Animal Health Australia

Technical Review of SheepMAP

Final Report

24 February 2014
Executive summary

GHD Pty Ltd, in association with Dr Richard Shephard and Dr Scott Williams, completed this technical review of SheepMAP. The review considered the current operations of SheepMAP and specifically examined the relative assurance of OJD freedom for the different Monitored Negative (MN) levels within the program. The review also provided information on potential efficiencies that could be gained if SheepMAP was combined with other disease control or quality assurance programs.

The main outcomes from the review are discussed below. These outcomes are for presentation to the SheepMAP Steering Committee in the first instance, and it is planned that wider industry consultation will be completed before any changes to the current SheepMAP will be made.

The review adopted an epidemiological model of OJD that incorporates a number of assumptions based on current research data. Modelling indicates that SheepMAP is meeting the primary objective of providing assurances to the market that sheep sourced from accredited flocks present a low probability of OJD. The modelling specifically examines the probability of OJD infection occurring in SheepMAP flocks and the probability of producers purchasing infected sheep from SheepMAP flocks. It does not consider the consequences of introduction and spread of infection according to flock status or area prevalence.

As flocks progress through different stages (ie MN1 to MN3) the level of assurance increases although there is a differential between the equivalence of each MN level depending on whether the flock is located in a low, medium or high OJD prevalence region.

Flocks at MN3 status – irrespective of prevalence region – present a reduced risk of OJD that is at least comparable to the risk posed from an unassessed flock in an OJD “nominal very low prevalence” zone.

However, because tests are not able to detect OJD with 100% accuracy, there is a risk that ‘false negative’ flocks can be admitted to SheepMAP. The presence of these false negative flocks can be detected via subsequent testing, but the program allows the maintenance of MN status without further testing via vaccination and this may lead to prolonged persistence of some infected flocks in the program.

Research has shown that vaccination does not eliminate disease from all infected flocks or in a timely manner, and does not offer complete protection against new infection. These observations emphasise the importance of effective and ongoing biosecurity reviews and veterinary surveillance to detect false negative flocks and future breakdowns thereby providing ongoing assurance. While the majority of small consignments of sheep from false negative MNV flocks present a very low probability (< 1%) of disease introduction for purchasers, larger consignments present a high risk of disease (for example more than 20% probability of infection for a consignment of 50 sheep where within-flock prevalence is 0.50%).

PFC350 testing would identify a large proportion of false negative flocks, but this is a costly and time consuming approach. One alternative to the PFC350 testing in MNV flocks is abattoir surveillance combined with tailored veterinary surveillance. Modelling shows that, depending on the percentage of the adult flock submitted for abattoir surveillance, post mortems of between two and eight sheep per year are required to detect disease at a 1% within-flock prevalence level.

A potential alternative is targeted veterinary surveillance of MNV flocks combined with PFC50 and/or HT-J-PCR50 testing of adult sheep of higher suspicion of OJD as selected by the veterinarian. (Note that guidelines for the use of the HT-J-PCR test are still under development.
and its use within SheepMAP would depend on the test meeting the appropriate standards identified by the Sub-Committee on Animal Health Laboratory Standards – SCAHLS). Targeted pooled faecal testing regime for vaccinating flocks clearly has potential to detect false negative flocks with high sensitivity and down to very low within-flock prevalence.

The potential conflict of interest faced by veterinarians who are both clinicians to commercial producers and also SheepMAP veterinarians to the same flocks needs to be considered. However, consultation with vets for this review indicated a level of diligence that gives comfort to their role in ensuring potentially diseased sheep are screened for the presence of OJD.

The review considered the feasibility of broadening the scope of the SheepMAP to include other diseases and found that the inclusion of ovine brucellosis accreditation as being most feasible. Industry could determine if a program that included a range of common elements (eg biosecurity, animal ID, audits) with additional elements for the specific diseases (most likely related to testing) could be developed.

It is noted that the national Sheep Health Statement includes provisions for owners to report on footrot, lice and other conditions. There are no Australia-wide control programs for these diseases that could be readily incorporated into a broadened SheepMAP. However, any revised SheepMAP could be flexible so that it allowed for the inclusion of additional diseases if required in the future.

The review also considered other industry programs or business practices in Australia or overseas that could be incorporated into SheepMAP with a view to identify the drivers to encourage increased uptake of the program. Both LPA and NLIS have components related to animal identification and livestock movements that are audited and as such could be recognised by SheepMAP without the need to duplicate these elements within the program. The removal of such duplication would likely be seen as a positive by sheep producers and may increase uptake of the program or at least reduce the rate of dropouts.

While the various livestock health schemes operating in the US and UK provide frameworks for adoption in Australia, it is likely that their acceptance would be dependent on economic drivers that currently do not exist. This could change over time as consumers demand more information on the food they consume and the conditions under which animals are raised.

The feasibility of group SheepMAP, whereby a number of similar flocks from a low prevalence region virtually merge their flocks and enter the merged flock as a single entity to SheepMAP, is not considered to be either technically or practically feasible. The decreased intensity of testing results in reduced detection sensitivity at the individual flock level. The time until detection of disease in the group flock will also increase and this provides increased opportunity for disease to spread to the other group flocks and to the wider sheep population due to the false accreditation.

Currently a number of states and regions have introduced Regional Biosecurity Plans (RBPs) that are designed to prevent the incursion and spread of OJD into the regions. RBPs set minimum entry requirements for sheep into the Regional Biosecurity Areas, including that SheepMAP flocks will be allowed entry. However, individual RBPs have the ability set more stringent entry requirements.

Industry could consider the results of the modelling completed in this review and determine if the MN flocks maintaining status via vaccination would be considered to have satisfied the definition of “tested assurance” based on negative abattoir surveillance and/or veterinary surveillance. Also, targeted testing of thin sheep using the PFC50 test or the yet to be approved PCR test could also be considered for its acceptability as a suitable test.
It is proposed that the outcomes from this review will be considered by the SheepMAP Steering Committee and for that Committee to identify areas for improvement in the rules within the current SheepMAP (Dec 2005 version as amended).
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Appendix A – International animal disease assurance programs
1. **Introduction**

1.1 **Background**

GHD Pty Ltd was contracted by Animal Health Australia (AHA) to complete a technical review of the SheepMAP. AHA considered that SheepMAP has, over time, become complex and difficult to interpret. This has been caused, in part, by changes that have been made to SheepMAP in an attempt to maintain consistency with national policies and technological developments (for instance new tests and vaccination).

As a result, a technical review was initiated to ensure SheepMAP continues to deliver the level of assurance against ovine Johne’s disease (OJD) that is required by sheep producers. In this regard, the objective of the review is to evaluate the scientific merit of, and provide recommendations on, the technical aspects of SheepMAP. The following terms of reference were established for the review:

- Review the SheepMAP (December 2005 version as amended) for relevance and currency and, identify areas for improvement e.g. format and technical content
- Determine whether the current method for providing assurance through biosecurity, flock testing and vaccination provides the levels of assurance that are appropriate for an audited MAP
- Determine the role that alternative testing methods could play in providing assurance
- Recommend how a revised SheepMAP would complement other means of assurance for OJD in the sheep industry
- Determine the feasibility of broadening the scope of the SheepMAP to include other diseases
- Determine how the SheepMAP could be aligned with other industry programs or business practices and identify the drivers for the uptake of the program
- Evaluate the feasibility of group SheepMAP programs on both a technical and practical basis.

1.2 **Methodology**

GHD completed the review in association with two sub-consultants: Dr Richard Shephard and Dr Scott Williams. The project commenced with an inception meeting in October 2013 with members of the SheepMAP Steering Committee to ensure there was an agreed understanding of the above terms of reference and identify relevant data sources and contacts for the scientific material required.

The GHD team then assembled the appropriate epidemiological data to model the levels of assurance provided by the SheepMAP protocols. The technical aspects of the model report and outcomes were peer reviewed by epidemiologists before being finalised. This epidemiological report is separately available as Volume 2 to accompany this main report (Volume 1).

In addition, experienced SheepMAP veterinarians were surveyed on their role in SheepMAP and the assurance provided by the annual veterinary review. The veterinarians interviewed were selected from the AHA database and assistance from the Steering Committee ensured interviewees were a cross-section of States (and, in the case of New South Wales, a range of
prevalence areas within the State). It was estimated from the responses that the interviewees represented approximately 150 SheepMAP flocks out of a total of 432 flocks (ie 35%).

The outputs from the above were then used to provide options for possible revisions to SheepMAP to ensure ongoing integrity of the program based on the latest scientific data. In addition, the alignment of SheepMAP to other industry programs was considered and options developed accordingly.

GHD understands that the options canvassed in this technical review will be subject to further consultation by the sheep industry before changes to SheepMAP are made.

1.3 Scope and limitations

This report has been prepared by GHD for AHA and may only be used and relied on by AHA for the purpose agreed between GHD and AHA as set out in section 1.1 above.

GHD otherwise disclaims responsibility to any person other than AHA arising in connection with this report. GHD also excludes implied warranties and conditions, to the extent legally permissible.

The services undertaken by GHD in connection with preparing this report were limited to those specifically detailed in the report and are subject to the scope limitations set out in the report.

The opinions, conclusions and any recommendations in this report are based on conditions encountered and information reviewed at the date of preparation of the report. GHD has no responsibility or obligation to update this report to account for events or changes occurring subsequent to the date that the report was prepared.

The opinions, conclusions and any recommendations in this report are based on assumptions made by GHD as described in the various sections of this report. GHD disclaims liability arising from any of the assumptions being incorrect.

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2. Theory underpinning SheepMAP

SheepMAP is a voluntary program for producers which enables them to identify and promote the negative Johne’s disease status of their flocks to their clients. Flocks in the MAP are not accredited as free of Johne’s disease, but they have a low risk of being infected compared to Non-Assessed flocks. Producers can minimise the spread of Johne’s disease by sourcing replacement animals from MAP-certified or other low-risk flocks.

Flocks participating in the SheepMAP are tested to determine their disease status and managed to reduce the risk of infection. Over four years, these flocks are able to progress from Monitored Negative 1 (MN1) through to Monitored Negative 3 (MN3) status – the highest level of assurance. The longer a flock is in the MAP and the higher the status, the greater the confidence that it is not infected. Figure 1 shows the testing and/or vaccination pathways for maintain or progressing assurance status. Vaccination allows maintenance of MN status without testing.
The tests available for OJD are not definitive with each having a range in sensitivity and specificity. Also, research has shown that Gudair vaccination delays and reduces shedding but does not prevent infection (Dhand et al 2013). Therefore, the effectiveness of vaccination on reducing infection and shedding in vaccinated sheep needs to be considered if vaccination is used as an assurance pathway.

The Annual Veterinary Review is a key component of maintaining assurance status because it allows targeted testing of high-risk animals (thin sheep if available), as well as providing the opportunity for a veterinarian to reinforce with the client the important principles of biosecurity. The relative assurance provided by different levels within SheepMAP can be modelled using epidemiological theory that predicts the probability of presence of OJD based on a range of parameters known to impact on disease prevalence. This is further described in the following section.

Figure 2 shows the number of SheepMAP certified flocks by state from 2005 to 2013. Total flocks have declined from about 800 in 2005 to 432 in 2013.
3. Epidemiological modelling of SheepMAP

Richard Shephard developed an epidemiological model to simulate current prevalence, testing and disease control (vaccination) of OJD to determine the probabilities of disease assurance provided by all levels within SheepMAP. This report includes the main outputs from the model. The entire epidemiological report is available separately and is titled the “Detailed Modelling Report”.

3.1 Model assessment approach

The model was constructed on the basis that the performance of SheepMAP in providing assurance can be assessed by:

1. Estimating the probability that an infected flock is detected on attempted entry to SheepMAP (i.e. detected at the first Sample Test)

2. Estimating the proportion of infected flocks within SheepMAP at each stage of the program (MN1-MN3) and via each pathway (repeat Sample Testing and/or vaccination) from high, medium and low prevalence areas. (While currently there are no formally designated prevalence regions in Australia, the risk of OJD infection is higher in flocks in those regions with a history of higher flock prevalence and this impacts on assurance levels within SheepMAP)

3. Estimating the time until detection of infected flocks (existing or newly infected) within SheepMAP for each pathway (repeat Sample Testing and/or vaccination)
4. Estimating the likelihood that a consignment of sale sheep of set size purchased from a SheepMAP flock of given status and pathway from each of high, medium and low prevalence regions of Australia contains infected sheep

5. Comparing the probability that a SheepMAP flock of MN3 status (maintained by repeat Sample Testing or vaccinating) is infected compared to the background probability that a flock within a region thought to be effectively free of OJD (‘nominal very low prevalence’) is infected. It should be noted that the nominal very low prevalence zone may not be totally free of disease. We have assumed that the nominal very low prevalence zone has a maximum of 0.5% of flocks infected and infected flocks have an average of 0.5% of sheep infected. This is the average upper credibility level of disease estimated from sampling of flocks in Queensland and South Australia.

The model constructs individual flocks using baseline distributions of flock size and within-flock OJD prevalence. Various combinations of sample-based testing (using PFC350 and PFC100), abattoir surveillance and veterinary surveillance focused on the thin adult sheep within a flock were then applied using a random selection process. The model simulates a starting population of infected flocks submitted for entry to SheepMAP using PFC350 testing. Detected flocks are eliminated from SheepMAP and undetected but infected flocks (false negative flocks) are recorded and sent forward as MN flocks which are then subject to subsequent testing within the current rules of the program.

The effect of regional differences in OJD prevalence was examined by changing the proportion of infected and uninfected flocks that attempt to enter SheepMAP. Different regions may have different prevalence of infected flocks and therefore the number of infected flocks that attempt to enter SheepMAP will vary resulting in differing proportions of false negative flocks at each stage of SheepMAP and different purchaser risks between the regions. In reality many producers (and their veterinarians) with an infected flock would be aware of disease and therefore would not attempt to enter SheepMAP. Therefore this modelling approach will overestimate the disease ‘challenge’ to SheepMAP. In reality, there will be fewer false negative flocks and purchaser risk will be less than predicted by the model. The model output therefore presents the worst case performance scenario for SheepMAP.

A key output of the model is defining the population of false negative flocks at each stage (MN1-MN3) of the program. Infected but undetected flocks (false negative) from the preceding stage are sent forward for testing at the next stage of the program. It should be noted that the model does not allow new infections in previously uninfected flocks in the program; the model follows the path of existing infected flocks only. New flock infections due to introductions of infected sheep or transfer of the pathogen onto a previously clean property have not been examined in this study.

Results from the model were then aggregated at the regional level to determine the proportion of false negative flocks and the prevalence of infected sheep in false negative flocks by combining model output with information on the prevalence of infected flocks in regions with assumed different background prevalence. This allowed estimation of the risk of disease by purchasers of sheep from SheepMAP flocks of given status from within each background prevalence area. Consignment risk was compared to baseline risk from an unassessed flock in a predefined nominal very low prevalence zone.

The impact of vaccination was specifically examined as current SheepMAP guidelines do not require ongoing PFC350 testing. The persistence of MNV false negative flocks within the program was determined by evaluation of abattoir surveillance, veterinary surveillance and PFC testing of these flocks. This was undertaken to provide insights into options for ongoing testing and affirmation of MNV flocks within a potentially modified SheepMAP testing regime.
3.2 Model assumptions

Key parameters for model construction are presented in Table 1. A more detailed description of model construction and operation is provided in Volume 2.
## Table 1 Summary of key simulation model input parameters

