based on discussion with MPI and NZ beef processor.
Delivery time of sample to laboratory - days	0-1 (average of 0.5)	4.5 (average)	0-1 (average of 0.5)	0-1 (average of 0.5)	NeoSeek - based on discussion with NZ beef processor.
Place of testing	Australian-based commercial laboratories	GeneSeek Operations - Lincoln, Nebraska, USA	GeneSeek Australasia - Gatton, Queensland	Australian-based commercial laboratory	Neoseek - MPI.
Place of analysis of front end test results	Australian-based commercial laboratories	GeneSeek Operations - Lincoln, Nebraska, USA	GeneSeek Australasia - Gatton, Queensland	GeneSeek Operations - Lincoln, Nebraska, USA	Neoseek - MPI.
Sample tested	culture	DNA	DNA	DNA	Neoseek - MPI.
Estimated increase in confirmed positives	0%	48%	33%	33%	48% is based on evaluation of current method vs NeoSeek by MPI. 33% is based on trial undertaken by CSIRO.

The situation for four specific abattoirs (Table 3) under current confirmation test method and under the NeoSeek test method ('NeoSeek US') were considered. The costings were based on actual data for confirmation testing and downgraded lots (reflected by prevalence and costs in Table 3), as well as the information in Table 1 and Table 2.

⁴ V.MFS.0403 Seminar Report – STEC in manufacturing beef: Where have we been? Where should we be going? 5-6 June 2017

Table 3: Details of four abattoirs

Abattoir	Antimicrobial interventions	Spray chill	STEC prevalence	Prevalence relative to industry average
A	hot water spray	yes	0.07%	24%
B	pre-slaughter wash	yes	0.09%	31%
C	none	yes	1.14%	393%
D	pre-slaughter wash	no	0.51%	175%

4 Results & Discussion

4.1 Whole of industry costs related to STECs

The annual cost of STECs for the Australian beef industry (Figure 3), apart from mandatory and pre-emptive STEC screening (pre-confirmation testing), has been calculated to range from \$1.85 million (2017; current results adjusted to estimate entire year) to \$4.60 million (2014). The majority of the cost (80%) is from confirmed positive lots being downgraded in value. Confirmation testing is 19% of the cost with storage costs being less than 1%. An average of 90% (2013-2017) of the cost is for manufacturing beef being exported to North America (US and Canada; Figure 4).