<table>
<thead>
<tr>
<th>Parameter family</th>
<th>Parameter</th>
<th>Estimate</th>
<th>Source</th>
<th>Application in model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>Flock size distribution (Australia)</td>
<td>Flock size: 50-2500 0.69 1200, 2501-5000 0.21 3000, 5001-10000 0.08 5200, 10001-25000 0.02 12000</td>
<td>ABARE&lt;sup&gt;1&lt;/sup&gt;</td>
<td>To define the population of flocks that may submit to the program</td>
</tr>
<tr>
<td>OJD disease</td>
<td>Adult sheep abattoir slaughter</td>
<td>Average number adults slaughtered: 10% of total flock size per annum</td>
<td>MLA&lt;sup&gt;2&lt;/sup&gt;</td>
<td>Determines number of sheep sent for potential abattoir surveillance</td>
</tr>
<tr>
<td>OJD disease</td>
<td>Proportion of infected flocks by region</td>
<td>Prevalence Area: High Prevalence 70%, Medium Prevalence 15%, Low Prevalence 1.0%, Nominal very low prevalence zone 0.5%</td>
<td>AHA&lt;sup&gt;3&lt;/sup&gt;, SheepMAP veterinarian survey</td>
<td>To define prevalence regions. Program performance within each prevalence region can be determined</td>
</tr>
<tr>
<td>OJD disease</td>
<td>Within-flock disease prevalence</td>
<td>Pre-vaccination: Median prevalence 2.72, 90&lt;sup&gt;th&lt;/sup&gt; percentile prevalence 16.04, Beta distribution (α) 0.472, Beta distribution (β) 7.648</td>
<td>PVM&lt;sup&gt;4&lt;/sup&gt;</td>
<td>The distribution of within-flock prevalence influences performance of the detection tests and the risk of diseased consignments from these flocks</td>
</tr>
<tr>
<td>OJD disease</td>
<td>Post-vaccination: Median prevalence 0.72, 90&lt;sup&gt;th&lt;/sup&gt; percentile prevalence 3.16, Beta distribution (α) 0.676, Beta distribution (β) 53.404</td>
<td></td>
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<sup>1</sup> www.apps.daff.gov.au/MLA/mla.asp  
<sup>2</sup> MLA 2007 Lamb Survey (and prior years)  
<sup>3</sup> January 2013 report to AHA  
<sup>4</sup> Dhand et al. PVM 2013
<table>
<thead>
<tr>
<th>Parameter family</th>
<th>Parameter</th>
<th>Estimate</th>
<th>Source</th>
<th>Application in model</th>
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</thead>
<tbody>
<tr>
<td>Disease spread within flock</td>
<td>Prevalence doubling time: Constant prevalence (default), 2-year 3-year and 5-year doubling times were also modelled</td>
<td>Sergeant(^5)</td>
<td>Determines prevalence within flocks at the next test</td>
<td></td>
</tr>
<tr>
<td>Ratio (^5):MB (^7) sheep</td>
<td>4:1</td>
<td>Abbott(^6)</td>
<td>PB and MB sheep have different Se for all tests</td>
<td></td>
</tr>
<tr>
<td>Diagnostic tests</td>
<td>PFC350 Se &amp; Sp</td>
<td><strong>Historical:</strong> Sp = 1.0; Se (MB pool) = 0.95, Se (PB pool) = 0.50&lt;br&gt;<strong>Recent data:</strong> Sp = 1.0; Se (MB pool) = 0.95, Se (PB pool) = -0.167ln(x) + 0.6791&lt;br&gt;(x = no. uninfected sheep per PB sheep in pool)</td>
<td>JClinMicro(^9), PVM(^10)</td>
<td>Model performance of the PFC350 test</td>
</tr>
<tr>
<td></td>
<td>AS (^11)</td>
<td>AS Sp = 1.0; PB Se = 0.30; MB Se = 0.70</td>
<td>AVJ(^12)</td>
<td>Model performance of AS (where used)</td>
</tr>
<tr>
<td></td>
<td>VS (^13)</td>
<td>VS Sp = 1; VS Se (PB and MB) = 0.95&lt;br&gt;Target sheep population (thin adults) estimated at 2.0% flock&lt;br&gt;All MB sheep and 50% of PB sheep selected to enter VS target population</td>
<td>Survey and expert estimates</td>
<td>Model performance of the VS / annual report</td>
</tr>
<tr>
<td>Combined</td>
<td>Combinations modelled: PFC350; PFC350 + VS; PFC350 + AS; PFC350 + VS + AS; AS Detection order: AS &gt; VS &gt; PFC (due to timelines of testing) – to assign detection modality to breakdowns</td>
<td>AHA SheepMAP guidelines</td>
<td>Model and compare effectiveness of combined surveillance system</td>
<td></td>
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</tbody>
</table>

\(^5\) MLA: Computer simulation modeling of OJD (Sept 2003)  
\(^6\) Paucibacillary  
\(^7\) Multibacillary  
\(^8\) Abbott et al. (2004) Exposure factors leading to establishment of OJD infection and clinical disease. MLA Report  
\(^10\) PVM 95(2010), 248-257  
\(^11\) Abattoir surveillance  
\(^12\) AVJ (2005) 85: 633-636  
\(^13\) Veterinary Surveillance
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<th>Parameter family</th>
<th>Parameter</th>
<th>Estimate</th>
<th>Source</th>
<th>Application in model</th>
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<tbody>
<tr>
<td>Vaccination</td>
<td>Clinical disease</td>
<td>Vaccination reduces incidence of clinical disease by up to 90%</td>
<td>Vet Microb.14</td>
<td>Influences likelihood of detection by VS and AS</td>
</tr>
<tr>
<td></td>
<td>PB : MB ratio</td>
<td>Predominant form of disease is PB form; sheep enter MB form in final stages</td>
<td></td>
<td>Influences likelihood of detection by VS and AS</td>
</tr>
<tr>
<td></td>
<td>Immunity</td>
<td>Incomplete for vaccinates</td>
<td>Vet Microb.14</td>
<td>Influences disease persistence and new infection in flocks</td>
</tr>
<tr>
<td></td>
<td>Within-flock prevalence</td>
<td>Modelled as not increasing year-on-year in vaccinating flocks</td>
<td>PVM4 Sm Rum Res15</td>
<td>Influences likelihood of detection by testing (PFC, VS and AS). Influences consignment risk</td>
</tr>
<tr>
<td></td>
<td>Vaccinated but infected flocks have lower prevalence of disease than unvaccinated flocks</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Eradication</td>
<td>Model assumes fewer than 20% of vaccinating flocks eradicate disease within 5 years - research has shown that vaccination does not eliminate disease from all infected flocks or in a timely manner, and does not offer complete protection against new infection).</td>
<td>PVM10 Sm Rum Res15</td>
<td>Influences consignment risk</td>
</tr>
<tr>
<td></td>
<td>Introduction</td>
<td>Introduction of disease in vaccinating flocks is assumed possible</td>
<td></td>
<td>Influences consignment risk</td>
</tr>
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</table>

14 Veterinary Microbiology 115 (2006) 77-90

15 Small Ruminant Research (Windsor) – article in press (confidential)
3.3 Model output

Five testing regimes were examined:

1. PFC350 testing\(^{16}\).
2. PFC350 testing with active veterinary surveillance.
3. PFC350 testing with abattoir surveillance.
4. PFC350 testing with active veterinary and abattoir surveillance.
5. PFC350 on entry and only ongoing abattoir surveillance.

The role of maintenance testing using a PFC50 (pooled faecal culture of up to two pools each of up to 50 sheep) was specifically examined to determine the effect of this program option on subsequent detection of false negative flocks and on assurance provided to purchasers of sheep. The impact of maintenance testing on flocks attaining MN1 status only was evaluated.

Note that the modelling specifically examines the probability of OJD infection occurring in SheepMAP flocks and the probability of producers purchasing infected sheep from SheepMAP flocks. It does not consider the consequences of introduction and spread of infection according to flock status or area prevalence.

3.3.1 Part A: Assessing ability of SheepMAP to detect disease

SheepMAP ability to detect diseased flocks was assessed by determining:

6. The proportion of diseased flocks detected on attempted entry to SheepMAP (i.e. detected at the first Sample Test)

7. The proportion of infected flocks within SheepMAP at each stage of the program (MN1-MN3) and via each pathway (repeat Sample Testing and/or vaccination) from each of high, medium and low prevalence regions of Australia.

Flow charts of the simulation model output for the traditional testing regime of PFC350 + veterinary surveillance for high, medium and low prevalence regions were constructed. Figure 3 and Figure 4 are the flow charts for the high and low prevalence areas respectively.

The working of the flow chart in Figure 3 can be demonstrated with the following example. If 1,000 random flocks from a high prevalence area (70% of flocks infected) tried to enter SheepMAP we would expect approximately 300 flocks to be truly free of disease and 700 flocks to be infected. At the first sample test all 300 of the disease-free flocks will return a negative result and attain MN1 status. Of the 700 infected flocks that attempt entry to SheepMAP the sample test will detect disease in 92.6% (648 flocks). The remaining 7.4% (or 52 flocks) will return an erroneous negative result (false negative flocks) due to the low level of shedding and low sensitivity of the test in these flocks, but these flocks will also attain MN1 status. Therefore only 352 of the 1,000 flocks attempting to enrol in SheepMAP will become accredited and of these 300 are truly free of disease (approximately 85%) with 52 false negative (diseased) flocks (approximately 15%).

When these 352 SheepMAP flocks are retested at the next sample test once again the 300 disease-free flocks will return a negative result and attain MN2 status. Of the 52 false negative

---

\(^{16}\) PFC350: Unless otherwise stated, PFC350 refers to the testing requirements as defined in Element 6 “Testing Strategies” of the SheepMAP Manual and includes for small flocks (i.e. fewer than 350 sheep aged two years and over) that all sheep over two years old are tested.
MN1 flocks, the second sample test is predicted to detect and remove around 53% (or approximately 28 flocks) leaving approximately 24 false negative flocks within SheepMAP at MN2 status. This process continues through the testing program until we have fewer than 10 of the false negative flocks surviving the MN3 sample test whilst all 300 disease-free flocks survive this test.

The dramatic reduction in detection rates from attempted enrolment (92.6% detected) to MN1 (52.9% detected) arises because low prevalence flocks are more likely to avoid detection at the PFC350 test than a high prevalence flock; MN1 and subsequent sample tests are trying to detect disease in fewer infected flocks that have disease at a lower prevalence within flock than for the preceding testing point and therefore performance (sensitivity) decreases.

Flow charts for the medium prevalence area and also for PFC350 sensitivity for paucibacillary pools less than 0.50 are available in the Detailed Modelling Report. Outputs were obtained for different sensitivities and specificities for PFC350 (historical versus recent data) as described in the assumptions in Table 1.

Figure 3 shows that sample testing using PFC350 results in about 7.4% of flocks from a high prevalence region being accepted as MN1 (i.e. 7.4% are false negatives). By the time flocks have attained MN3 status via sample testing and veterinary surveillance according to the testing protocols, about 2.5% of MN3 flocks in a high prevalence region are infected (i.e. false negatives). There is a decline in false negatives for MN flocks from the low prevalence area with only 0.01% false negatives for MN3 (Figure 4).

Results for all testing regimes (PFC350, PFC350+VS\textsuperscript{17}, PFC350+AS\textsuperscript{18}, PFC350+VS+AS, AS) across the various prevalence areas and the average prevalence of disease in infected flocks (the proportion of sheep within the infected flock that have OJD) on entry to and on passage through the SheepMAP program from Unassessed to MN3 are summarised in Table 2, Table 3 and Table 4.

These results demonstrate that the sample test is highly efficient at detecting diseased flocks containing a high proportion of sheep with OJD (high within-flock prevalence). Infected flocks with few infected sheep (low within-flock prevalence) are more likely to avoid detection at the screening test and therefore to progress further through the program than infected flocks with a high proportion of diseased sheep.

\textsuperscript{17} Veterinary surveillance
\textsuperscript{18} Abattoir surveillance
Figure 3 Flow chart of flock infection (high prevalence area)

<table>
<thead>
<tr>
<th>High Prevalence Area</th>
<th>70% flocks infected</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non Assessed</strong></td>
<td></td>
</tr>
<tr>
<td>Sample Test</td>
<td></td>
</tr>
<tr>
<td>% Flocks Free 30.0%</td>
<td>% Flocks Infected 70.0%</td>
</tr>
<tr>
<td></td>
<td>Negative test 100.0%</td>
</tr>
<tr>
<td></td>
<td>Positive test 92.6%</td>
</tr>
<tr>
<td><strong>MN1</strong></td>
<td></td>
</tr>
<tr>
<td>Sample Test</td>
<td></td>
</tr>
<tr>
<td>% MN1 Flocks Free 85.3%</td>
<td>% MN1 Flocks Infected 14.7%</td>
</tr>
<tr>
<td></td>
<td>Negative test 100.0%</td>
</tr>
<tr>
<td></td>
<td>Positive test 52.9%</td>
</tr>
<tr>
<td><strong>MN2</strong></td>
<td></td>
</tr>
<tr>
<td>Sample Test</td>
<td></td>
</tr>
<tr>
<td>% MN2 Flocks Free 93.5%</td>
<td>% MN2 Flocks Infected 6.5%</td>
</tr>
<tr>
<td></td>
<td>Negative test 100.0%</td>
</tr>
<tr>
<td></td>
<td>Positive test 36.3%</td>
</tr>
<tr>
<td><strong>MN3</strong></td>
<td></td>
</tr>
<tr>
<td>Sample Test</td>
<td></td>
</tr>
<tr>
<td>% MN3 Flocks Free 96.0%</td>
<td>% MN3 Flocks Infected 4.0%</td>
</tr>
<tr>
<td></td>
<td>Negative test 100.0%</td>
</tr>
<tr>
<td></td>
<td>Positive test 36.3%</td>
</tr>
<tr>
<td><strong>MN3</strong></td>
<td></td>
</tr>
<tr>
<td>% MN3 Flocks Free 97.5%</td>
<td>% MN3 Flocks Infected 2.5%</td>
</tr>
</tbody>
</table>
Figure 4 Flow chart of flock infection (low prevalence area)

<table>
<thead>
<tr>
<th>Low Prevalence Area</th>
<th>1% flocks infected</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non Assessed</strong></td>
<td></td>
</tr>
<tr>
<td>Sample Test</td>
<td>% Flocks Free 99.0%</td>
</tr>
<tr>
<td></td>
<td>Negative test 100.0%</td>
</tr>
<tr>
<td></td>
<td>Positive test 92.6%</td>
</tr>
<tr>
<td><strong>MN1</strong></td>
<td></td>
</tr>
<tr>
<td>Sample Test</td>
<td>% MN1 Flocks Free 99.9%</td>
</tr>
<tr>
<td></td>
<td>Negative test 100.0%</td>
</tr>
<tr>
<td></td>
<td>Positive test 52.9%</td>
</tr>
<tr>
<td><strong>MN2</strong></td>
<td></td>
</tr>
<tr>
<td>Sample Test</td>
<td>% MN2 Flocks Free 99.96%</td>
</tr>
<tr>
<td></td>
<td>Negative test 100.0%</td>
</tr>
<tr>
<td></td>
<td>Positive test 36.3%</td>
</tr>
<tr>
<td><strong>MN3</strong></td>
<td></td>
</tr>
<tr>
<td>Sample Test</td>
<td>% MN3 Flocks Free 99.98%</td>
</tr>
<tr>
<td></td>
<td>Negative test 100.0%</td>
</tr>
<tr>
<td></td>
<td>Positive test 36.3%</td>
</tr>
<tr>
<td><strong>MN3</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>% MN3 Flocks Free 99.99%</td>
</tr>
</tbody>
</table>
Table 2 Program stage infected flock detection rates and prevalence of disease within infected flocks (% sheep infected)

<table>
<thead>
<tr>
<th>PFC PB&lt;sup&gt;19&lt;/sup&gt; Se</th>
<th>Regime</th>
<th>Entry</th>
<th>Average Prevalence (% sheep in flock)</th>
<th>Detection Rate (%)</th>
<th>MN1</th>
<th>Average Prevalence (% sheep in flock)</th>
<th>Detection Rate (%)</th>
<th>MN2</th>
<th>Average Prevalence (% sheep in flock)</th>
<th>Detection Rate (%)</th>
<th>MN3</th>
<th>Average Prevalence (% sheep in flock)</th>
<th>Detection Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>OLD</td>
<td>PFC350</td>
<td>3.17</td>
<td>90.8</td>
<td>0.17</td>
<td>52.1</td>
<td>0.12</td>
<td>43.6</td>
<td>0.08</td>
<td>48.8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Se = 0.50</td>
<td>PFC+VS&lt;sup&gt;20&lt;/sup&gt;</td>
<td>3.18</td>
<td>92.6</td>
<td>0.15</td>
<td>52.9</td>
<td>0.096</td>
<td>36.3</td>
<td>0.08</td>
<td>36.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PFC+AS&lt;sup&gt;21&lt;/sup&gt;</td>
<td>3.38</td>
<td>93.4</td>
<td>0.14</td>
<td>56.9</td>
<td>0.10</td>
<td>38.9</td>
<td>0.079</td>
<td>48.8</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PFC+VS+AS</td>
<td>3.20</td>
<td>94.1</td>
<td>0.14</td>
<td>60.6</td>
<td>0.079</td>
<td>46.2</td>
<td>0.078</td>
<td>35.1</td>
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<tr>
<td></td>
<td>AS</td>
<td>3.32</td>
<td>90.8</td>
<td>0.17</td>
<td>14.7</td>
<td>0.16</td>
<td>15.0</td>
<td>0.15</td>
<td>10.9</td>
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</tr>
<tr>
<td>NEW</td>
<td>PFC350</td>
<td>3.25</td>
<td>86.8</td>
<td>0.25</td>
<td>45.4</td>
<td>0.17</td>
<td>37.6</td>
<td>0.14</td>
<td>26.8</td>
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</tr>
<tr>
<td>Se &lt; 0.50</td>
<td>PFC+VS</td>
<td>3.19</td>
<td>89.8</td>
<td>0.21</td>
<td>49.1</td>
<td>0.14</td>
<td>37.4</td>
<td>0.09</td>
<td>27.5</td>
<td></td>
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<tr>
<td></td>
<td>PFC+AS</td>
<td>3.51</td>
<td>91.2</td>
<td>0.20</td>
<td>55.5</td>
<td>0.14</td>
<td>45.3</td>
<td>0.13</td>
<td>30.3</td>
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<tr>
<td></td>
<td>PFC+VS+AS</td>
<td>3.37</td>
<td>92.6</td>
<td>0.16</td>
<td>51.0</td>
<td>0.12</td>
<td>43.0</td>
<td>0.09</td>
<td>33.0</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AS</td>
<td>3.32</td>
<td>86.8</td>
<td>0.17</td>
<td>14.7</td>
<td>0.16</td>
<td>15.0</td>
<td>0.15</td>
<td>10.9</td>
<td></td>
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</tbody>
</table>

<sup>19</sup> Paucibacillary
<sup>20</sup> Veterinary surveillance
<sup>21</sup> Abattoir surveillance
Table 3 Infected SheepMAP flock cumulative detection rates by stage

<table>
<thead>
<tr>
<th>PFC350</th>
<th>Regime</th>
<th>MN1</th>
<th>MN2</th>
<th>MN3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pool</td>
<td>PB</td>
<td>Se</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OLD</td>
<td>PFC350</td>
<td>52.1</td>
<td>73.0</td>
<td>86.2</td>
</tr>
<tr>
<td>Se = 0.50</td>
<td>PFC+VS</td>
<td>52.9</td>
<td>70.0</td>
<td>80.9</td>
</tr>
<tr>
<td></td>
<td>PFC+AS</td>
<td>56.9</td>
<td>73.7</td>
<td>86.5</td>
</tr>
<tr>
<td></td>
<td>PFC+VS+AS</td>
<td>60.6</td>
<td>78.8</td>
<td>86.2</td>
</tr>
<tr>
<td></td>
<td>AS</td>
<td>14.7</td>
<td>27.5</td>
<td>35.4</td>
</tr>
<tr>
<td>NEW</td>
<td>PFC350</td>
<td>45.4</td>
<td>65.9</td>
<td>75.0</td>
</tr>
<tr>
<td>Se &lt; 0.50</td>
<td>PFC+VS</td>
<td>49.1</td>
<td>68.1</td>
<td>76.9</td>
</tr>
<tr>
<td></td>
<td>PFC+AS</td>
<td>55.5</td>
<td>75.7</td>
<td>83.1</td>
</tr>
<tr>
<td></td>
<td>PFC+VS+AS</td>
<td>51.0</td>
<td>72.1</td>
<td>81.3</td>
</tr>
<tr>
<td></td>
<td>AS</td>
<td>14.7</td>
<td>27.5</td>
<td>35.4</td>
</tr>
</tbody>
</table>

Table 4 Predicted SheepMAP false negative (FN) flock distribution by program stage, testing program and PFC350 test performance

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>FN at MN1</td>
<td>FN at</td>
<td>MN1</td>
<td>FN at</td>
<td>MN1</td>
<td>FN at</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MN3</td>
<td></td>
<td>MN3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OLD</td>
<td>PFC350</td>
<td>17.7%</td>
<td>3.0%</td>
<td>1.6%</td>
<td>0.6%</td>
<td>0.09%</td>
<td>0.04%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PFC+VS</td>
<td>14.7%</td>
<td>2.4%</td>
<td>1.3%</td>
<td>0.5%</td>
<td>0.07%</td>
<td>0.03%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PFC+AS</td>
<td>13.3%</td>
<td>1.9%</td>
<td>1.2%</td>
<td>0.4%</td>
<td>0.07%</td>
<td>0.03%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PFC+VS+AS</td>
<td>12.1%</td>
<td>1.6%</td>
<td>1.0%</td>
<td>0.3%</td>
<td>0.06%</td>
<td>0.02%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AS</td>
<td>17.7%</td>
<td>5.1%</td>
<td>1.6%</td>
<td>1.1%</td>
<td>0.09%</td>
<td>0.07%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NEW</td>
<td>PFC350</td>
<td>23.5%</td>
<td>4.7%</td>
<td>2.3%</td>
<td>1.0%</td>
<td>0.13%</td>
<td>0.07%</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>PFC+VS</td>
<td>19.2%</td>
<td>3.5%</td>
<td>1.8%</td>
<td>0.7%</td>
<td>0.10%</td>
<td>0.05%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PFC+AS</td>
<td>17.0%</td>
<td>2.6%</td>
<td>1.5%</td>
<td>0.6%</td>
<td>0.09%</td>
<td>0.04%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PFC+VS+AS</td>
<td>14.7%</td>
<td>2.4%</td>
<td>1.3%</td>
<td>0.5%</td>
<td>0.07%</td>
<td>0.03%</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>AS</td>
<td>17.7%</td>
<td>5.1%</td>
<td>1.6%</td>
<td>1.1%</td>
<td>0.09%</td>
<td>0.07%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Percentages for PFC + VS correspond to Figure 3 and Figure 4 flow chart values. Slight differences are due to rounding errors only.

Impact of maintenance testing using the PFC100 test on program performance

The impact of maintenance testing of MN1 flocks for producers selecting to retain MN1 status rather than progressing to MN3 status was examined for the different testing combinations. Maintenance testing is performed using the pooled faecal culture test but limited to a maximum of two pools of 50 adult sheep selected at random (100 sheep in total). The PFC100 test is applied as an alternative to the PFC350 test within the program and a negative result allows existing SheepMAP status to be maintained for the ensuing period. Results are presented in Table 5.

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22 Paucibacillary
23 Veterinary surveillance
24 Abattoir surveillance
There is a significant reduction in detection rate for false negative flocks when maintenance testing (PFC100) is chosen (MN1 – MT1&2) compared to the PFC350 test with progression through the program to MN3 status. Approximately twice as many false negative flocks persist within the program when the PFC100 test is applied instead of the PFC350 test. The assurance provided to purchasers of sheep from SheepMAP MN1 flocks that have selected to maintain status using maintenance testing is accordingly reduced.

The low detection rates for false negative SheepMAP flocks provided by the PFC100 test supports the maintenance of SheepMAP status if a negative PFC100 test is returned. However, the low detection rates for false negative MN1 flocks suggest that this avenue of testing and maintenance is of little value to the program in general. This differs from the potential of incorporating targeted testing to maintain status using PFC or pooled faecal PCR testing of up to 50 sheep as selected by the MAP veterinarian as described in section 3.3.4.

Table 5: Infected flock detection rate (cumulative survival) for various testing combinations within SheepMAP and for various number of years of maintenance testing (using PFC100 testing) within the program

<table>
<thead>
<tr>
<th>Status</th>
<th>PFC350</th>
<th>PFC100</th>
<th>PFC100+VS</th>
<th>PFC100+AS</th>
<th>PFC100+VS+AS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entry</td>
<td>87.8 (12.2)</td>
<td>87.8 (12.2)</td>
<td>89.4 (10.6)</td>
<td>91.8 (8.2)</td>
<td>97.5 (2.5)</td>
</tr>
<tr>
<td>MN1</td>
<td>44.8 (6.7)</td>
<td>20.5 (9.7)</td>
<td>26.4 (7.8)</td>
<td>34.4 (5.4)</td>
<td>36.4 (1.6)</td>
</tr>
<tr>
<td>MN1 – MT1</td>
<td>33.9 (4.5)a</td>
<td>11.9 (8.5)</td>
<td>22.3 (6.1)</td>
<td>30.9 (3.7)</td>
<td>32.8 (1.1)</td>
</tr>
<tr>
<td>MN1-MT2</td>
<td>23.6 (3.4)b</td>
<td>16.9 (7.1)</td>
<td>16.2 (5.1)</td>
<td>35.9 (2.4)</td>
<td>35.2 (0.7)</td>
</tr>
</tbody>
</table>

a – MN2 status; b – MN3 status

The key observations from this modelling are:

1. There is a high detection rate for infected flocks on attempted entry to the program. Approximately 90% of infected flocks do not attain MN1 status. Approximately 10% of infected flocks will evade detection at the first Sample Test and therefore attain MN1 status. These infected flocks are typically low prevalence flocks.

2. The sensitivity of the PFC350 test in detecting infection in flocks with low within-flock prevalence (< 1.0% of sheep infected) is less than 80% and falls away rapidly at lower within-flock prevalence. This suggests that low prevalence flocks are more likely to attain MN1 status. The model therefore is likely to slightly under-predict false negative rates within early stages of the program because it is assumed that few flocks with moderate to high within-flock prevalence would seek entry to SheepMAP.

3. The within-flock prevalence of false negative flocks is markedly less than for unassessed flocks (the median within-flock prevalence for false negative flocks that remain undetected is much lower than the median within-flock prevalence in false negative flocks that were tested at each stage of SheepMAP).

4. Subsequent detection rates for false negative flocks are low at each testing point. This is primarily due to the low within-flock prevalence of disease in false negative flocks. However, cumulatively, fewer than 25% of false negative flocks will attain MN3 status (assuming new flock infections are not occurring in SheepMAP).
5. Vigilant veterinary surveillance and/or abattoir surveillance provide modest improvements in detection when superimposed on PFC testing. This is because PFC testing is highly effective.

6. The proportion of false negative MN1 flocks varies between regions ranging from 0.1% in low prevalence regions up to 4.0% for MN1 in high prevalence regions depending on the testing regime (see Table 4).

7. The proportion of false negative MN3 flocks (for testing combinations involving PFC350) varies between regions ranging from 0.01% in low prevalence regions up to 1.0% in high prevalence regions, again depending on the testing regime (see Table 4).

8. Changing the PFC350 test sensitivity to the (suspected) lower estimate for paucibacillary positive pools (< 0.50) resulted in 2-4% fewer OJD flocks being detected at the entry test and subsequently 5-10% fewer false negative detections when MN3 status was achieved (Table 3). The potential negative impact of reduced PFC350 test sensitivity for paucibacillary pools on the overall performance of SheepMAP does not appear to be large.

9. Abattoir surveillance, whilst effective at the entry test level, is essentially ineffective at detecting false negative SheepMAP flocks. This is primarily because very large lines of sheep are required to detect disease at very low within-flock prevalence and the majority of commercial flocks simply do not have enough cull adult sheep to meet the sample size requirements to provide the required confidence from abattoir surveillance. This problem is further exacerbated by the fact that for a large number of SheepMAP flocks abattoir surveillance is never or rarely applied because of non-participation by the local abattoir and/or sale of cull-for-age sheep directly to other producers.

10. MN1 flocks that choose to maintain status using a pooled faecal culture test of up to 100 sheep in two pools (PFC100) have higher false negative rates and provide lower disease freedom assurance to purchasers of sheep than flocks that choose to progress to higher SheepMAP status.

3.3.2 Part B: Assessing timeliness of SheepMAP in detecting disease in false negative flocks

SheepMAP performance in relation to timely detection of false negative flocks was assessed by:

1. Estimating the time until detection of infected flocks (existing or newly infected) within SheepMAP for each pathway (repeat Sample Testing and/or vaccination)

2. Comparing modelled time to detection with records of actual time to detection from the SheepMAP database.

The actual performance of the SheepMAP testing system in detecting diseased flocks in the program for the period 2003 to 2007 inclusive is presented in Table 6. Approximately 1% of SheepMAP flocks were subsequently detected with disease each year for the period 2003 to 2007 (flock breakdowns). Table 7 shows the model predictions of false negatives and the modality of detection.

Predicted and observed breakdown rates are similar (noting that observed numbers of breakdowns are low). The predicted breakdown rate matches the observed breakdown rate in the program under the assumption of a lower PFC350 paucibacillary pool sensitivity (< 0.50) whilst the predicted breakdown detection mode distribution matches the observed breakdown detection mode distribution under the assumption that the PFC350 paucibacillary pool sensitivity is 0.50.
Table 6 Number of SheepMAP flocks and number of breakdowns in SheepMAP program from 2003 to 2007

<table>
<thead>
<tr>
<th>Year</th>
<th>No. flocks</th>
<th>No. MNV flocks</th>
<th>No. non-MNV flocks</th>
<th>No. flock breakdowns</th>
<th>% of non-MNV flocks</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>741</td>
<td>0</td>
<td>741</td>
<td>8</td>
<td>1.08%</td>
</tr>
<tr>
<td>2004</td>
<td>766</td>
<td>0</td>
<td>766</td>
<td>8</td>
<td>1.04%</td>
</tr>
<tr>
<td>2005</td>
<td>778</td>
<td>134</td>
<td>644</td>
<td>6</td>
<td>0.93%</td>
</tr>
<tr>
<td>2006</td>
<td>779</td>
<td>189</td>
<td>590</td>
<td>6</td>
<td>1.02%</td>
</tr>
<tr>
<td>2007</td>
<td>646</td>
<td>215</td>
<td>431</td>
<td>2</td>
<td>0.46%</td>
</tr>
</tbody>
</table>

Total 3710* 538* 3172* 30* 0.95%#

* - totals for all years, # - % flocks per year

Table 7 Predicted SheepMAP false negative (FN) flock detection rates and modality of detection distribution for low and high PFC350 paucibacillary pool sensitivities

<table>
<thead>
<tr>
<th>PFC350 PB25 Pool Se</th>
<th>Testing regime</th>
<th>Total detections</th>
<th>VS26 % detected</th>
<th>PFC % detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>Old (Se = 0.50)</td>
<td>PFC + VS</td>
<td>0.890%</td>
<td>20%</td>
<td>80%</td>
</tr>
<tr>
<td>New (Se &lt; 0.50)</td>
<td>PFC + VS</td>
<td>1.384%</td>
<td>28%</td>
<td>72%</td>
</tr>
</tbody>
</table>

It needs to be noted that few breakdowns were reported therefore definitive evidence does not exist for any given cause. However, given the small number of breakdowns observed approximates the number predicted from a model assuming no new infections there must be few (if any) new infections in SheepMAP accredited flocks. There may also be a reporting bias in this data such that positive screening test flocks may be included as breakdowns before the results of confirmatory testing are available.

The key observations from this modelling are:

1. Most false negative flocks are detected before attaining MN3 status.
2. For PFC + VS (the required minimum SheepMAP program) approximately 30% of breakdowns between entry and before MN3 status are predicted to be by veterinary surveillance with 70% detected by PFC testing (see Table 7).
3. The modelled and observed detection rates for false negative flocks are similar. This suggests that new infection in previously uninfected SheepMAP flocks is not a major problem within the program.
4. The delayed time to detection of breakdowns in flocks appears likely to be due to the increase in prevalence in false negative flocks that have avoided detection at a sample test. An increase in prevalence over the ensuing years makes later detection more likely than early detection for many false negative flocks.

25 Paucibacillary
26 Veterinary surveillance
3.3.3 **Assessing assurance provided to purchasers of sheep from SheepMAP flocks**

SheepMAP’s ability in providing assurance to purchasers of sheep was assessed by estimating the likelihood that a consignment of sale sheep of set size purchased from a SheepMAP flock of given status and pathway from each of high, medium and low prevalence regions of Australia contains infected sheep.

The probability of disease within a consignment of sheep purchased from a SheepMAP flock can be calculated. This is a function of the following criteria:

1. Ability of the program to detect and exclude infected flocks.
2. Flock SheepMAP accreditation level (and route to achieve that level).
3. Prevalence of infected flocks within the source region.
4. The within-flock prevalence of OJD in false negative SheepMAP flocks for the region.
5. Number of sheep in the consignment.

The consignment risk from a SheepMAP flock can be calculated by adopting assumptions for the above criteria. This can then be directly compared to the risk for a comparable consignment for sheep sourced from an unassessed flock in the nominal very low prevalence zone. Four geographical regions with different prevalence of infected flocks were examined. These were:

1. High prevalence region – 70% of flocks infected with OJD
2. Medium prevalence region – 15% of flocks infected with OJD
3. Low prevalence region – 1.0% of flocks infected with OJD
4. Nominal very low prevalence zone region – 0.5% (maximum) of flocks infected with OJD.

The number of infected sheep per 1,000,000 sheep by prevalence area, SheepMAP status and testing regime is presented in Figure 5. A comparable plot of the number of infected sheep per 1,000,000 sheep per prevalence area for MN1 flocks that elect to maintain status using the maintenance test (PFC100) is presented in Figure 6.

These plots is clearly shows that MN3 status presents a low probability of disease (less than or equal to the probability of disease in a random sheep selected from an unassessed flock in the nominal very low prevalence area) for a single sheep selected at random from a SheepMAP flock from any region. In fact a single sheep selected at random from a MN1 status flock from any region except a high prevalence region provides this level of assurance.

The probability of disease from MN1 flocks that have elected to maintain status using the PFC100 test (MT1 and MT2) is lower than if PFC100 is not used to maintain status in the absence of effective veterinary and/or abattoir surveillance in the nominally higher prevalence area of Australia (Figure 6).

Rarely is a single sheep purchased. Table 8 presents the expected number of disease-free consignments of sheep per OJD diseased consignment from the different regions and from flocks at different SheepMAP status. To aid assessment, consignment risk was converted from a probability of an infected lot being purchased to the expected number of uninfected lots per infected lot. Clearly, the higher this number, the lower the risk of purchase. For example, if a consignment of 5 rams were to be purchased from an unassessed flock in the high prevalence region there would be an average of 10 clean consignments for every consignment with at least one OJD ram. If the purchaser decided to source the 5 rams from a SheepMAP flock at MN1 status then there would only be 1 chance in 870 that the consignment of 5 rams would contain one
or more diseased ram. This clearly shows that flocks with an accredited status within SheepMAP provide significantly less risk to purchasers of sheep than unassessed flocks.

Key observations from this modelling are:

1. Sheep purchased from a SheepMAP flock at MN3 status present a lower risk of OJD than sheep purchased from a non-assessed flock within the nominal very low prevalence zone. This is irrespective of OJD prevalence region, consignment size or performance of the PFC350 test on paucibacillary-positive pools. This result validates the basic premise of SheepMAP; MN3 status flocks present an acceptably low risk of disease.

2. Sheep purchased from a SheepMAP flock in the low prevalence region provide a lower risk of OJD than sheep purchased from a non-assessed flock from the nominal very low prevalence zone for all SheepMAP status levels. Sourcing 500 sheep from a MN1 flock in the low prevalence region provides a 1 in 1,061 chance of disease (Table 8). This compares favourably to the background risk of disease of 1 chance in 218 for a similar sized consignment sourced from an unassessed flock in the nominal very low prevalence zone (Table 10).

3. Sheep purchased from a SheepMAP flock below MN3 status from either the medium or high prevalence regions may present an increased risk of disease compared to sheep sourced from the nominal very low prevalence zone depending on consignment size and testing regime deployed.

4. More effective veterinary surveillance and/or increased abattoir surveillance can provide a high level of assurance for buyers of small consignments from MN1 flocks within the medium or high prevalence regions under the assumption of high PFC350 sensitivity for paucibacillary pools. However, this assurance does not exist for MN1 flocks within the high prevalence region if the performance of the PFC350 test is lower than initially estimated for paucibacillary pools (Se < 0.50).