Figure 3: Cost of STEC for Australian beef industry

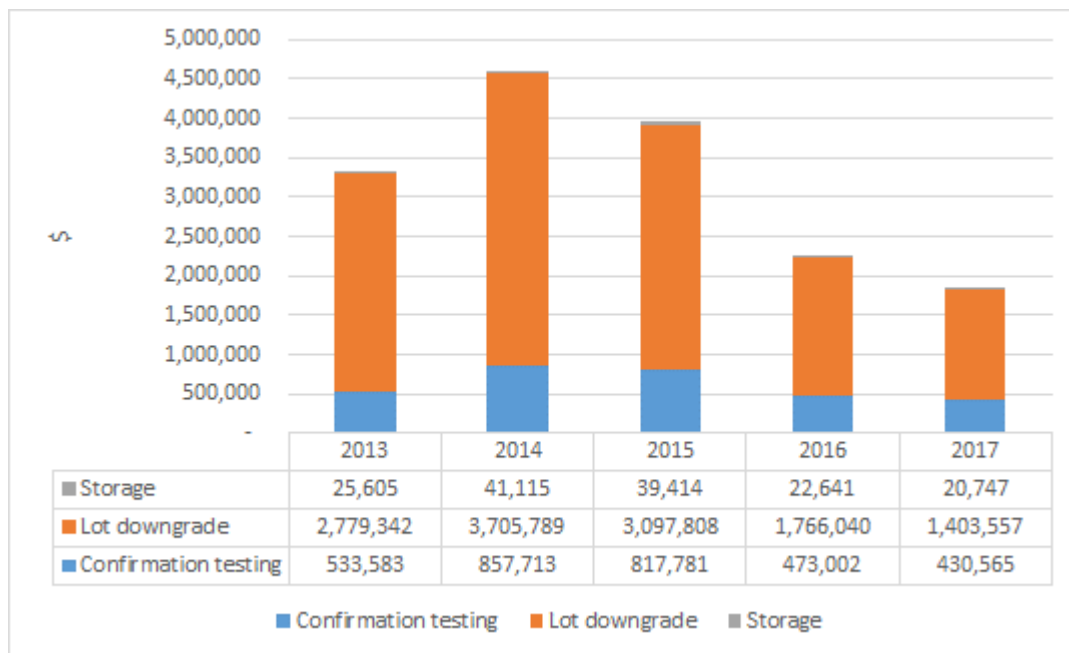
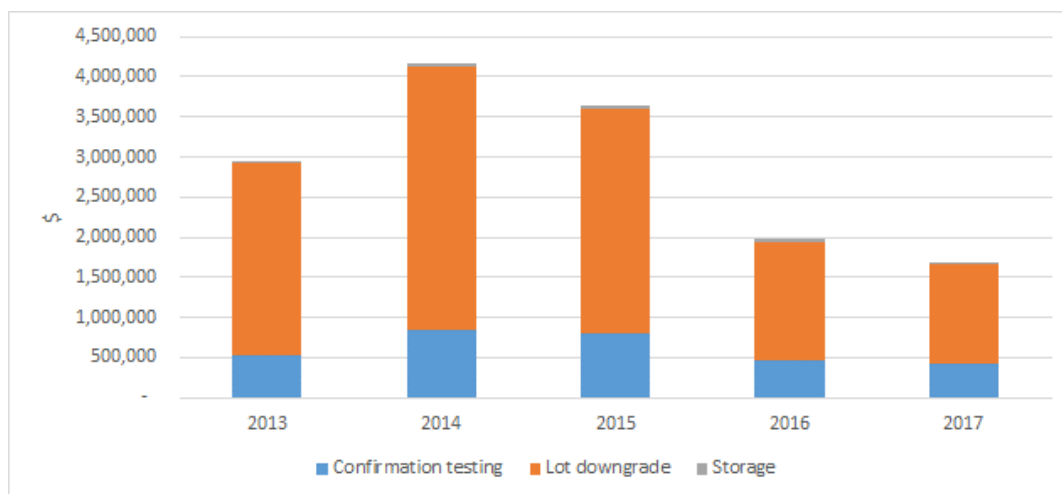
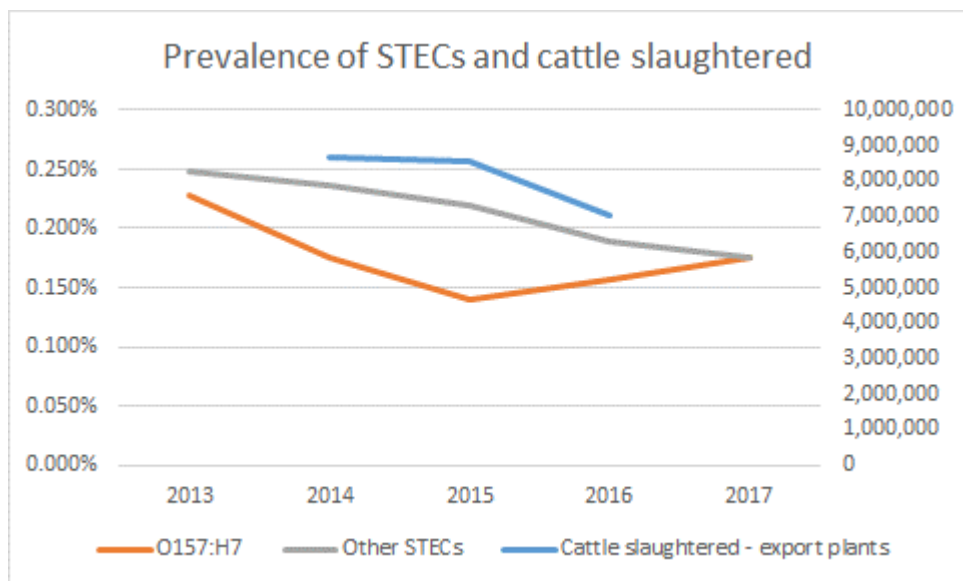
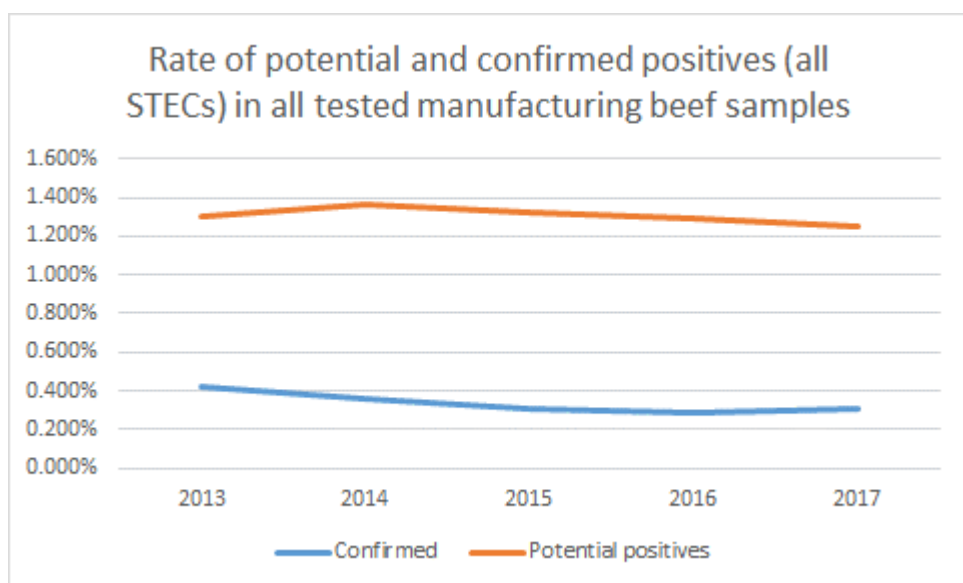


Figure 4: Cost of STEC for product going to North American market



The relative decrease in STEC costs since 2014 are a result of lower cattle numbers and reduced STEC prevalence (Figure 5 and Figure 6). Reducing STEC prevalence by 20% (from 2013-2017 average) would result in 4.5% reduction in total costs/annum.