5. Confidence of OJD freedom decreases as consignment size increases across all prevalence regions. The effect of large consignment size is most pronounced in the high prevalence region.
Figure 5 Number of infected sheep per 1,000,000 sheep by region

<table>
<thead>
<tr>
<th>Testing regime</th>
<th>No. OJD Sheep per 1,000,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>HP-NA</td>
<td>HP-NA</td>
</tr>
<tr>
<td>HP-NA</td>
<td>HP-NA</td>
</tr>
<tr>
<td>MP-NA</td>
<td>MP-NA</td>
</tr>
<tr>
<td>LP-NA</td>
<td>LP-NA</td>
</tr>
</tbody>
</table>

No OJD sheep per 1,000,000 by region, status and testing program

Nominal very low prevalence area

No OJD sheep per 1,000,000 (Log scale)
Figure 6 Number of infected sheep per 1,000,000 sheep by region, SheepMAP status and testing regime for MN1 flocks electing to maintain status using the PFC100 test (MT = maintenance test)
### Table 8: Number of disease-free consignments per diseased consignment for sheep sourced from the high, medium, low and disease-free regions (PFC350 Se PB\textsuperscript{27} < 0.50). A maximum infected flock prevalence of 0.6% with a maximum within-flock prevalence of 0.5% was assumed for the nominal very low prevalence region

<table>
<thead>
<tr>
<th>Testing regime</th>
<th>SheepMAP stage</th>
<th>High 5 Rams</th>
<th>500 Adults</th>
<th>Medium 5 Rams</th>
<th>500 Adults</th>
<th>Low 5 Rams</th>
<th>500 Adults</th>
<th>Nominal Very Low 5 Rams</th>
<th>500 Adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFC (&lt; 0.50)</td>
<td>Unassessed</td>
<td>10</td>
<td>1</td>
<td>44</td>
<td>7</td>
<td>666</td>
<td>100</td>
<td>8,080</td>
<td>218</td>
</tr>
<tr>
<td></td>
<td>MN1</td>
<td>870</td>
<td>15</td>
<td>4,061</td>
<td>71</td>
<td>60,910</td>
<td>1,061</td>
<td>1,505,835</td>
<td>20,870</td>
</tr>
<tr>
<td></td>
<td>MN2</td>
<td>21,512</td>
<td>298</td>
<td>100,389</td>
<td>1,391</td>
<td>1,095,120</td>
<td>14,847,703</td>
<td>33,483,151</td>
<td>464,058</td>
</tr>
<tr>
<td></td>
<td>MN3</td>
<td>478,331</td>
<td>6,629</td>
<td>2,232,210</td>
<td>30,937</td>
<td>1,505,835</td>
<td>20,870</td>
<td>1,095,120,466</td>
<td>14,847,703</td>
</tr>
<tr>
<td></td>
<td>MN3+</td>
<td>15,644,578</td>
<td>212,110</td>
<td>73,008,031</td>
<td>989,847</td>
<td>1,095,120</td>
<td>14,847,703</td>
<td>33,483,151</td>
<td>464,058</td>
</tr>
<tr>
<td>PFC + VS\textsuperscript{28}</td>
<td>Unassessed</td>
<td>10</td>
<td>1</td>
<td>44</td>
<td>7</td>
<td>666</td>
<td>100</td>
<td>8,080</td>
<td>218</td>
</tr>
<tr>
<td></td>
<td>MN1</td>
<td>1,339</td>
<td>22</td>
<td>6,251</td>
<td>100</td>
<td>93,764</td>
<td>1,507</td>
<td>1,602,804</td>
<td>37,493</td>
</tr>
<tr>
<td></td>
<td>MN2</td>
<td>38,646</td>
<td>536</td>
<td>180,347</td>
<td>2,500</td>
<td>2,705,203</td>
<td>37,493</td>
<td>1,602,804</td>
<td>37,493</td>
</tr>
<tr>
<td></td>
<td>MN3</td>
<td>1,847,825</td>
<td>22,897</td>
<td>8,623,182</td>
<td>106,854</td>
<td>129,347,727</td>
<td>1,602,804</td>
<td>1,602,804</td>
<td>1,602,804</td>
</tr>
<tr>
<td></td>
<td>MN3+</td>
<td>83,025,332</td>
<td>1,017,064</td>
<td>387,451,552</td>
<td>4,746,297</td>
<td>5,811,773,273</td>
<td>71,194,453</td>
<td>5,811,773,273</td>
<td>71,194,453</td>
</tr>
<tr>
<td>PFC + AS\textsuperscript{29}</td>
<td>Unassessed</td>
<td>10</td>
<td>1</td>
<td>44</td>
<td>7</td>
<td>666</td>
<td>100</td>
<td>8,080</td>
<td>218</td>
</tr>
<tr>
<td></td>
<td>MN1</td>
<td>1,630</td>
<td>26</td>
<td>7,606</td>
<td>120</td>
<td>114,092</td>
<td>1,797</td>
<td>1,833,073</td>
<td>57,615</td>
</tr>
<tr>
<td></td>
<td>MN2</td>
<td>59,387</td>
<td>823</td>
<td>277,141</td>
<td>3,841</td>
<td>4,157,121</td>
<td>57,615</td>
<td>1,833,073</td>
<td>57,615</td>
</tr>
<tr>
<td></td>
<td>MN3</td>
<td>2,985,124</td>
<td>40,472</td>
<td>13,930,580</td>
<td>188,872</td>
<td>208,958,693</td>
<td>2,833,073</td>
<td>208,958,693</td>
<td>2,833,073</td>
</tr>
<tr>
<td></td>
<td>MN3+</td>
<td>199,939,967</td>
<td>2,710,797</td>
<td>933,053,180</td>
<td>12,650,386</td>
<td>13,995,797,699</td>
<td>189,755,793</td>
<td>13,995,797,699</td>
<td>189,755,793</td>
</tr>
<tr>
<td>PFC + VS + AS</td>
<td>Unassessed</td>
<td>10</td>
<td>1</td>
<td>44</td>
<td>7</td>
<td>666</td>
<td>100</td>
<td>8,080</td>
<td>218</td>
</tr>
<tr>
<td></td>
<td>MN1</td>
<td>2,421</td>
<td>35</td>
<td>11,297</td>
<td>164</td>
<td>169,460</td>
<td>2,453</td>
<td>2,453</td>
<td>2,453</td>
</tr>
<tr>
<td></td>
<td>MN2</td>
<td>88,947</td>
<td>1,179</td>
<td>415,088</td>
<td>5,504</td>
<td>6,226,321</td>
<td>82,564</td>
<td>6,226,321</td>
<td>82,564</td>
</tr>
<tr>
<td></td>
<td>MN3</td>
<td>5,734,678</td>
<td>71,061</td>
<td>26,761,828</td>
<td>331,617</td>
<td>401,427,427</td>
<td>4,974,261</td>
<td>401,427,427</td>
<td>4,974,261</td>
</tr>
<tr>
<td></td>
<td>MN3+</td>
<td>423,520,083</td>
<td>5,224,017</td>
<td>1,976,427,052</td>
<td>24,378,747</td>
<td>29,646,405,780</td>
<td>365,681,198</td>
<td>29,646,405,780</td>
<td>365,681,198</td>
</tr>
</tbody>
</table>

Note: Darker font indicates higher disease risk (i.e., lower number of disease-free consignments) compared to the nominal very low prevalence area

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\textsuperscript{27} Paucibacillary

\textsuperscript{28} Veterinary surveillance

\textsuperscript{29} Abattoir surveillance
3.3.4 Part D: Assessing impact of ceasing sample testing of SheepMAP vaccinating flocks

There is evidence of false negative flocks within SheepMAP. It also remains possible for disease-free SheepMAP flocks to become infected (stray sheep, purchases etc.). Assurances provided by SheepMAP would improve under increased targeted surveillance (i.e. veterinary surveillance) or testing (either regular abattoir surveillance or statistically-based sample testing) aimed at detecting disease within SheepMAP flocks and thereby confirming current status of flocks within the program. This has implications for MNV flocks within SheepMAP because currently the program allows MNV flocks to maintain status without further systematic sample testing of adults if the producer vaccinates all retained animals at or below 16 weeks of age and vaccinates all introduced animals on arrival.

There is evidence of:

1. Prolonged persistence of disease in vaccinating flocks (less than 20% return negative PFC350 tests after five years).
2. Suppression of clinical disease and a reduced within-flock prevalence of disease in infected and vaccinating flocks (Dhand et al 2013).

These factors make it likely that a number of MNV flocks that do not undertake sample testing could harbour disease and this is compounded by the suspicion that detection in the absence of vigilant veterinary and/or abattoir surveillance is unlikely.

The model was re-run with vaccination and with and without subsequent sample testing for flocks that achieved MN1 (approximately 10% of infected flocks attain MN1 status i.e. false negatives). Under the current SheepMAP rules, subsequent detection of infected and vaccinating flocks in the program is reliant upon either veterinary surveillance and/or abattoir surveillance. The proportion detected each year by detection modality is presented in Table 9. Also shown is detection if PFC100 is used instead of PFC350.

It must be noted that abattoir surveillance is not applied to all flocks in all years therefore the estimated detection rate and cumulative detection rate for abattoir surveillance from this modelling is certainly an overestimation of performance. A flock would need to submit for abattoir surveillance for all of the ten years simulated to average this level of detection.

A clear finding from Table 9 is that despite the reduced sensitivity of the PFC350 test in these low prevalence flocks application of the PFC test remains currently the most effective way of detecting false negative vaccinating SheepMAP flocks. It appears that MNV flocks that choose not to undertake further sample testing pose some risk to the integrity of SheepMAP, albeit small.

Table 9 shows subsequent cumulative detection using veterinary surveillance alone is 39% after 10 years. The median time to detection (50% cumulative detection) for infected MNV flocks when abattoir surveillance of all cull lines of adult sheep is completed is between five and six years after attaining MN1 status, however 30% of infected MNV flocks may remain undetected after 10 years. The median time to detection when veterinary and abattoir surveillance are combined is three years with approximately 20% remaining undetected after ten years. All compare poorly to a median time to detection of approximately 4 years (i.e. 2 sample tests) for PFC350 testing. Cumulative detection using PFC100 is only marginally higher than for veterinary surveillance only (39.8% versus 39.1%).
Table 9 Proportion of MNV flocks detected per year by modality in the absence of biennial PFC350 sample testing

<table>
<thead>
<tr>
<th>Years since MN1</th>
<th>PFC100 Detected (%)</th>
<th>PFC100 Cumul. Detection (%)</th>
<th>VS (only) Detected (%)</th>
<th>VS (only) Cumul. Detection (%)</th>
<th>PFC350 Detected (%)</th>
<th>PFC350 Cumul. Detection (%)</th>
<th>PFC350 + VS Detected (%)</th>
<th>PFC350 + VS Cumul. Detection (%)</th>
<th>PFC350 + AS Detected (%)</th>
<th>PFC350 + AS Cumul. Detection (%)</th>
<th>PFC350 + VS + AS Detected (%)</th>
<th>PFC350 + VS + AS Cumul. Detection (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>-</td>
<td>7.0%</td>
<td>7.0%</td>
<td>-</td>
<td>-</td>
<td>8.6%</td>
<td>8.6%</td>
<td>-</td>
<td>-</td>
<td>14.3%</td>
<td>14.3%</td>
</tr>
<tr>
<td>2</td>
<td>10.9%</td>
<td>10.9%</td>
<td>5.1%</td>
<td>11.7%</td>
<td>34.9%</td>
<td>34.9%</td>
<td>9.4%</td>
<td>17.2%</td>
<td>13.2%</td>
<td>25.6%</td>
<td>19.6%</td>
<td>36.9%</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>-</td>
<td>5.6%</td>
<td>16.7%</td>
<td>-</td>
<td>-</td>
<td>9.6%</td>
<td>25.1%</td>
<td>11.9%</td>
<td>34.5%</td>
<td>20.1%</td>
<td>49.6%</td>
</tr>
<tr>
<td>4</td>
<td>10.1%</td>
<td>19.9%</td>
<td>5.8%</td>
<td>21.5%</td>
<td>32.9%</td>
<td>56.3%</td>
<td>9.2%</td>
<td>32.0%</td>
<td>11.8%</td>
<td>42.2%</td>
<td>19.7%</td>
<td>59.5%</td>
</tr>
<tr>
<td>5</td>
<td>-</td>
<td>-</td>
<td>4.3%</td>
<td>24.9%</td>
<td>-</td>
<td>-</td>
<td>7.9%</td>
<td>37.4%</td>
<td>8.2%</td>
<td>46.9%</td>
<td>15.7%</td>
<td>65.9%</td>
</tr>
<tr>
<td>6</td>
<td>10.6%</td>
<td>28.4%</td>
<td>5.0%</td>
<td>28.6%</td>
<td>30.9%</td>
<td>69.8%</td>
<td>5.9%</td>
<td>41.1%</td>
<td>11.5%</td>
<td>53.0%</td>
<td>12.5%</td>
<td>70.1%</td>
</tr>
<tr>
<td>7</td>
<td>-</td>
<td>-</td>
<td>4.9%</td>
<td>32.1%</td>
<td>-</td>
<td>-</td>
<td>5.6%</td>
<td>44.4%</td>
<td>11.7%</td>
<td>58.5%</td>
<td>11.3%</td>
<td>73.5%</td>
</tr>
<tr>
<td>8</td>
<td>8.8%</td>
<td>34.7%</td>
<td>3.9%</td>
<td>34.8%</td>
<td>23.8%</td>
<td>77.0%</td>
<td>4.1%</td>
<td>46.7%</td>
<td>7.2%</td>
<td>61.5%</td>
<td>12.2%</td>
<td>76.7%</td>
</tr>
<tr>
<td>9</td>
<td>-</td>
<td>-</td>
<td>2.6%</td>
<td>36.5%</td>
<td>-</td>
<td>-</td>
<td>3.3%</td>
<td>48.4%</td>
<td>11.7%</td>
<td>66.0%</td>
<td>12.8%</td>
<td>79.7%</td>
</tr>
<tr>
<td>10</td>
<td>7.8%</td>
<td>39.8%</td>
<td>4.1%</td>
<td>39.1%</td>
<td>23.8%</td>
<td>82.5%</td>
<td>3.2%</td>
<td>50.1%</td>
<td>7.7%</td>
<td>68.6%</td>
<td>14.0%</td>
<td>82.6%</td>
</tr>
</tbody>
</table>
The risk of introduction of disease by purchasers of sheep from a false negative MNV flock across the range of likely within-flock prevalence and consignment sizes can be calculated and this is presented in Table 10.

### Table 10 Percentage of infected consignments sourced from false negative MNV flocks by flock prevalence and consignment size

<table>
<thead>
<tr>
<th>Within-flock Prevalence (%)</th>
<th>Consignment size</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>0.01</td>
<td>0.0%</td>
</tr>
<tr>
<td>0.05</td>
<td>0.0%</td>
</tr>
<tr>
<td>0.10</td>
<td>0.1%</td>
</tr>
<tr>
<td>0.15</td>
<td>0.1%</td>
</tr>
<tr>
<td>0.20</td>
<td>0.2%</td>
</tr>
<tr>
<td>0.30</td>
<td>0.3%</td>
</tr>
<tr>
<td>0.40</td>
<td>0.4%</td>
</tr>
<tr>
<td>0.50</td>
<td>0.5%</td>
</tr>
<tr>
<td>0.60</td>
<td>0.6%</td>
</tr>
<tr>
<td>0.70</td>
<td>0.7%</td>
</tr>
<tr>
<td>1.00</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

These results suggest that:

1. The majority of small consignments of sheep from false negative MNV flocks present very low risk (< 1%) of disease introduction for purchasers.
2. Larger consignments of sheep purchased from false negative MNV flocks present a high risk of disease across the feasible range of within-flock prevalence (for example more than 20% probability of infection for a consignment of 50 sheep where within-flock prevalence is 0.50%).
3. As within-flock prevalence in false negative MNV flocks increases, the risk of transmission of disease to purchasers also increases. Concurrent increases in within-flock prevalence and in consignment size markedly increase the risk of an infected consignment.

The low within-flock prevalence in false negative MNV flocks reduces the ability of the PFC350 test to detect disease. Modelling of subsequent detection rates if PFC350 testing is applied alongside veterinary surveillance indicates that less than 50% of infected flocks will be detected at the next sample test and only around 2/3rds will be detected before acquiring MN3-V status. Increasing pool size is also not particularly effective. Ten pools of 50 sheep will provide 75% detection before MN3-V status and doubling the number of pools provides around 85% detection before MN3-V status.

Imposition of PFC350 testing on MNV flocks should be carefully considered before implementation as there are some significant issues that need to be considered:

- PFC testing for low prevalence flocks has low sensitivity. Increasing the number of pools has marginal effect on flock-level sensitivity. PFC testing may not greatly reduce the risk of infected consignments of sheep from false negative MNV flocks (by detecting false negative MNV flocks).
- The cost of PFC testing (if imposed) is additional to the cost of vaccination for the producer. This may result in some producers opting out of SheepMAP or ceasing to vaccinate.
- Systematic sample-based testing may not be as efficient at detecting false negative MNV flocks as effective targeted veterinary surveillance.

Alternatives to PFC testing of MNV flocks are:

- Combined abattoir surveillance and veterinary surveillance
- Targeted PFC or pooled faecal PCR testing of up to 50 sheep as selected by the MAP veterinarian per flock. Selection would focus on including sheep of higher clinical suspicion of OJD (e.g. thin, scouring etc.) to the MAP veterinarian. This differs from both the PFC350 and the PFC100 sample test described previously where individual animal selection is random; this is a targeted sampling application.