Figure 5: Prevalence of STECs and cattle slaughtered in export abattoirs (data sourced from DAWR)**Figure 6: Rate of potential and confirmed positives (O157:H7 or all 7 STECs, depending on confirmation test/market) in manufacturing beef lots (data sourced from DAWR)**

4.2 All 7 STEC testing – current and NeoSeek

With decreasing slaughter numbers and STEC prevalence, the number of screening and confirmation tests for all 7 STECs has decreased since 2014 (Figure 7). The annual cost of all 7 STEC screening tests is \$2.1 million (2014-2017 average, Table 4). If NeoSeek was used instead of current combination of BAX or GDS test system (3.2), the cost of screening would increase to between \$6.3-7.5 million (Table 4 and Table 5). A recent CSIRO trial showed that GDS test system had 16% less potential positives than BAX⁵. Based on this the

⁵ V.MFS.0403 Seminar Report – STEC in manufacturing beef: Where have we been? Where should we be going? 5-6 June 2017.

benefit of moving to 100% GDS is estimated to be \$51,542/annum (Table 5). In the CSIRO trial, the PALL GeneDisc System showed a 25% and 10% reduction in potential positives relative to BAX or GDS, respectively. Based on this, if the entire Australian industry moved to PALL GeneDisc System, the reduction in confirmation testing and associated storage would be \$126,845/annum (Table 5).

Figure 7: Number of screening and confirmation tests for all 7 STECs

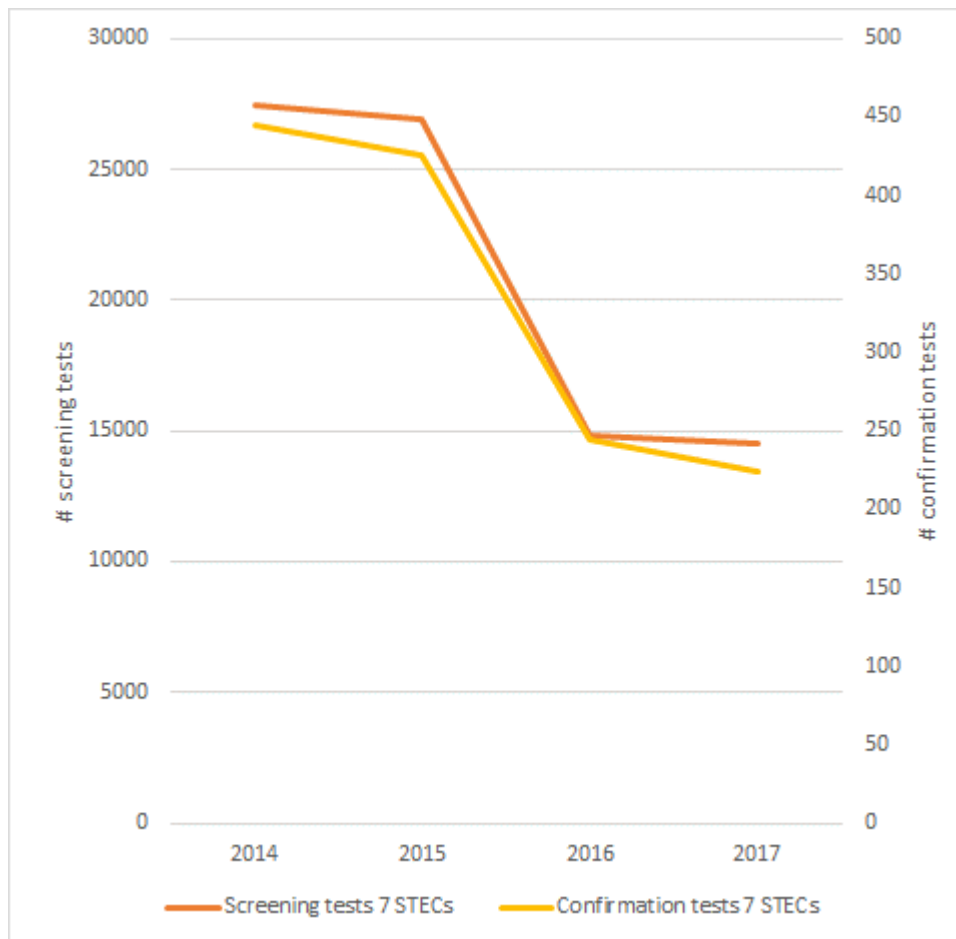


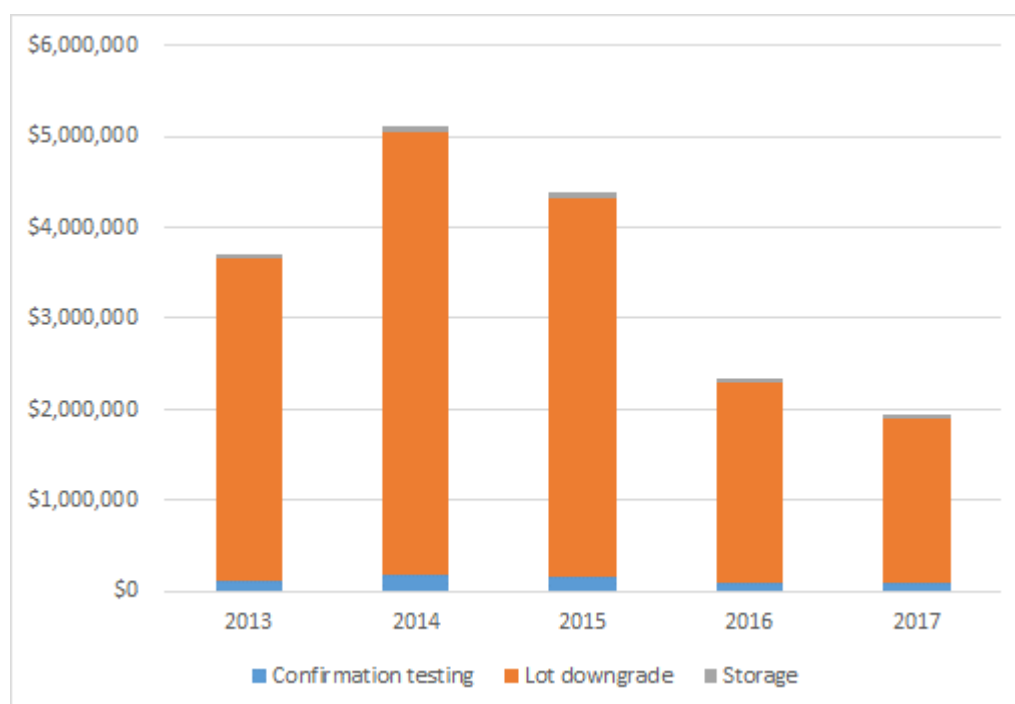
Table 4: Comparison of costs for current situation with NeoSeek scenarios

	NeoSeek used instead of screening test		
Scenario	Current situation	NeoSeek US	NeoSeek Australia
Screening test method	BAX or GDS	NeoSeek method	NeoSeek method
# of screening tests per annum	20911.125	20911.125	20911.125
Screening testing cost - \$/test	100	360	300
Confirmation test method	culture based	N/A	N/A
# of confirmation tests per annum	323.3514	0	0
Confirmation testing cost - \$/test	1900	360	300
Total testing cost	\$2,705,480	\$7,528,005	\$6,273,338
change in cost		\$4,822,525	\$3,567,857
Transport time for sample to laboratory - days	0.5	4.5	0.5
Time taken for test on receipt of sample by laboratory - days	3	1.5	1
Storage cost - \$/carton/day	0.065	0.065	0.065
# cartons/lot	406.519	406.519	406.519
Total storage cost	\$29,905	\$0	\$0
change in cost		-\$29,905	-\$29,905
# of downgraded lots	77.05404	114.0399792	102.4818732
Weight of carton - kg	27.4	27.4	27.4
Weight of lot - kg	11138.6206	11138.6206	11138.6206
Price of non-downgraded product - \$/kg	5.21	5.21	5.21
Price of downgraded lot - \$/kg	2.605	2.605	2.605
% increase in confirmed positives	0%	48%	33%
Total downgraded lot cost	\$2,235,808	\$3,308,996	\$2,973,625
change in cost		\$1,073,188	\$737,817
Total cost \$/annum	\$4,971,193	\$10,837,001	\$9,246,962
change in costs		\$5,865,808	\$4,275,770
Total cost \$/screening test	\$237.73	\$518.24	\$442.20
change in costs		\$281	\$204

Table 5: Comparison of costs for current screening situation with two scenarios

Scenario	Current situation	All GDS	All PALL GeneDisk
Screening test method	BAX or GDS	GDS only	PALL GeneDisk only
% reduction in potential positives	0%	8%	18%
# of screening tests per annum	20911.125	20911.125	20911.125
Screening testing cost - \$/test	100	100	100
Confirmation test method	culture based	culture based	culture based
# of confirmation tests per annum	323.3514	297.483288	266.764905
Confirmation testing cost - \$/test	1900	1900	1900
Total testing cost	\$2,705,480	\$2,656,331	\$2,597,966
change in cost		-\$49,149	-\$107,514
Transport time for sample to laboratory - days	0.5	0.5	0.5
Time taken for test on receipt of sample by laboratory - days	3	3	1
Storage cost - \$/carton/day	0.065	0.065	0.065
# cartons/lot	406.519	406.519	406.519
Total storage cost	\$29,905	\$27,512	\$10,573
change in cost		-\$2,392	-\$19,331
# of downgraded lots	77.05404	77.05404	77.05404
Weight of carton - kg	27.4	27.4	27.4
Weight of lot - kg	11138.6206	11138.6206	11138.6206
Price of non-downgraded product - \$/kg	5.21	5.21	5.21
Price of downgraded lot - \$/kg	2.605	2.605	2.605
% increase in confirmed positives	0%	0%	0%
Total downgraded lot cost	\$2,235,808	\$2,235,808	\$2,235,808
change in cost		\$0	\$0
Total cost \$/annum	\$4,971,193	\$4,919,651	\$4,844,347
change in costs		-\$51,542	-\$126,845
Total cost \$/screening test	\$237.73	\$235.26	\$231.66
change in costs		-\$2	-\$6