For the abattoir surveillance/ veterinary surveillance option, Table 11 and Table 12 show the number of sheep required to be examined under veterinary surveillance in the presence or absence of abattoir surveillance. This comparison shows that to detect disease at a 1.0% within-flock prevalence in a flock of 1,000 adults requires:

- 2 sheep if 20% of the adult flock is submitted to abattoir surveillance
- 8 sheep if none of the adult flock is submitted to abattoir surveillance

This option quickly becomes unfeasible as the minimum prevalence of disease required to detect decreases below 0.5% and especially in flocks with few (or no) animals sent for abattoir surveillance.
Table 11 Number of veterinary surveillance sheep required to support abattoir surveillance whereby 20% of the adult sheep population was submitted for abattoir surveillance each year by flock size and assumed OJD prevalence

<table>
<thead>
<tr>
<th>OJD Prev</th>
<th>500</th>
<th>1,000</th>
<th>1,500</th>
<th>2,000</th>
<th>2,500</th>
<th>5,000</th>
<th>7,500</th>
<th>10,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.05%</td>
<td>128</td>
<td>128</td>
<td>128</td>
<td>128</td>
<td>128</td>
<td>37</td>
<td>37</td>
<td>37</td>
</tr>
<tr>
<td>0.10%</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>19</td>
<td>19</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>0.50%</td>
<td>5</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>0.75%</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1.00%</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>1.50%</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2.00%</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 12 Number of veterinary surveillance sheep required under the assumption that no adult sheep were submitted for abattoir surveillance by flock size and assumed flock OJD prevalence

<table>
<thead>
<tr>
<th>OJD Prev</th>
<th>500</th>
<th>1,000</th>
<th>1,500</th>
<th>2,000</th>
<th>2,500</th>
<th>5,000</th>
<th>7,500</th>
<th>10,000</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.05%</td>
<td>128</td>
<td>128</td>
<td>128</td>
<td>128</td>
<td>128</td>
<td>128</td>
<td>128</td>
<td>128</td>
</tr>
<tr>
<td>0.10%</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>0.50%</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>0.75%</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>1.00%</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>1.50%</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>2.00%</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
</tbody>
</table>

One potential problem with targeted use of PFC testing is the time delay from sample collection until results become available. There appears to be no advantage in targeting older adult sheep as (theoretically) there is no age gradient in OJD prevalence within flocks and targeting older sheep may actually delay detection in flocks where disease is introduced.

An alternative option that may be considered is targeted pooled faecal PCR testing of the sub-population of sheep of greatest clinical suspicion of OJD by the SheepMAP veterinarian (although it must be noted that the pooled PCR test is not yet commercially available).

If the pooled faecal PFC or PCR sample-collection-to-results turn-around time is short enough to have minimal numbers of sampled sheep dying from their condition before results are available (allowing effective follow-up of positive results) and/or if the positive result of a pool that contains one or more sheep that has subsequently died stands despite not being able to undertake any confirmatory testing then targeting this group of animals may effectively increase test performance.

The effectiveness of this targeting was examined under the following assumptions:

- The test sensitivity of the PCR test is the same as for the PFC test
- Up to 50 target sheep are examined per flock. This number may be less than 50 (if fewer than 50 eligible animals exist)
- The maximum pool size is 50.
Simulation estimates of flock sensitivity of targeted PFC/PCR sampling of 50 suspect sheep are presented graphically in Figure 7. A targeted pooled faecal PFC or PCR testing regime for vaccinating flocks clearly has potential to detect false negative flocks with high sensitivity and down to very low within-flock prevalence. The implementation of such a testing regime will depend upon the final test performance parameters of the PCR test (especially specificity), the cost of testing, the time delay until results are available (especially for the PFC test) and the acceptability (or otherwise) of a positive pool result that cannot be subsequently confirmed due to the intervening death of one or more sheep from the pool.

The key points are:

1. A proportion of MNV flocks will be infected. Some of these flocks were not detected at the entry PFC350 test whilst some may be new infections in previously free flocks. The prevalence of false negative flocks may paradoxically be higher for MNNV flocks than for the equivalent MNN flocks due to the requirement for regular sample-based testing of MNN flocks (not currently required for MNNV flocks).

2. False negative (FN) MNNV flocks are likely to have very low within-flock prevalence. Vaccination has been shown to maintain within flock prevalence at very low levels in most (but not all) flocks that diligently vaccinate.

**Figure 7 Flock sensitivity of PF-PCR**

![Graph of Flock sensitivity of targeted PFC-PCR single-pool test](image)

3. Detection of infection in false negative MNNV flocks is problematic due to the low prevalence within the flock. The PCF350 test is not particularly efficient at detecting disease in flocks with <
1.0% prevalence but is clearly the most effective detection tool to hand. There appear to be no effective adult sheep targeting options for application of the PFC test in vaccinating flocks.

4. Abattoir surveillance can be effective at detecting false negative MNnV flocks but many sheep are required to be sent for slaughter and examined to detect disease. Many MNnV flocks will not send sufficient adult sheep through abattoir surveillance to meet surveillance requirements.

5. Veterinary surveillance provides targeted surveillance for suspect animals but again the effectiveness of veterinary surveillance depends upon the relative proportion of OJD sheep in the target population. Limiting the number of post mortem examinations to three thin sheep markedly reduces the capacity of veterinary surveillance to detect low prevalence false negative flocks.

6. Implementation of PFC350 testing of adult sheep in MNnV flocks as per the requirements for non-vaccinating SheepMAP flocks to maintain or advance status is currently the most effective option for SheepMAP. This may however result in a number of farmers opting out of the program and/or ceasing to vaccinate.

7. Combined surveillance (abattoir surveillance and veterinary surveillance) offers potential for cost effective detection of false negative MNnV flocks that may avoid the requirement for ongoing PFC350 testing. However determining surveillance requirements for flocks from two modalities is logistically difficult to manage. The number of sheep required for post mortem increases dramatically as the minimum detectable prevalence decreases below 0.5% and this effect is compounded as fewer animals are sent for abattoir surveillance.

8. One alternative to the post mortem of large number of target thin adult sheep may be pooled PFC testing of up to 50 eligible sheep in this category. Investigating positive pools under this scenario may be problematic, as deaths of a number of these thin adult sheep before results are available would be expected and this may require a redefining of the rules of the program to avoid conflict over interpretation of a positive result in the event of a death of a sampled sheep before results are available. The time lag from sample collection to test results from application of the pooled faecal PCR test is markedly less than for the PFC test and this may potentially offer advantages over the PFC test.

9. Introduction of a targeted PFC and/or PCR test (once guidelines are approved) targeted at the population of thin sheep potentially offers a suitably high sensitivity for detection of infected MNV flocks. A single pool of 50 sheep appears to have very high sensitivity for detection of disease and therefore this approach is recommended if high specificity can be assured, there is a rapid turn-around of results (allowing targeting of sheep at increased risk of death), the rules for interpretation of a positive result are clear and acceptable (especially in the event of death of sampled sheep before results are available), and if the cost of testing is not substantial.

10. The high sensitivity of a single pool of up to 50 targeted sheep suggests targeted PFC/PCR testing of thin sheep may present a viable and cost-effective alternative to the current PFC350 test that is currently applied randomly to adults as the sample test for the program. However, the logistics of aggregating all thin sheep combined with changes to the prevalence of thin sheep within flocks throughout the course of the year require careful consideration before progressing this option as a replacement for the PFC350 test in SheepMAP.

3.3.5 Model sensitivity

The sensitivity of outputs to various inputs was examined. The model was run using different input values for the following variables:

- Ratio of paucibacillary to multibacillary sheep
- Prevalence of thin target sheep
- Sensitivity of the PFC350 test for paucibacillary positive pools
- Doubling time for within-flock prevalence

The model outputs indicated that the performance of the SheepMAP was not sensitive to changes to the above variables except for the changes to the doubling time for within flock prevalence. Increasing the rate of spread of disease within flocks results in higher detection rates for false negative flocks at each subsequent testing point. The model used did not allow prevalence within flock to alter and therefore SheepMAP is likely to be more effective at detecting disease and therefore at accrediting flocks than predicted by the steady state model.

### 3.4 Summary of conclusions from modelling

1. The SheepMAP (Dec 2005 version) is meeting the primary objective of providing assurances to the market that sheep sourced from accredited flocks present an acceptably low risk of OJD.

2. Flocks at MN3 status – irrespective of prevalence region – present a reduced risk of acquisition of OJD that is at least comparable to the risk posed from an unassessed flock in an OJD nominal very low prevalence zone.

3. The PFC350 test is highly efficient at detecting diseased flocks when the prevalence within the flock is 2% or greater. The sensitivity of detection of this flock test declines rapidly as within-flock prevalence declines below 2%. However, the impact of this decline in PFC350 test sensitivity on the program appears to be small.

4. Maintenance testing using the PFC100 test is less efficient than the PFC350 test at detecting false negative diseased flocks. The risk for purchasers of sheep from MN1 flocks that have maintained status by one or more PFC100 tests may be unacceptably high for flocks in areas with moderate to high prevalence of infection.

5. The faecal polymerase chain reaction test (HT-J-PCR) currently under refinement and accreditation appears to be an effective replacement for the PF350 test. This test will be a pool-based test similar to PFC350 testing. Performance parameters (sensitivity and specificity) are likely to mirror the PFC350 test therefore the key advantage provided by a change from PFC to HT-J-PCR testing is in timeliness of results and perhaps cost of testing.

6. Vigilant veterinary surveillance and/or abattoir surveillance provide modest improvements in detection when superimposed on PFC testing. This is because PFC testing is highly effective and essentially underpins the program.

7. Approximately 10% of infected flocks can be expected to evade detection at initial PFC350 entry test for SheepMAP. These false negative flocks typically have very low within-flock prevalence of disease. The impact of false negative flocks on the assurance provided by the program on a regional basis depends upon the prevalence of infected flocks in a region but this is generally small. The general trend towards increasing prevalence between sample tests makes subsequent detection of false negative flocks more likely. Therefore flocks with high SheepMAP status provide high assurance of freedom from disease.

8. Observational studies have shown that the majority of infected flocks that vaccinate with Gudair® remain infected for at least 5 years or longer. Studies also indicate that vaccination is effective at reducing clinical disease incidence, restricting within-flock prevalence and suppressing shedding of bacteria in the majority of vaccinated but infected sheep. Research indicates that vaccination alone does not eliminate disease and does not prevent introduction of disease for the majority of vaccinating flocks. Vaccinating SheepMAP flocks therefore...
require regular ongoing sample-based surveillance to detect false negative flocks as per non-
vaccinating SheepMAP flocks. PFC350 testing is the most effective form of regular testing of
vaccinating flocks however the sensitivity of this sample-based test may be lower than for non-
vaccinating flocks due to the lower prevalence of disease in infected but vaccinating flocks. The
added costs of program compliance from the introduction of regular PFC350 testing in MNV
flocks may result in many producers leaving SheepMAP, ceasing to vaccinate or both and the
implications of such a change to the program on the participation rate of producers needs to be
carefully considered.

9. One alternative to introduction of PFC350 testing in MNV flocks that may be considered is
combined abattoir surveillance with tailored veterinary surveillance (i.e. variable numbers of
post mortems each year). This combined approach can provide increased assurance of
disease freedom (below a certain predefined level – e.g. 1% of sheep) using recently
recognised approaches to combining different sources of negative surveillance information.
Targeted PFC testing does not appear to be a feasible alternative because there is no age-
related concentration of disease and the time delay from sample collection and PFC results
makes application of culture-based testing of thin adult sheep problematic as intervening
deaths compromise ability to investigate positive results and eliminate false positive tests.
However, application of pooled faecal polymerase chain reaction test (HT-J-PCR) of all thin
adult sheep may allow effective targeting of disease in MNV. The polymerase chain reaction
test has a fast result turnaround time and this would likely minimise the number of deaths in
sampled sheep between sampling and results minimising problematic follow-ups of positive
results.

10. Vaccination does not guarantee disease will be eradicated from flocks or that vaccinated sheep
are immune to infection by OJD. Vaccination is not fully protective in SheepMAP flocks.
Gudair® does not eliminate disease from all flocks in a timely manner and it does not eliminate
risk of new infection in vaccinated sheep when challenged. These observations emphasise the
importance of effective and ongoing biosecurity reviews and veterinary surveillance within
SheepMAP. Targeted and diligent veterinary surveillance may provide more cost-effective and
timely detection of disease in low prevalence flocks however the large number of sheep
required to be killed and examined by the veterinarian may preclude uptake. Veterinary
surveillance is best combined with abattoir surveillance in these flocks. The application of
regular PFC350 sample testing currently provides the most effective detection option for MNV
flocks in SheepMAP. Further development of the pooled faecal PCR test may allow targeted
testing of the whole population of thin adult sheep in vaccinating flocks. This will require rapid
result turnaround to allow effective investigation of positive results whilst the majority of these
high mortality sheep remain alive for effective follow-up.

11. The imposition of regular sample testing on Gudair®-vaccinating SheepMAP flocks needs
careful consideration. Vaccinating flocks already bear the cost of vaccine and vaccinating.
Imposition of additional costs through compulsory PFC350 sample testing may prompt some
producers to either leave SheepMAP or to stop using the vaccine. The implications of
producers leaving the program and/or ceasing to vaccinate needs to be carefully considered by
SheepMAP managers. The cost-benefit of PFC350 testing or implementation of a targeted PFC
or HT-J-PCR test applied to up to 50 adult sheep of higher suspicion of disease than clinically
healthy and normal adults in vaccinating flocks needs to be further assessed in light of these
potential outcomes.

12. Veterinary surveillance (as part of the annual veterinary review) with requirements for targeted
post mortem and histopathology of suspect sheep may be underperforming within SheepMAP.
Identifying ways to improve veterinary surveillance coverage and effectiveness within
SheepMAP is recommended. Targeted PFC or HT-J-PCR testing of the high-suspicion adult sheep population (as identified by the SheepMAP veterinarian) may provide a satisfactory alternative to multiple animal post mortems. The number of sheep to be tested would be determined by the program based on the sensitivity (and specificity) of individual pools, the minimum prevalence of disease to be detected, the confidence in detection required and the number of target sheep available for testing. The development of protocols to investigate positive pools will be required to ensure adequate follow-up and confirmatory testing of screening test positive results is undertaken to the satisfaction of all parties. This will be partly dependent on the innate specificity of the PFC and/or HT-J-PCR test, the time required to obtain results, the expected number of deaths in sampled sheep before results are available and the agreed interpretation of a positive pool that cannot be subsequently followed up with a confirmatory test due to the intervening death of one or more sheep from the pool. Application of targeted PFC or HT-J-PCR and/or veterinary post mortem within annual veterinary surveillance is likely to be more cost-effective than implementation of sample-based (i.e non-targeted) testing (e.g. PFC350) within low prevalence MNV flocks.

13. The potential conflict of interest faced by veterinarians who are both clinicians to commercial producers and also SheepMAP veterinarians to the same flocks needs to be considered, and will be one of the issues examined in the next phase of the OJDMAP review.

14. Abattoir surveillance is a highly effective flock detection test and the sensitivity increases markedly as flock size increases and/or prevalence increases. Abattoir surveillance – especially for large flocks – provides an effective, low cost detection system. Abattoir surveillance may provide an effective alternative to PFC350 testing of vaccinating SheepMAP flocks.

15. Calculating and assigning a disease-freedom assurance level by combining the results from multiple (combined) negative surveillance information (abattoir surveillance, veterinary surveillance and PFC) is possible. However, this adds complexity to the program, has administrative overheads and may result in confusion amongst producers, purchasers of sheep and veterinarians when trying to assess a flock’s status.

4. **Consultation with SheepMAP veterinarians**

4.1 **Introduction and methodology**

The assurance of minimal disease risk presented by a SheepMAP flock depends to a significant extent on the decisions and actions of the supervising veterinarian. Notably, page 8 of the Program’s Guidelines for Veterinarians (July 2006) stipulates that:

*Suspected cases of Johne's disease must be investigated as they occur. For the SheepMAP, if insufficient investigations have been undertaken in a year in which a Sample or Maintenance Test has not been conducted, you must consider conducting post mortem examinations of up to three thin sheep in the flock...If there are no suitable sheep for post mortem this must be recorded as part of the Annual Veterinary Review.*

Vets are left with considerable discretion as to the interpretation of this section, in respect to terms such as ‘insufficient investigations’ and ‘thin sheep’. A cross-section of vets was therefore interviewed as part of this Review to gain an understanding of actual implementation of the above guidelines.
The methodology adopted was as follows:

1. A draft questionnaire was developed and was circulated to the veterinary representative on the SheepMAP Steering Committee for comment. A final version of the questionnaire was then developed and interviews were based on a semi-structured approach to allow the most important points to be investigated fully.

2. A list of approved vets was developed. The vets to be interviewed were selected from the AHA database to provide a cross-section of States (and, in the case of New South Wales, a range of prevalence areas within the State). The Steering Committee vet provided advice as to suitable contacts. For the New England region of NSW and South Australia, names of appropriate interviewees were sought from the local Livestock Health and Pest Authority (LHPA) vet and the Primary Industries and Regions South Australia (PIRSA) OJD vet respectively.

   In each case, an effort was made to interview vets with a significant number of SheepMAP clients. In some cases, however, interviewees had less than five clients. One was recently retired. It was estimated from the responses that the interviewees represented approximately 150 SheepMAP flocks (although they have collectively managed a much higher number than this in the past). At the time of preparing this report there was a total of 432 SheepMAP properties (NAHIS, June 2013).

3. Each of the vets on the list was interviewed by telephone. The interviews were confidential to ensure that vets did not feel they were being audited. Each interview took 20-40 minutes. Thirteen vets were interviewed in total, although a number of others were approached but not interviewed because of a lack of response or suitability.

4.2 Outcomes

The findings of the vet interviews are qualitative rather than quantitative in nature and should be interpreted accordingly. The intent was to gain a sense of the practicalities of implementing the SheepMAP and the vets’ ideas for improving the Program, not to quantify (for example) the number of post-mortems conducted in each SheepMAP flock.