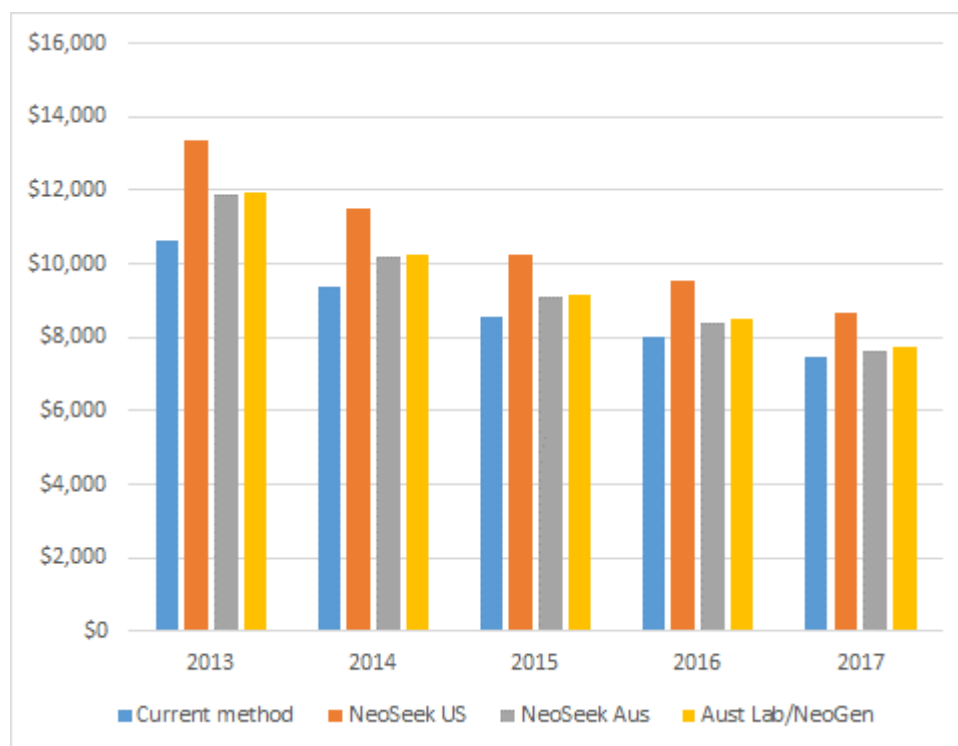
In the short term, moving from the current confirmation test method to the NeoSeek method (complete test being undertaken by NeoGen in US based on New Zealand system) would increase per annum STEC costs for Australia's North American market by an average of 21% or \$596,587 (Figure 8 and Table 6). The confirmation testing costs would decrease by 81% but the storage costs and the costs of lot downgrades would increase by 71% and 48%, respectively.

Figure 8: Proposed costs with NeoSeek method as confirmation test

Relative to sending samples to NeoGen in the US for confirmation by method currently used by New Zealand, the other two longer term NeoSeek options considered would have similar or reduced test costs, lower storage costs and less confirmed positive lots (Table 6 and Figure 9). When comparing a calculated 'total cost' per confirmation test (including confirmation testing cost, storage cost and lot downgrade cost) these two NeoSeek options (NeoSeek Aus - \$9,536/test, Aust Lab/NeoGen - \$9,596/test) are only 7-8% more expensive than the current confirmation method (\$8,907/test, Table 6). If the increase in confirmed positives was only 22-23%, from current confirmation method rather than 33% (Table 2), then the total costs for these options would be the same as current. If confirmed positive lots were at the same rate with NeoSeek as with current method (0% increase), the NeoSeek options would be cheaper by \$1,474 to \$1,653/confirmation test, equating to \$476,601 - \$534,451/annum saving (industry wide, Table 7).

Table 6: Comparison of costs between current situation and NeoSeek scenarios

Scenario	Current situation	NeoSeek US	NeoSeek Australia	Aust Lab/NeoGen
Test method	culture based	NeoSeek method	NeoSeek method	NeoSeek method
# of confirmation tests per annum	323.3514	323.3514	323.3514	323.3514
Testing cost - \$/test	1900	360	300	360
Total testing cost	\$614,368	\$116,407	\$97,005	\$116,407
change in cost		-\$497,961	-\$517,362	-\$497,961
Transport time for sample to laboratory - days	0.5	4.5	0.5	0.5
Time taken for test on receipt of sample by laboratory - days	3	1.5	1	1
Storage cost - \$/carton/day	0.065	0.065	0.065	0.065
# cartons/lot	406.519	406.519	406.519	406.519
Total storage cost	\$29,905	\$51,265	\$12,816	\$12,816
change in cost		\$21,360	-\$17,088	-\$17,088
# of downgraded lots	77.05404	114.0399792	102.4818732	102.4818732
Weight of carton - kg	27.4	27.4	27.4	27.4
Weight of lot - kg	11138.6206	11138.6206	11138.6206	11138.6206
Price of non-downgraded product - \$/kg	5.21	5.21	5.21	5.21
Price of downgraded lot - \$/kg	2.605	2.605	2.605	2.605
% increase in confirmed positives	0%	48%	33%	33%
Total downgraded lot cost	\$2,235,808	\$3,308,996	\$2,973,625	\$2,973,625
change in cost		\$1,073,188	\$737,817	\$737,817
Total cost \$/annum	\$2,880,080	\$3,476,668	\$3,083,447	\$3,102,848
change in costs		\$596,587	\$203,366	\$222,767
Total cost \$/confirmation test	\$8,907	\$10,752	\$9,536	\$9,596
change in costs		\$1,845	\$629	\$689

Figure 9: Total cost (confirmation testing cost, storage cost, lot downgrade cost) per confirmation test for current method and NeoSeek scenarios**Table 7: Comparison of costs between current situation and NeoSeek scenarios with no increased rate of confirmed positives**

Scenario	Current situation	NeoSeek US	NeoSeek Australia	Aust Lab/NeoGen
Test method	culture based	NeoSeek method	NeoSeek method	NeoSeek method
# of confirmation tests per annum	323.3514	323.3514	323.3514	323.3514
Testing cost - \$/test	1900	360	300	360
Total testing cost	\$614,368	\$116,407	\$97,005	\$116,407
change in cost		-\$497,961	-\$517,362	-\$497,961
Transport time for sample to laboratory - days	0.5	4.5	0.5	0.5
Time taken for test on receipt of sample by laboratory - days	3	1.5	1	1
Storage cost - \$/carton/day	0.065	0.065	0.065	0.065
# cartons/lot	406.519	406.519	406.519	406.519
Total storage cost	\$29,905	\$51,265	\$12,816	\$12,816
change in cost		\$21,360	-\$17,088	-\$17,088
# of downgraded lots	77.05404	77.05404	77.05404	77.05404
Weight of carton - kg	27.4	27.4	27.4	27.4
Weight of lot - kg	11138.6206	11138.6206	11138.6206	11138.6206
Price of non-downgraded product - \$/kg	5.21	5.21	5.21	5.21
Price of downgraded lot - \$/kg	2.605	2.605	2.605	2.605
% increase in confirmed positives	0%	0%	0%	0%
Total downgraded lot cost	\$2,235,808	\$2,235,808	\$2,235,808	\$2,235,808
change in cost		\$0	\$0	\$0
Total cost \$/annum	\$2,880,080	\$2,403,480	\$2,345,630	\$2,365,031
change in costs		-\$476,601	-\$534,451	-\$515,049
Total cost \$/confirmation test	\$8,907	\$7,433	\$7,254	\$7,314
change in costs		-\$1,474	-\$1,653	-\$1,593

The estimated capital cost for the front end to be setup in Australian laboratory (as per NeoSeek Aus/US scenario) is \$137/confirmation test (based on 365/year, average from 2014-2017). If the average number of confirmation tests remains at the lower 2016-2017

average (259/annum) then this capital cost increases to \$212/test, which based on an estimated \$300/test price would become cost prohibitive for the laboratory to invest.

4.3 Comparison of costs for individual abattoirs

STEC prevalence and related costs vary significantly between abattoirs⁶. The increased total cost related to the NeoSeek confirmation test method (based on 'NeoSeek US', Table 2) will vary between abattoirs based on factors related to STEC prevalence with an increase of 17-33% total cost (\$3,264-\$74,591/annum) for the four abattoirs considered (Table 8).

Table 8: Comparison of STEC-related costs under current confirmation test method and NeoSeek test

Current method	Cost of testing	Cost of lots downgraded	Storage costs	Total costs per annum	Total cost per confirmation test	Saving per annum	Saving per confirmation test
Abattoir A	\$4,750	\$14,476	\$231	\$19,457	\$7,783		
Abattoir B	\$4,750	\$14,476	\$231	\$19,457	\$7,783		
Abattoir C	\$8,170	\$60,798	\$398	\$69,366	\$16,132		
Abattoir D	\$34,696	\$211,472	\$1,689	\$247,856	\$13,573		
NeoSeek method							
Abattoir A	\$900	\$21,424	\$396	\$22,720	\$9,088	-\$3,264	-\$1,305
Abattoir B	\$900	\$21,424	\$396	\$22,720	\$9,088	-\$3,264	-\$1,305
Abattoir C	\$1,548	\$89,981	\$682	\$92,211	\$21,444	-\$22,845	-\$5,313
Abattoir D	\$6,574	\$312,978	\$2,895	\$322,447	\$17,658	-\$74,591	-\$4,085