The following provides an overview of the responses provided by the SheepMAP vets who were interviewed:

General observations

- Almost all of the vets interviewed have far fewer SheepMAP clients – usually less than 50% – than they had 10 years ago. The widespread availability of vaccine from the early 2000s played a large part in flocks leaving the Program, as has a steady decrease in the economic benefit of MN status for many studs, and the restricted access to genetics from lower-status studs. There has also been a decline in the number of studs in some areas. In the New England region of NSW, it has been difficult to maintain enthusiasm for a disease that ‘never appears’.

- Most of the vets are advocating, strongly in some cases, that SheepMAP clients vaccinate their flocks (although not necessarily to cease testing) to protect themselves from risks that cannot be eliminated, such as highly infected neighbouring flocks. At least three highly influential vets expressed great concern about the availability of the MNV option without any additional testing. One claimed to have very good evidence of a very high rate (30%) of ineffective vaccination due to faulty technique, and believes this explained a high within-flock detection of OJD on abattoir surveillance in a flock with a ten-year vaccination history. These vets are advising their clients against purchasing from MNV flocks.
Vet/client relationship

- Vets are conscious that they are acting on behalf of two ‘clients’ when they undertake SheepMAP work: the flock owner, and the group of clients of that owner. They admit that this can create some ethical challenges, particularly in respect to the balance between incurring costs on behalf of the immediate client and reducing the risk of purchasing infected sheep for downstream clients.

- The vet is highly reliant on the flock owner’s honesty and willingness to cooperate. There is little a vet can do to prevent poor sheep being disposed of prior to the Annual Review, nor flocks being kept from veterinary inspection. Even if all mobs are made available, it is not feasible for a vet to inspect (say) 10,000 sheep, and there is a reliance on the owner to present those of greatest concern. One vet gave the example of advising a client he must truck rather than drove sheep from one of his paddocks to another one further down the road because the road presented a biosecurity risk. The trucking would impose additional cost so there is an immediate incentive to take the risk of droving. The vet can only accept the owner’s word that the sheep were not exposed to that risk.

- Notwithstanding this, the vets believe that the vast majority of clients are honest and cooperative. In many cases the relationship between vet and client is quite close and the vets claim to have a good ongoing understanding of what is happening on the farm and (usually) on surrounding farms.

- There is very little trouble with pressuring of vets to ‘go easy’ on at the Annual Review (although owners of smaller flocks resent post-mortems when there is no real suspicion of OJD). The vet / client relationship is usually very trustful. If clients do not like the conduct of the Program, they will drop out rather than change vets. Many flock owners have limited or no choice of vets anyway.

Veterinary surveillance

- All interviewees reported that they carried out the provisions of the Manual in respect to post-mortems with great initial enthusiasm. Over time, though, this enthusiasm has been replaced by a more pragmatic approach and it is relatively uncommon now for ‘up to three’ post-mortems to be conducted in years between Sample and Maintenance Tests. (Two vets with large numbers of clients were the exception to this rule, each reporting that they conduct post-mortems on almost all occasions, except in small flocks.) When conducting their review, vets apply their professional judgement, and will take into account:
  - The prevalence of thin sheep. In many cases, there are few if any thin sheep present in the flock. The flocks involved are almost without exception studs, whose normal practice is to keep sheep in good condition for marketing purposes. This is especially true when the Review falls in late spring / summer. Any thin sheep that are present usually have obvious reasons for their poor condition such as broken mouths, foot abscesses or other one-off conditions. A number of the vets stated that they will look for sheep that lag the rest of the mob when moved, are clearly in lower condition than the other sheep and have no other obvious signs. They will only post-mortem those sheep.
  - The size of the flock. Many stud flocks are small – several hundred sheep – so the cost to the client to sacrifice three sheep (on top of vet and laboratory charges) is relatively high. This cost seems all the more wasteful when the sheep involved are in good condition.
- Other information influencing the risk assessment. For example, in cases where negative abattoir surveillance data has been received, or where there have been no introductions of sheep in the previous year, and/or neighbours do not present a high risk, vets will generally be less concerned to conduct post-mortem.

- One vet argued that regional abattoir surveillance data should be made available to vets and producers – without identifying the flocks involved – so the regional prevalence is better understood.

- Some clients will bring sheep in for post-mortem at any time in the cycle where they are concerned OJD may be present, while others will not. The vets believe that clinically-affected sheep are very readily identified before post-mortem.

Administrative aspects of the program

- There were few common suggestions to improve the administrative aspects of the Program. The Manual is considered to be large and cumbersome but not unmanageable. The addition of a 2-page ‘executive summary’ of actions required under the Program was suggested. One of the vets reported having a software program to automate some processes including the generation of reminders to clients.

- At least one of the vets has his/her clients use their ‘NLIS books’ to make the paperwork quicker.

- Some vets expressed the view that certain provisions of the Program are unrealistic given the farmer audience. One vet opined that ‘No one audits themselves every 6 months – they simply make one up’. The problem is with the recording rather than the farm practices themselves. One vet said that his/her clients would quickly fix a broken fence because they understand the biosecurity implications – but they would not necessarily record the event as they are supposed to do. Another argued that recording could be simplified, questioning whether it was necessary to record mobs in every paddock, especially where the flock is self-replacing and introductions are limited to rams or AI/ET.

- There are mixed feelings on the independent audits. Some see the value of these. Others reported that some clients resent the audits as unnecessary and that they were a contributing factor to the decline in participating flocks. One vet is strongly opposed to the current format of the independent audit, believing that some of the defects identified are unimportant and reflect the lack of veterinary knowledge of the auditor. This vet argued for a periodic audit of a random sample of clients instead of the current blanket audit.

- Most of the vets are not fully charging for their time on SheepMAP. They may cover the time spent on-farm but not the background administrative time.

- Several of the vets made the point, quite strongly, that communication from SheepMAP to them is poor. Examples were provided of vets being embarrassed because clients had information on new developments first – for example, the availability of a new test under AlpacaMAP. These vets asked that they be sent emails to inform them of any changes to the Program or other relevant developments. Simply posting new information on the web site does not work because few people will check a web site unprompted.

Opportunities to combine SheepMAP with other programs

- The only comparable program identified was ovine brucellosis (OB). The great majority of SheepMAP clients are also clients for OB and instances were cited where both were attended to during the same visit. Biosecurity provisions are more onerous for OJD than
for OB. However in some States, including Victoria, Government vets conduct the initial property inspection while private vets do only the annual blood testing.

4.3 Implications in reference to modelling above

The information gained from the vet interviews highlights the difficulty of modelling those assurance aspects of the program where human judgement and behaviour come into play and justify the inclusion of this component in the review.

Vets are not conducting post mortems to the level anticipated by the Program, but this is reportedly in response to a lack of suitable sheep (i.e. sheep in poor condition, without some obvious alternative cause). Such judgements should not reduce the level of assurance of the Program compared with that predicted by the model and might in fact increase the assurance, as the model assumes a prevalence of 2% thin sheep, only some of which will be subject to post-mortem.

However, the implementation of the Program as described in the interviews is built upon several assumptions, all of which are open to question:

1. That individual thin sheep or the highest-risk mobs are being presented by clients to the vets and not disposed of or concealed. Clients are generally reported as being honest and willing to submit sheep that are suspicious for OJD, but there are considerable financial incentives in not doing so.

2. That vets are diligently attempting to identify sheep that could be infected with OJD and are therefore a candidate for post mortem. Most vets are not inspecting all sheep on all properties, even at mob level, because this is deemed not to be practical. Also, the condition of sheep is difficult to assess without palpation, especially when sheep are in long wool. Some vets describe moving the sheep so that laggards are identified.

3. That, even if they are following all the correct procedures, vets are not subject to some subconscious bias, however subtle, in favour of their immediate client. Such biases are inevitable to a greater or lesser degree – this is why double-blind designs are used in most medical trials. Blinding both the participant and the clinician (and sometimes the statistician) reduces subconscious bias. The presence of an existing client relationship may impact on the effectiveness of veterinary surveillance through these mechanisms.

It is not possible, from the data available, to quantify precisely how far the sensitivity and specificity of veterinary surveillance are affected by these assumptions and in any case, the ‘true’ value of veterinary surveillance in providing assurance of low disease risk will vary between individual vets. However, the observation that veterinary surveillance should identify 30% of breakdowns in MAP, but has actually identified only 20% (Section 3.3.2), provides some suggestion that veterinary surveillance may be performing slightly below its predicted potential.

The only way to minimise the variables associated with human judgement and behaviour in the SheepMAP would be to reduce the reliance on veterinary surveillance and increase the role of objective tests such as the PFC or abattoir surveillance. However, veterinary surveillance provides the only targeted surveillance component with SheepMAP. Effective targeted surveillance is best suited for detection of low prevalence disease and as such veterinary surveillance is an important component for providing overall assurance to SheepMAP flocks.
5. **Broadening SheepMAP to include other diseases**

A number of sheep diseases are ‘notifiable’ under state legislation in Australia. This means there is a legal obligation to notify authorities if the owner knows or suspects that an animal has that disease. While all diseases considered to be exotic to Australia are notifiable (e.g. foot and mouth disease) there are a number of other diseases of sheep that are considered sporadic or endemic in Australia that are notifiable because they are subject to control programs or because the industry wants to prevent disease introduction due to their productivity impacts.

Notifiable sheep diseases (apart from those considered Emergency Animal Diseases) of most importance are: OJD, ovine brucellosis, footrot and lice.

The national Sheep Health Statement (SHS) provides a means for producers to declare their flock disease status when selling sheep. The SHS currently has provision for owners to declare the status of ovine brucellosis, footrot and lice as well as OJD (both MAP and non-MAP status). In addition, the SHS has provision for additional information including worm resistance test results. Completing a SHS is mandatory in South Australia and voluntary in other states.

While it is an offence to provide information that is incorrect, unless owners are enrolled in an audited control program for a disease, the information on disease status within a SHS may not carry a high level of assurance.

For SheepMAP members, the inclusion of diseases in addition to OJD as part of a broader assurance program is likely to be considered favourably. For example, a Review of the Australian Johne's Disease Market Assurance Program (AHA 2009) showed that SheepMAP producers considered that SheepMAP would be more cost effective and require less paper work if it was available as an option within a broader biosecurity program or included within other on-farm QA programs. Many gave an example where their veterinarian conducted ovine brucellosis testing at the same time as completing SheepMAP responsibilities. The same review included a survey of MAP veterinarians, coordinators and auditors who considered there would be improved efficiencies if SheepMAP was included as an option within a broader biosecurity program. Many auditors were currently involved with a range of QA programs (CattleCare, Flockcare and Livestock Production Assurance – LPA) and saw efficiency benefits in completing multi-faceted audits on a property during the one visit.

The inclusion of ovine brucellosis within an assurance scheme is likely to be readily assimilated for reasons described below.

### 5.1 Ovine brucellosis-free accreditation schemes

All states operate voluntary ovine brucellosis (OB) free accreditation schemes that are managed by state animal health authorities. Many breed and show societies support the schemes by requiring members, exhibitors or vendors to be accredited (for instance, flocks proposed for membership of the NSW Stud Merino Breeders Association must be accredited by NSW DPI as Ovine Brucellosis Free or, if in the process of being accredited, the first test must be successfully completed with a negative result, before the application can be accepted).

In all states, the number of flocks participating in OB-free accreditation programs exceeds the number of SheepMAP flocks (Table 13). The number of flocks that participate in both programs simultaneously is not readily available but it is likely that a high proportion of SheepMAP flocks, predominantly ram breeders, participate in OB-free accreditation schemes and use the same
veterinarian for both programs. The information on joint participation could be collated but privacy issues would need to be considered.
Table 13  Number of OB-free accredited flocks and SheepMAP flocks, June 2013

<table>
<thead>
<tr>
<th>State</th>
<th>Accredited brucellosis free</th>
<th>SheepMAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>NSW/ACT</td>
<td>842</td>
<td>180</td>
</tr>
<tr>
<td>Qld</td>
<td>69</td>
<td>1</td>
</tr>
<tr>
<td>SA</td>
<td>578</td>
<td>149</td>
</tr>
<tr>
<td>Tas</td>
<td>73</td>
<td>19</td>
</tr>
<tr>
<td>Vic</td>
<td>490</td>
<td>69</td>
</tr>
<tr>
<td>WA</td>
<td>191</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>2243</td>
<td>432</td>
</tr>
</tbody>
</table>

Source: NAHIS, October 2013

The design of OB-free accreditation schemes in each state is similar and there is similarity with the design of the JDMAP. There is a biosecurity plan and testing regime. The involvement of accredited/approved private veterinarians varies between states. In Victoria, for example, DEPI officers undertake the initial property inspection and accreditation while private vets are responsible for annual blood testing and clinical examination. In NSW, private vets have a broader responsibility for property risk assessment and recommendation for accreditation as well as annual testing. Biosecurity is reviewed at the initial accreditation, and sometimes subsequently, and rams are tested every one to three years depending on the duration of participation in the scheme. Guidelines are provided on biosecurity and records of test results are kept by the respective state animal health authority. Unlike SheepMAP there are no internal or external audits.

SheepMAP and the various OB-free schemes could readily become two modules of an overarching scheme built on a common biosecurity platform. Some States may need to slightly modify their OB-free schemes to make this work but the changes should be minimal.

5.2  Other diseases

While the SHS includes a provision for owners to report on footrot, lice and other conditions, there are no Australia-wide control programs that could be readily incorporated into a revised SheepMAP. However, any revised SheepMAP could be flexible so that it allowed for the inclusion of additional diseases if required.

6. Potential alignment with other industry programs

There are a number of industry quality assurance programs in Australia that include various audit processes as verification of compliance. GHD, in association with Scott Williams, reviewed these programs in a recent report to AHA (Australian Johne's Disease Market Assurance Program Review of Verification Approaches, 2012) and the relevant sections of that report have been updated to reflect the current situation specific to SheepMAP.
A range of programs were reviewed with particular emphasis on their audit arrangements and the potential complementarity with the JDMAP audit process. The programs that were reviewed were:

- Livestock Production Assurance (LPA)
- National Livestock Identification System
- NSW Dairy Food Safety Scheme
- SA Dairy ManaJD
- Ovine brucellosis-free accreditation schemes

Ovine brucellosis was discussed above while the two dairy programs are not considered relevant for this review. As such LPA and NLIS only are discussed in further detail.

### 6.1 Livestock Production Assurance

LPA is a program that underpins the National Vendor Declaration and Waybill (NVD/Waybill). LPA is a simple on-farm food safety assurance program that enables producers to substantiate claims made on the LPA NVD/Waybills. LPA considers five key elements or areas of compliance as detailed in Table 14. Standard Element 5 of LPA considers livestock transactions and movements, including traceability, and as such overlaps with a number of elements in JDMAP.

#### Table 14 LPA elements

<table>
<thead>
<tr>
<th>Standard Element</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Property risk assessment</td>
<td>On Farm systems have been implemented to minimise the risk of livestock being exposed to sites that are unacceptably contaminated with chemicals.</td>
</tr>
<tr>
<td>2 Safe and responsible animal treatments</td>
<td>On Farm systems have been implemented to ensure that animal treatments are administered in a safe and responsible manner to minimise the risk of chemical residues and physical hazards in livestock intended for human consumption.</td>
</tr>
<tr>
<td>3 Fodder crop, grain and pasture treatments and stock foods</td>
<td>On Farm systems have been implemented to manage the exposure of livestock to foods containing unacceptable chemical contamination to minimise the risk of chemical residues in livestock and to eliminate the risk of animal products being fed to ruminant livestock intended for human consumption.</td>
</tr>
<tr>
<td>4 Preparation for dispatch of livestock</td>
<td>On Farm systems have been implemented to ensure that the selected livestock are fit for transport and that the risk of stress and contamination of livestock during assembly and transport is minimised.</td>
</tr>
<tr>
<td>5 Livestock transactions and movements</td>
<td>A system has been implemented to enable traceability of the current status of all livestock with respect to treatment or exposure to relevant food safety hazards for all livestock movements between livestock production enterprises including to slaughter and live export.</td>
</tr>
</tbody>
</table>

Table 15 outlines the LPA audit process in which 2,000 random audits are completed per year by an external auditor. Audit costs are borne by the program and not by individual producers.
Table 15  LPA audit process

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who is audited?</td>
<td>All producers accredited in the LPA program are eligible to participate in the random audit program. The current LPA random audit program involves at least 2,000 audits of producers each year.</td>
</tr>
<tr>
<td>What does the audit involve?</td>
<td>The audit involves an on-site visit to review the producer's LPA record keeping systems and provide an assessment of how the five food safety elements of LPA are being met.</td>
</tr>
<tr>
<td>How is the audit conducted?</td>
<td>Producers that are randomly selected will be contacted by the auditor to organise a mutually convenient time to perform the audit. Specific questions about how records are maintained and general food safety-related management practices will also be asked. The auditor may also wish to accompany the producer on an inspection of property facilities relating to food safety, including chemical storage or contaminated areas.</td>
</tr>
<tr>
<td>Cost of the audit?</td>
<td>No direct charge applies for the random audit as the cost is incorporated into the purchase price of NVDs. In the unlikely event of any subsequent audits a producer may be charged for the cost.</td>
</tr>
<tr>
<td>How long does the audit take?</td>
<td>The average audit duration will be about 1.5–2.5 hours.</td>
</tr>
</tbody>
</table>

6.2 National Livestock Identification System

The National Livestock Identification System (NLIS), administered by MLA, is a whole of life traceability system for cattle, sheep and goat movements nationwide. NLIS accredited devices are linked to the animal’s Property Identification Code (PIC) for the property of birth. For cattle, electronic tags are used and transactions recorded in a national database. For sheep and goats, transactions and traceability are via non-electronic devices in combination with NVDs. Figure 8 is a diagram of NLIS for cattle.
Figure 8  NLIS database information flow

Source: MLA

NLIS is regulated by state and territory authorities. As such, audits are carried out by specific state and territory authorities on a random basis, usually at the saleyard or abattoir level, to measure compliance. This is carried out through on-site inspections of livestock to ensure physical application of NLIS tags and inspection of NVDs and other documentation to assure PICs are accurately listed.