4.4 Potential benefits of reduced risk or increased assurance with NeoSeek

The New Zealand bobby calf and veal industry have adopted the NeoSeek method for all 7 STEC confirmation testing. The drivers for this were to assure the North American market that their bobby calf and veal was STEC-free and to future-proof New Zealand product. However, several other aspects of the New Zealand approach are important to note:

- GDS method is used as screening test and potential positives are submitted to confirmation testing by NeoSeek method
- If a lot is confirmed positive the sampled cartons are removed from the lot and the lot is sent to another non-North American market (not to heat treatment plant)
- Samples from older animals (older than veal) are still tested by the culture isolation method (current method used in Australia) and the industry do not intend to change from that.

Australia's manufacturing beef exports to North America, which is worth \$1,407,119,543/annum (2014-2016 average), does not currently have market access or assurance issues related to STECs. In recent years, STEC prevalence has decreased and no lots have been confirmed positive and subsequently rejected at port of entry. From 2014-2017 there have been 83,645 lots sent to North American market and an estimated 5,576 of these tested at port of entry (FSIS test 1 in 15), with no confirmed positives (no false negatives in Australian testing). Based on this data, due to the very low risk, there would be no improvement in reducing risk, of lot rejection and market suspension for Australian product, with the NeoSeek method.

In regards to lot rejection and associated loss of market access, several other points provide little support to a significant benefit from the NeoSeek method (over current test method):

- Limited bobby calf processed in Australia (these animals have highest STEC prevalence, which decreases with age)

⁶ See V.MFS.0424 Milestone 1 report – Cost benefit analysis of spray chilling interventions

- Improved antimicrobial operational performance in Australian beef abattoirs as a result of many overall carcass management and specific antimicrobial interventions⁷
- Low STEC prevalence (2014-2017 average) of 0.35% in lots prepared for North American market
- Equivalent testing process in US port of entry (FSIS) and Australia.

A second area of consideration was the potential for NeoSeek to be an insurance policy against the potential loss of Australia's current agreement with the US over how samples are taken for testing and what they are representative of. Australia is currently able to use lot based testing. This current lot based testing is thought to be much cheaper than a potential time based testing requirement. The full consideration of this is outside the scope of this project, and has not been costed, but having to move from lot to time based testing would include increased testing costs, more regular in-plant cleaning of belts and the requirement of product having to be in sequence. Thus there is significant value in keeping the current agreement in place through complete compliance and no port of entry detections. However, based on the evidence presented above there is no compelling reason that NeoSeek would provide an improved insurance policy.

If and when the FSIS move to another testing method, would be the point at which the Australian industry could potentially gain reduced risk and increased assurance by adopting a new method.

4.5 Regulatory and laboratory considerations

For the Australian industry to change or adopt a new confirmation test method would require approval by DAWR. Although the NeoSeek method being used by the New Zealand industry is FSIS accredited, there would still be a requirement for communication between DAWR and FSIS to update Australia's current agreement. Laboratories would then require DAWR approval and associated auditing. In the situation of Australia's confirmation testing being undertaken in the US, the auditing of the testing laboratory (e.g. NeoGen) by DAWR would presumably be through an arrangement with FSIS.

It is very unlikely that changes in the testing of Australian samples will occur prior to FSIS changing their testing system (with very good reason based on present evidence). However, there is a widespread trend for microbiological testing to shift from traditional methods to molecular methods (e.g. NeoSeek) and FSIS are actively looking to transition to molecular methods. FSIS currently receive genomic information on certain positive STEC samples through a program run by DAWR. From discussions with DAWR it is estimated that within the next five years port of entry testing in the US will be by a molecular method.

The economic feasibility for testing to be undertaken in Australia will depend on capital and consumable costs, as well as the number of confirmation tests. As more microbiological testing shifts to molecular methods the actual capital cost will decrease and the amount of other non-STEC samples that could use the capital will increase. The recent establishment of Neogen's GeneSeek Australasia facility in Queensland (following acquisition of The

⁷ Processor's Guide to Improving Microbiological Quality and Shelf Life of Meat 3rd Edition. Published by SARDI and PIRSA in collaboration with MLA and AMPC.

University of Queensland Animal Genetics Laboratory) may provide the most suitable testing location.

The focus of ongoing molecular method development and validation work should be on Australian STEC strains, whilst maximising collaboration and leverage with similar work in New Zealand and the US. On consultation with technical expert, it is expected that a trial running side by side comparison of the current confirmation method with a molecular method would be a suitable context for 'tweaking' the molecular method in regards to snips (specific relationships and linkages for Australian STEC strains) and improving sensitivity. This presumably would be similar to the approach used by MPI NZ and NeoGen, and is thought to be a reasonably straight forward process.