6.3  Summary table of audit arrangements

Table 16 provides a summary of the attributes of the above industry QA programs and includes an indication of the potential they provide to substitute SheepMAP elements, or the potential for the QA programs to include OJD as a component for the purposes of providing audit processes to satisfy SheepMAP requirements.

LPA and NLIS are primarily food safety and animal traceability programs with a number of compliance procedures which duplicate elements within SheepMAP.

Ovine brucellosis-free accreditation schemes have a similar basic design to the JDMAP (biosecurity plan, testing regime, involvement of approved veterinarian etc.) but tend to be much simpler with fewer elements, less conditions and no internal or external audits.
### Table 16 Industry QA programs - potential role in SheepMAP

<table>
<thead>
<tr>
<th>Program</th>
<th>LPA</th>
<th>NLIS</th>
<th>Ovine brucellosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Producer involvement</td>
<td>Vast majority of sheep producers.</td>
<td>All sheep producers</td>
<td>Producers who participate in OB-free accreditation schemes</td>
</tr>
<tr>
<td>Administrator</td>
<td>MLA / AUS-MEAT</td>
<td>MLA / state animal health authorities</td>
<td>State animal health authorities</td>
</tr>
<tr>
<td>External audit</td>
<td>Yes, accredited auditor</td>
<td>Yes, state authority</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Random, on site</td>
<td>Ad hoc, generally not on site</td>
<td></td>
</tr>
<tr>
<td>Test results available</td>
<td>Not applicable</td>
<td>Not applicable</td>
<td>Yes</td>
</tr>
<tr>
<td>Auditor</td>
<td>Independent external auditor</td>
<td>State regulatory bodies</td>
<td>Approved veterinarian</td>
</tr>
<tr>
<td></td>
<td>(LPA QA auditors list)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potential for substitution of existing SheepMAP elements (1-6)</td>
<td>Parts of 1, 2 &amp; 4</td>
<td>Parts of 1, 2, 3 &amp; 4</td>
<td>Yes, some routine biosecurity related elements</td>
</tr>
<tr>
<td>Potential opportunities to add SheepMAP elements to the QA program</td>
<td>Yes, but low audit frequency/coverage</td>
<td>No</td>
<td>Yes, but potentially a relatively large number of extra elements due to the very different nature of the two diseases</td>
</tr>
</tbody>
</table>

### 7. International comparisons

This chapter provides a summary of a more detailed review of international Johne’s disease and multi-disease market assurance programs that was completed for AHA by GHD in June 2009.

#### 7.1 International Johne’s disease market assurance programs

Information on animal disease quality assurance programs in other countries was collected from publications, websites and personal contacts. Detailed information was collected for Canada, Denmark, Netherlands, United Kingdom and United States of America; less detailed information was collected for Austria, Czech Republic, France, Ireland, Israel, Japan, New Zealand, Norway and Sweden. For the latter countries, information was either not available or programs appeared less relevant.

The method of enquiry was not suitable for assessing how successful any of these programs were in achieving their goals. Formal evaluations of international programs appear not to be available. Their absence appears to be because programs have not been running long enough or because the reasons for failure such as low uptake by farmers or excessive costs were obvious. The countries of most interest are Canada, Denmark, the Netherlands, UK and USA and possibly France, Ireland and Israel.
Although there are numerous longstanding forums for international exchange of information on controlling Johne’s disease, there is considerable heterogeneity in approaches between and within countries. Some of the reasons for such heterogeneity include:

- socio-economic and cultural differences;
- differences between national, provincial and state governments;
- the high costs of testing and culling;
- failure to make good progress anywhere in control of the disease;
- inadequacy of knowledge of the ecology of the organism;
- the relative insensitivity of testing on individual animals;
- the unpredictability of the immune response and course of the disease in individual animals; and
- different perceptions of possible trade-related matters including public health.

There seems to be constant remodelling, most of which is directed at increasing farmer participation rather than increasing assurance of low disease risk.

Strategies to increase farmer participation have included:

- Reducing testing costs by introducing environmental and pooled faecal culture samples from beef herds and antibody ELISA on individual milk samples from dairy herds collected for herd recording (North America and Europe).
- Coercion by meat and milk processors by them setting penalties for non-participation in programs (Netherlands, Denmark).
- Coercion by breed societies by them making participation in programs a condition of membership (UK).
- Vigorous promotion of the cost-effectiveness of disease prevention and control to encourage participation (UK).
- Avoiding the stigma of having infected status by awarding status based on duration of participation or level of risk rather than positive or negative for disease (USA).
- Designing programs that don’t relegate a herd’s status back to that at program start if disease is detected (Canada, Netherlands).
- Designing programs with conservative approaches to culling using risk likelihood and risk control systems where farmers make their own decisions about culling positive animals (Denmark).
- Using the internet to promote discretionary buying of animals (and biosecurity awareness) by publicly listing all herd and flock risk statuses (Denmark).

No effort or real interest in coupling of other disease control programs with Johne’s disease was found; the closest was a shared extension campaign for Johne’s disease and *Salmonella dublin* control in Denmark. It appears that there is insufficient congruence between Johne’s disease and other diseases for conjoined programs.

The New York State Cattle Health Assurance Program (NYSCHAP) and the UK’s health schemes for cattle, sheep and goats provide models of multi-disease quality assurance programs that may have application in Australia and could be a suitable alternative to the JDMAPs. These models have a core biosecurity theme to which disease modules can be added if the farmer so chooses. A fundamental principle is that general biosecurity will exclude many...
diseases and can be enhanced in specific areas (using modules) for selected diseases regarded by industry as more important for reasons of trade or public health.

The NYSCHAP is managed jointly by the state government and a university and offers quality assurance modules on Johne’s disease, bovine virus diarrhoea, enzootic bovine leucosis, salmonellosis, mastitis, lameness, neosporosis, drug residues, animal welfare, herd expansion, market cow, and bull beef quality.

The six UK cattle health schemes and one sheep health scheme are all privately run by or operated in conjunction with a private veterinary laboratory, and offer modules for bovine virus diarrhoea, Johne’s disease, infectious bovine rhinotracheitis and leptospirosis in cattle herds, and maedi-visna, caprine arthritis encephalitis, enzootic abortion, scrapie and caseous lymphadenitis for sheep flocks and goat herds.

While the livestock health schemes operating in the US and UK provide a framework for Australia, it is likely that their success in Australia would be dependent on economic drivers that currently do not exist. This could change over time as consumers demand more information on the food they consume and the conditions under which animals are raised.

8. Conclusions and options for consideration

The review has considered the current functioning of SheepMAP and identified the relative assurance of OJD freedom provided by the protocols required for participation within the program. The review has also provided information on potential efficiencies that could be gained if SheepMAP was combined with other disease control or quality assurance programs.

Following are the conclusions from the above for each of the terms of reference addressed by the review. Note that the order of the terms of reference is based on the technical components followed by the operational components of SheepMAP.

8.1 Determine whether the current method for providing assurance through biosecurity, flock testing and vaccination provides the levels of assurance that are appropriate for an audited MAP

Section 3 includes information on the epidemiology of OJD using a modelling approach that incorporates a number of assumptions based on current research data. The model outcomes demonstrated that SheepMAP is meeting the primary objective of providing assurances to the market that sheep sourced from accredited flocks present a low risk of OJD. As flocks progress through different stages (i.e. MN1 to MN3) the level of assurance increases although there is a differential between the equivalence of each MN level depending on whether the flock is located in a low, medium or high OJD prevalence region.

Flocks at MN3 status – irrespective of prevalence region – present a reduced risk of OJD that is at least comparable to the risk posed from an unassessed flock in an OJD “nominal very low prevalence” zone.

However, because tests are not able to detect OJD with 100% accuracy, there is a risk that ‘false negative’ flocks can be admitted to SheepMAP with approximately 10% of infected flocks expected to evade detection at the initial PFC350 entry test. These false negative flocks typically have very low within-flock prevalence of disease. The presence of these false negative
flocks can be detected via subsequent testing, but the program allows the maintenance of MN status without further testing via vaccination. This may allow false negative flocks to persist undetected within the program for an unacceptably long time.

Also, research has shown that Gudair vaccination delays and reduces shedding but does not prevent infection. These observations emphasise the importance of effective and ongoing biosecurity reviews and veterinary surveillance within SheepMAP.

Observational studies have shown that the majority of infected flocks that vaccinate remain infected for at least five years or longer. Also, vaccination is effective at reducing clinical disease incidence, restricting within-flock prevalence and suppressing shedding of bacteria in the majority of vaccinated but infected sheep.

Table 10 shows that the majority of small consignments of sheep from false negative MNV flocks present very low risk (< 1%) of disease introduction for purchasers. However, larger consignments of sheep purchased from false negative MNV flocks present a high risk of disease (for example more than 20% probability of infection for a consignment of 50 sheep where within-flock prevalence is 0.50%). Also, as within-flock prevalence in false negative MNV flocks increases, the risk of transmission of disease to purchasers also increases. Concurrent increases in within-flock prevalence and in consignment size markedly increase the risk of an infected consignment.

The industry will need to determine the acceptable risk levels required within SheepMAP and then decide on the level of ongoing testing (if any) that is required.

8.2 Determine the role that alternative negative testing methods could play in providing assurance

One alternative to the introduction of PFC350 testing in MNV flocks that may be considered is combined abattoir surveillance with tailored veterinary surveillance (i.e. variable numbers of post mortems each year). This combined approach can provide increased assurance of disease freedom (below a certain predefined level – e.g. 1% of sheep) using recently recognised approaches to combining different sources of negative surveillance information.

Modelling shows that depending on the percentage of the adult flock submitted for abattoir surveillance, post mortems of between two and eight sheep per year are required to detect disease at a 1% within-flock prevalence level.

A further alternative is targeted pooled faecal testing (including PFC50 or the potential future use of the HT-J-PCR test) of high-suspicion sheep in the adult sheep population as identified by the SheepMAP veterinarian. This may provide a satisfactory alternative to multiple animal post mortems. A targeted testing regime for vaccinating flocks clearly has potential to detect false negative flocks with high sensitivity and down to very low within-flock prevalence.

The potential conflict of interest faced by veterinarians who are both clinicians to commercial producers and also SheepMAP veterinarians to the same flocks needs to be considered. However, consultation with vets for this review indicated a level of diligence that gives comfort to their role in ensuring potentially diseased sheep are screened for the presence of OJD.

The above shows there are alternatives to PFC350 testing to provide assurance and that such tests are likely to be more cost effective and provide more timely results which are likely to be supported by producers.

The issue of the variable availability of abattoir surveillance will need to be considered in determining if it has a future role as a negative testing method.
8.3 Determined the feasibility of broadening the scope of the SheepMAP to include other diseases

Section 5 discussed the potential of including other diseases within SheepMAP and it is clear that ovine brucellosis accreditation is most feasible. Industry could determine if a program that included a range of common elements (e.g. biosecurity, animal ID, audits) with additional elements for specific diseases (most likely related to testing) could be developed.

It is noted that the national Sheep Health Statement includes provisions for owners to report on footrot, lice and other conditions. There are no Australia-wide control programs for these diseases that could be readily incorporated into a broadened SheepMAP. However, any revised SheepMAP could be flexible so that it allowed for the inclusion of additional diseases if required in the future.

8.4 Determine how the SheepMAP could be aligned with other industry programs or business practices and identify the drivers for the uptake of the program

Section 6 and Section 7 outlined Australian and international industry programs that provide opportunities for either streamlining SheepMAP or including SheepMAP in a broader market driven assurance program.

Both LPA and NLIS have components related to animal identification and livestock movements that are audited and as such could be recognised by SheepMAP without the need to duplicate these elements within the program. The removal of such duplication would likely be seen as a positive by sheep producers and may increase uptake of the program or at least reduce the rate of dropouts.

While the various livestock health schemes operating in the US and UK provide possible frameworks for adoption in Australia, it is likely that their acceptance would be dependent on economic drivers that currently do not exist. This could change over time as consumers demand more information on the food they consume and the conditions under which animals are raised.

8.5 Evaluate the feasibility of group SheepMAP programs on both a technical and practical basis.

The concept of a ‘Group SheepMAP’ approach to accreditation has been suggested. This is essentially the (virtual) merging of two or more flocks (separate owners) that have no evidence of OJD and the submission of the ‘merged’ flock to the program as a single entity. All flocks contributing to the group flock earn the same status following enrolment and subsequent testing. This approach has been suggested as a way of keeping the costs of compliance to individual producers down and to encourage more producers to enrol in SheepMAP.

We do not recommend this be adopted for a number of reasons including: decreased likelihood of detection of disease within individual infected (or false negative) constituent flocks in the program; increased logistical overheads; increased compliance burden for the SheepMAP veterinarian; and pressures on the SheepMAP veterinarian to use the ‘average’ level of compliance instead of the ‘lowest’ level of compliance of individual biosecurity components by each producer in the group flock.

The primary reason for not adopting this approach is the decreased intensity of testing and therefore reduced detection sensitivity at individual flock level. Infectious low-prevalence, slow spreading disease is by its very nature highly clustered in the early stages of establishment. In the situation of a group flock, disease (if present) is likely to only occur in a small number of
sheep in just one flock. By sharing the testing burden between all flocks the sensitivity of detection in individual flocks is markedly reduced.

For example, if allocating 2-3 pools of 50 sheep to each of three constituent flocks in a group flock in order to meet the requirements for the PFC350 test, the likelihood of detecting the single infected false negative flock from effectively a PFC100 or PFC250 test is markedly less than for a dedicated PFC350 test (as we have shown by modelling) in that particular flock. The time until detection of disease in the group flock will also increase and this provides increased opportunity for disease to spread to the other group flocks and to the wider community due to the false accreditation. Introduction of a Group SheepMAP option will devalue the current program.

8.6 **Recommend how a revised SheepMAP would complement other means of assurance for OJD in the sheep industry**

The OJD National Management Plan recognises that producers have the responsibility to manage risk for all animal health diseases. The policy is built around risk-management – that is, individuals implementing animal health controls and good farm biosecurity practices, and making informed choices when buying livestock. The strength of these systems is enhanced when producers work together as a collective and this can be achieved through Regional Biosecurity Plans (RBPs) designed to prevent the incursion and spread of disease. RBPs for the control of OJD are considered to be Protected Areas.

Participation in RBPs is voluntary for all producers and their formation can be encouraged by the fact that there are already livestock production groups operating that would be in a good position to develop an RBP – e.g. Lifetime Ewe Management, Best Prac Groups etc.

RBPs set minimum entry requirements for sheep into their Protected Areas. The Business Rules Template for establishing an RBP states that SheepMAP flocks will be allowed entry into a Protected Area. However, individual RBPs have the ability to set more stringent entry requirements.

Industry could consider the results of the modelling completed in this review and determine if the MN flocks maintaining status via vaccination would be considered to have satisfied the definition of “tested assurance” based on negative abattoir surveillance and/or veterinary surveillance. Also, targeted testing of thin sheep using the PCR test should also be considered for its acceptability as a suitable test.

8.7 **Review the SheepMAP (Dec 2005 version as amended) for relevance, and currency and identify areas for improvement e.g. format and technical content**

The outcomes from this review will be presented and discussed with the SheepMAP Steering Committee for future direction.
References


Appendices
Appendix A – International animal disease assurance programs
1. **Background**

Information was sought on Johne’s disease and multi-disease quality assurance programs operating in other countries that might offer lessons or ideas to improve the Australian Johne’s Disease Market Assurance Programs.

2. **Approach**

Information was gathered using:

- an online literature search using PubMed;
- browsing the web site of the International Association for Paratuberculosis (IAP) for personal contacts, conference abstracts and examination of proceedings of recent conferences;
- e-mail correspondence with international contacts; and
- general internet browsing.

3. **Findings**

This results section is divided into two, the first part describing in detail, programs of relevance to the JDMAP review in the countries of Canada, Denmark, the Netherlands, United Kingdom (UK) and United States of America (USA). The second part describes in less detail the situation, if not the programs, in the countries of Austria, Czech Republic, Finland, France, Germany, Ireland, Israel, Japan, New Zealand, Norway and Sweden where the programs have points of interest or where little information was obtainable.

4. **Relevant programs in other countries**

4.1 **Canada**

4.1.1 **Bovine Johne’s disease programs - general**

Canada has made slow progress with respect to Johne’s disease control and at this stage has no established market assurance programs, either at the national or provincial levels. However, there has been considerable investment in planning for a national program by the Canadian Animal Health Coalition that has taken into account lessons learnt from Johne’s disease.
programs in other countries, particularly USA. Currently there is commitment for any program to be voluntary with industry and federal and provincial governments working in partnership.

There has been a number of attempts to implement a Canadian Voluntary Johne’s Disease Prevention and Control Program (CVJDPCP) but so far without success. The design of the program has been agreed in-principle by all provinces, and three provinces - Alberta, Ontario and Quebec - are developing funding and work plans. Increasing the number of participants, identifying the farms needing more intensive assistance to control the disease and minimising penalties for herds that test positive were important considerations in design. It was considered particularly important that herds testing positive are not automatically relegated back to the beginning of the test program. Notably, a status or accredited herd certification component to the program has not yet been clearly defined.

The proposed CVJDPCP has two pathways\(^{36}\): a Prevention Pathway to accommodate infected herds and a Status Pathway for non-infected herds. The Prevention Pathway is a management pathway where the farmer does not have to test; the Status Pathway additionally requires testing and culling of positive animals.