4.6 Handling of lots that are confirmed positive

As outlined in section 4.3 the majority of the current STEC-related cost (excluding screening tests) is due to downgraded lots, and molecular test methods (such as NeoSeek) are anticipated to increase the number of downgraded lots through increased confirmed positives. As noted in section 4.4, the New Zealand industry mitigates the cost of downgrading lots to heat treatment plant by removing the cartons that were sampled and sending the rest of the lot to another market. In discussions with the Australian abattoirs and processing companies in this project, there is reticence to adopt a similar approach. Furthermore feedback received indicates that an increasing number of non-North American based manufacturing beef buyers are planning to make STEC testing a requirement of their suppliers.

5 Summary and recommendations

The current confirmation test method (culture based) for all 7 STECs has served the Australian industry well in regards to 0 false negatives being found through North American port of entry testing over the past five years. If Australia adopted the NeoSeek confirmation test method (molecular, non-culture based) the confirmation testing and sample storage costs would decrease but there would be increased costs through more downgraded lots (as a result of more confirmed positives). Overall the total costs are predicted to increase by 7-20% (\$207,036-\$610,282/annum).

FSIS are looking to shift from the current culture based method to a molecular method (e.g. NeoSeek) and it is thought that within five years US port of entry confirmation testing may have shifted to molecular method. The New Zealand bobby calf and veal industry have moved to a molecular method by adopting the NeoSeek method to guarantee market assurance and future proof their product.

The recommendations for the Australian industry (including MLA, AMPC, beef abattoirs, DAWR, commercial laboratories, CSIRO) are as follows:

- Continue to reduce STEC prevalence through adoption of best practice holistic carcase management and specific antimicrobial interventions.
- In the short term, continue with current screening and confirmation methods and don't transition to NeoSeek method.

- Work closely with FSIS to know when FSIS will shift from current method to molecular method and plan timeframe for shifting Australia's test method accordingly.
- Leverage and collaborate with FSIS transition process and the NeoSeek method, being used by New Zealand, as much as possible.
- Examine the opportunity, feasibility and requirement for Australian laboratory to undertake part (i.e. front end of testing) or all of molecular method 1-2 years prior to anticipated FSIS shift. This would involve dialogue between DAWR, Australian commercial laboratories and NeoGen. This would include adapting molecular method to have suitable specificity and sensitivity for Australian STEC strains.

6 Appendix

6.1 List of Tables

TABLE 1: AUSTRALIAN BEEF INDUSTRY INFORMATION RELATED TO STEC COSTS	9
TABLE 2: COMPARISON OF CURRENT CONFIRMATION TEST METHOD AND NEOSEEK METHOD	10
TABLE 3: DETAILS OF FOUR ABATTOIRS	11
TABLE 4: COMPARISON OF COSTS FOR CURRENT SITUATION WITH NEOSEEK SCENARIOS	15
TABLE 5: COMPARISON OF COSTS FOR CURRENT SCREENING SITUATION WITH TWO SCENARIOS	16
TABLE 6: COMPARISON OF COSTS BETWEEN CURRENT SITUATION AND NEOSEEK SCENARIOS	18
TABLE 7: COMPARISON OF COSTS BETWEEN CURRENT SITUATION AND NEOSEEK SCENARIOS WITH NO INCREASED RATE OF CONFIRMED POSITIVES.....	19
TABLE 8: COMPARISON OF STEC-RELATED COSTS UNDER CURRENT CONFIRMATION TEST METHOD AND NEOSEEK TEST.....	20

6.2 List of figures

FIGURE 1: COST OF STEC FOR AUSTRALIAN BEEF INDUSTRY	2
FIGURE 2: TOTAL COST (TESTING COST, STORAGE COST, LOT DOWNGRADE COST) PER CONFIRMATION TEST FOR CURRENT METHOD AND THREE POTENTIAL NEOSEEK TEST METHOD OPTIONS.....	3
FIGURE 3: COST OF STEC FOR AUSTRALIAN BEEF INDUSTRY	12
FIGURE 4: COST OF STEC FOR PRODUCT GOING TO NORTH AMERICAN MARKET	12
FIGURE 5: PREVALENCE OF STECS AND CATTLE SLAUGHTERED IN EXPORT ABATTOIRS (DATA SOURCED FROM DAWR)	13
FIGURE 6: RATE OF POTENTIAL AND CONFIRMED POSITIVES (O157:H7 OR ALL 7 STECS, DEPENDING ON CONFIRMATION TEST/MARKET) IN MANUFACTURING BEEF LOTS (DATA SOURCED FROM DAWR).....	13
FIGURE 7: NUMBER OF SCREENING AND CONFIRMATION TESTS FOR ALL 7 STECS.....	14
FIGURE 8: PROPOSED COSTS WITH NEOSEEK METHOD AS CONFIRMATION TEST.....	17
FIGURE 9: TOTAL COST (CONFIRMATION TESTING COST, STORAGE COST, LOT DOWNGRADE COST) PER CONFIRMATION TEST FOR CURRENT METHOD AND NEOSEEK SCENARIOS	19