The Prevention Pathway is designed for infected herds or herds where infection is suspected. The former may include herds that have tested and found a moderate to high prevalence of infected animals where culling is impractical, the latter may include herds where disease is suspected by the farmer and the farmer wants to avoid the stigma attached to a positive test. No testing is required unless the farmer so chooses, hence the stigma of positive test results is avoided. There are however yearly risk assessments and customized management plans assisted by specially trained and accredited veterinarians to progressively reduce or eradicate the disease by biocontainment and biosecurity measures. Producers are recognized by the number of years in the Prevention Pathway. They can choose to enter the Status Pathway with its requirement for testing and culling if they wish.

The Status Pathway is designed for herds having low disease prevalence or that are not suspected of being infected and that are interested in testing. Like the Prevention Pathway it has an annual risk assessment and customised farm plans but differs by having an annual testing requirement of cows 3 years and older using individual milk or serum ELISAs or pooled faecal culture (5-10 animals per pool) as screening tests. Samples positive to screening tests are followed up by individual faecal culture. Faecal culture positive animals must be culled.

There are two levels of testing in the Status Pathway, however the program is not intended to be a certification program. Producers are recognized for the number of years of maintaining their status at Level 1 or 2. Level 1 is achieved if all tests are negative or all culture positive cows are culled within 45 days. Level 1 is maintained by biennial culture (every two years) of environmental or pooled faecal samples with negative results or if environmental samples or pools are positive, individual faecal cultures of positive pools are used to detect shedding animals that are then culled.

Level 2 is achieved if Level 1 herds, tested in subsequent years by pooled faecal cultures are negative. If a positive pool is detected, the positive animals are identified by individual faecal culture and are culled and the herd reverts to Level 1 status. Promotion to Level 2 status can be achieved as early as one year later by achieving a negative herd test based on pooled faecal culture. Herds maintain Level 2 by annual negative pooled faecal culture. Level 1 and 2 herds not culling positive animals revert to the Prevention Pathway. Producers will be encouraged to sell positive cattle to slaughter rather than sell them as replacements.

4.1.2 Bovine Johne’s disease programs - Provincial

The province of Alberta has had since 2001, a voluntary test and certification program for beef and dairy herds designed to identify and categorise herds on the strength of apparent freedom from Johne’s disease. There were four status levels established using specific sampling and testing protocols overseen by an accredited veterinarian. Each increase in level represented an increased level of confidence that the herd was free of Johne’s disease. The program closely resembled the test-negative component of the US program (see below). There has been little uptake by farmers (in 2005 there were 119 accredited veterinarians but only eight dairy and nine beef herds enrolled in the program). Alberta is now moving toward the two pathway approach of the proposed National Johne’s Disease Prevention and Control Program (see below).

The province of Ontario has had a pilot project since 2005 using individual milk ELISA collected for herd recording with a focus on best management practice for Johne’s disease prevention. The project was expanded to the four western provinces of Manitoba, Saskatchewan, Alberta and British Columbia. The project is now completed, activities have ceased and a draft report is being prepared.

4.1.3 Other disease programs

There are separate certification programs for enzootic bovine leucosis, scrapie and chronic wasting disease coordinated by the Canadian Food Inspection Agency (CFIA). One of these is the Canada Health Accredited Herd Program37 (CHAP-BL) designed to certify EBL-freedom in qualifying herds to meet the EBL-free import requirements of countries to which Canada exports live cattle. Such a program is required because EBL is not a notifiable disease in Canada and is not subject to a regulatory program. The program meets international health standards and is delivered by private CFIA-accredited veterinarians and laboratories. The CHAP-BL program is based on test results, the removal of cattle infected with the EBL, and the maintenance of a herd that permits the entry of only those animals free of infection. Uptake is poor - Ontario, the largest dairying province, has less than ten participants.

There are no Johne’s disease programs for small ruminants. There are no multi-disease certification programs for any species in Canada although the Ontario Sheep Health Program (see below) comes close.

The Ontario Sheep Health Program38 was developed by the University of Guelph and administered by the Ontario Sheep Marketing Agency. The program is comprised of three parts to be completed annually: (i) evaluation of flock health management; (ii) evaluation of biosecurity; and (iii) evaluation of productivity and goal setting. A notable feature of the program is that if the flock veterinarian agrees, a risk classification (low, moderate or high) can be given for certain diseases (the more common diseases that affect sheep in Canada) however the classification is not based on results of testing. The risk classification can be used to advertise disease status if the flock veterinarian is willing to agree to the advertisement. Claims for freedom from disease cannot be made. Low risk = no disease present / control measures excellent; Moderate risk = disease present in flock / control measures instituted but improvement required; High risk = disease present and not controlled. The advertisement must specifically indicate that this risk was assigned as part of the Ontario Sheep Health program and not another disease status program. Similarly, producers can have their veterinarian score the farm's biosecurity. The veterinarian can assign a score to each section with 0 = Low Risk; 1 = Moderate Risk; and 2 = High Risk.

37 www.inspection.gc.ca/english/anima/disea/bovineleu/bovineleufse.shtml
38 www.uoguelph.ca/~pmenzies/OSHP_Home.htm
The prospect of combining delivery of a Johne’s disease program with programs for control of other trade-linked diseases, and developing biosecurity standards for the livestock industries that includes specific elements of Johne’s disease and other specific disease prevention measures, is under consideration by the Canadian Animal Health Coalition and Canadian Food Inspection Agency.

Bibliography


4.2 Denmark

4.2.1 Bovine Johne’s disease programs

In Denmark there are over 25,000 cattle herds comprising about 4,500 dairy herds (average herd size=100 cows), 500 true beef herds and the remainder hobby farms with small numbers of beef cattle. Johne’s disease is widespread in the dairy industry and is very costly to farmers due to loss of production. No regulatory controls exist. There have been no reports of Johne’s disease in sheep or goats.

An industry-coordinated, voluntary, control program named Operation Paratuberculosis\(^{39}\) was established in 2006 and approximately 25% of Denmark’s dairy herds now participate. There are no Johne’s disease programs for beef cattle, sheep, alpacas or goats.

Operation Paratuberculosis is paid for by farmers through testing fees. Uniquely, it relies on a milk ELISA with a high sensitivity and low specificity to categorise cows into three major risk classes based on probability of infection and taking into account a drop in milk production as indicative of infection.

Participating herds test all lactating cows four times per year with an antibody ELISA on milk collected for herd recording. There is no confirmatory testing.

A key program design-principle is the conservative approach taken in making culling decisions based on a positive test result, particularly with a milk ELISA set at low specificity. The program’s practical application of this is that positive animals are only culled under some circumstances although all positives are regarded as potential transmitters of disease and are managed as such. Many positive results are seen with the milk antibody ELISA because of a deliberate focus on sensitivity rather than specificity of the test. Culling is only recommended if cattle are developing clinical symptoms, milk production is declining unexpectedly or there are very few test positives.

Test negative cows are referred to as green cows and are considered non infectious on the date of testing. These cows are recommended as sources of colostrum and milk for calves and can calve with other green cows with lower hygiene levels applied. Test positives are considered infectious and are divided into red cows if they have consistently high ELISA reactions and yellow cows if they have intermittently high ELISA reactions. It is recommended that Red cows not calve again and be culled. Yellow cows can calve again but preferably away from green cows and extra hygiene should be applied. Thus, all cows are categorised into risk groups which can be used for making decisions on calving, hygiene and calf feeding.

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\(^{39}\) [www.paratuberkulose.dk](http://www.paratuberkulose.dk). Follow links to English version of video sent to all Danish dairy farmers in 2006
There is no test scheme used for herd classification and no officially recognized recommendations related to trade of cattle from participating and non-participating herds. Environmental and bulk milk samples using PCR are being considered for possible future strategies for herd classification.

4.2.2 Other disease programs

Notably, Denmark has eradicated enzootic bovine leucosis and infectious bovine rhinotracheitis (largely via bulk milk testing) and bovine virus diarrhoea (BVD) is almost eradicated with only three infected herds remaining by 2008. In the BVD surveillance program, bulk milk is tested four times per year (except for herds bordering Germany which are tested monthly) and every sixth animal slaughtered is tested for serum antibodies.

Denmark has ambitious plans to eradicate *Salmonella dublin* from all dairy and beef herds by 2014 when *Salmonella* will be declared illegal with meat, milk and animals from infected herds banned from sale. Currently, control of salmonellosis is voluntary even though all herds are under surveillance using bulk milk samples collected quarterly from dairy herds and serum samples collected from all beef cattle when slaughtered at abattoirs. In 2009 and 2010 a price penalty will be introduced for beef and milk from infected herds.

Level 1 farms in the Salmonella program are considered as likely to be free of salmonella based on low or negligible antibody levels, Level 2 farms are considered as likely to be infected if the level of antibodies is higher, and Level 3 farms are where salmonella bacteria have been isolated from cattle in the herd, usually in connection with an investigation of clinical disease. Herds in Level 3 are placed under restrictions by veterinary authorities. Movements of cattle between herds are continuously recorded through the Central Husbandry Register. Movement of cattle from a Level 2 or 3 farm to a Level 1 farm automatically leads to a change to Level 2 of the farm receiving animals. The levels of all herds in Denmark are publicly available on an internet site. Farmers are encouraged to avoid buying cattle from infected herds by asking sellers to document their herd’s surveillance status before they buy cattle from them.

Consideration has been given to combining different disease control programs however the Danish Cattle Federation has resisted, preferring to deal with one disease at a time. Even though the two major disease programs affecting the dairy industry in Denmark are Johne’s disease control and *Salmonella dublin* eradication, and the two diseases have similar prevention and control measures, there are no intentions of combining the two programs. There have been however, training manuals prepared and training sessions for veterinary advisors where combined salmonella and Johne’s disease prevention strategies were presented.

Bibliography

4.3 Netherlands

4.3.1 Bovine Johne's disease programs

There are approximately 46,000 cattle herds in the Netherlands of which 20,000 are dairy, with 1.6 million dairy cows (average herd size of 80). The majority of Dutch dairy herds are closed meaning they don’t introduce animals. The dairy industry has two industry-coordinated voluntary programs for controlling paratuberculosis. Uptake by farmers had been limited because of lack of incentives and absence of consequences of a herd status but this has recently changed with the dairy processing industries requiring all Dutch dairy herds to participate in one of the two Johne’s disease programs discussed below. Pressure to make control cheaper and simpler and increase the number of participants has seen the control strategy in the Netherlands evolve through many pilot versions to its current state. The two Johne’s disease programs are:

1. The Intensive Paratuberculosis Programme (IPP), which started in 1998, aims to eradicate infection in known infected herds and certify test-negative herds as Johne’s disease free. There are currently 400 herds certified as free. For herds to be certified free, there must be five annual herd tests of cattle 3 years or older, the first by serum ELISA and the second to fifth by pooled faecal culture. Maintenance of certified free status is by biennial pooled faecal culture (five animals per pool) of cattle 2 years and older. Control in known infected herds is by annual individual faecal culture (or pooled faecal culture followed by individual faecal culture of positive pools).

   Cattle introduced to herds free of Johne’s disease must originate from other free herds. Cattle introduced to herds that are in the process of gaining free status must be from herds that are at the same or greater level of negative annual testing. Cattle raised in a Johne’s disease free herd can be agisted to herds of a lower status because it is assumed by the Dutch that the risk of introducing Johne’s disease through such introductions is small.

2. The Paratuberculosis Program Netherlands (PPN), which started in 2006, is a bulk milk quality assurance program for dairy herds aimed at reducing the number of Johne’s disease bacteria per litre of bulk milk. Note that no bulk milk testing for antibodies or bacteria is involved, rather the level of antibodies detected in serum or individual milk samples in the herd is used as an indicator of risk of bulk milk contamination. The PPN was an attempt to make participation in Johne’s disease control more attractive by making it simpler and cheaper.

   There are four statuses:

   - Status A: ‘Paratuberculosis unsuspected’
   - Status B: ‘Paratuberculosis-infected with test positive cattle removed
   - Status C: ‘Paratuberculosis-infected with test positive cattle still in the herd
   - Status ‘unknown’

   Initial assessment is by a single herd examination using serum-ELISA or individual milk ELISA. Surveillance of test-negative herds (Status A, and assumed to have low risk bulk milk) is by biennial serum or individual milk-ELISA. Control in test-positive herds (Status B and C) which are assumed to have higher risk bulk milk is by enhancing hygienic calf rearing practices and purchasing animals from Status A herds only together with annual serum or milk-ELISA to assist culling decisions.

   In the PPN program, a test positive “red” herd (Status B or C) can become a test negative “green” herd (Status A) in one annual herd test in contrast to the five annual herd tests it takes in the IPP to achieve Johne’s disease free status.

   In both the IPP and PPN, farmers pay a subscription fee and sampling and testing fees.
Other disease programs

In the Netherlands there are also separate, mostly voluntary, certification programs for bovine virus diarrhoea, leptospirosis, infectious bovine rhinotracheitis, salmonellosis (S. dublin and S. typhimurium), neospora and liver fluke open to beef and dairy herds all of which are paid for directly by the farmers. Bulk milk testing is used for some of these diseases in dairy herds. Note that the Netherlands is free of enzootic bovine leucosis. In 2008 the Dutch dairy processing industries started to develop a combined program for controlling Johne’s disease and salmonellosis in dairy herds because of the similar control measures for both diseases.

The Dutch dairy production board requires all dairy herds to be accredited free for leptospirosis or have a strict control program in place, the Dutch processing industries require all herds to be tested for Salmonella, and in 2010 the dairy processing industries will require all Dutch dairy herds to participate in one of the two Johne’s disease control programs. It is the latter requirement which has boosted enrolment in the PPN from 1,500 dairy herds in 2007 to 15,000 in 2008 (ie 80% of dairy herds).

In these programs, serum and faecal sampling is done by private veterinarians, bulk milk samples are collected by the milk tanker drivers and individual milk samples are those collected for herd recording and forwarded to the laboratory.

Bibliography

- Franken P. Paratuberculosis control in the Netherlands - the target and an overview of the activities. Available at: www.verbraucherschutz.sachsen-anhalt.de/veterinaer/symposium2007/c06franken.pdf

4.4 United Kingdom

4.4.1 Bovine Johne’s disease programs

Johne’s disease is not a notifiable disease in the UK except in Northern Ireland where no statutory action is taken when the disease is reported - any actions taken are the decision of the owner. Although discussed at length by government and industry, there has been little interest in starting a national control program in the UK. Johne’s disease control is at the discretion of individual farmers. Many with pedigree beef herds, seeking to become accredited-free to improve market access or profile participate in an animal health scheme (see below). Some dairy and beef herds suffering large losses from Johne’s disease also work with the health scheme providers in customized programs to control the disease. To motivate commercial
farmers in particular to join, cost-benefit models on controlling and preventing Johne’s and other endemic diseases are promoted by the health schemes and DEFRA.\textsuperscript{40,41}

The \textit{Cattle Health Certification Standards body} \textsuperscript{4} (CHeCS) licenses the six cattle health schemes currently operating in the UK.\textsuperscript{a-f} Health schemes have been in operation in the UK since the mid 1990s. Most scheme operators are private laboratories or private organizations partnering with a laboratory that offer discounted testing fees for scheme members.

CHeCS was established by the British cattle industry for the control and eradication of non-statutory diseases by a set of standards to which all licensed Cattle Health Schemes must adhere. The standards ensure that herd health status in one scheme is equivalent to that of all other schemes in the UK. Close collaboration by CHeCS with industry groups and animal health authorities in other countries ensures that the health schemes meet the requirements of trading partners. The CHeCS website claims that even though CHeCS only currently deals with four diseases (bovine virus diarrhoea, Johne’s disease, infectious bovine rhinotracheitis and leptospirosis in beef and dairy herds), the biosecurity measures put in place for these diseases have a spin-off benefit by preventing the introduction of bovine tuberculosis, salmonellosis and \textit{Escherichia coli} \textsuperscript{157}.

CHeCS sets the rules for two types of Johne’s disease programs run by health schemes. The \textbf{Accredited Free Program} demonstrates that the herd is free of Johne’s disease to allow sale of stock as accredited-free of Johne’s disease. The \textbf{Screening and Eradication Program} is to assist management decisions to reduce the impact of Johne’s disease on herd productivity, to allow the sale of animals of known status and in the long term to achieve accredited free status. Some of the CHeCS rules for Johne’s disease programs are as follows:

\begin{itemize}
  \item \textbf{a.} A herd is Accredited Free if two clear qualifying tests at an interval between 12 and 24 months have been achieved without any reactor being detected. If a test and cull program has been carried out prior to this, three clear annual tests are required.
  \item \textbf{b.} To maintain accreditation, there is a choice between having annual or biennial herd tests:
  \item \textbf{c.} Annual testing requires testing of all animals 2 years of age or older every 12 months.
  \item \textbf{d.} Biennial testing requires testing of
    \begin{itemize}
      \item all homebred animals 2 years of age or older every 24 months.
      \item all non-homebred animals 2 years of age or older from non-accredited herds every 12 months.
      \item collecting blood and faeces from all animals 2 years of age or older prior to removal from the herd. The blood is tested, with faeces only cultured when the animal tests positive by the blood test.
    \end{itemize}
  \item \textbf{e.} In a screening and eradication program, the initial herd test involves blood sampling of all animals 2 years of age or older. If all samples are negative, then this is the first qualifying test for accreditation.
  \item \textbf{f.} All reactors and their offspring should be culled as soon as is practical. Routine annual herd testing continues and management procedures to reduce the exposure of cattle to infection are implemented.
  \item \textbf{g.} If the number of positive animals is such that a culling policy cannot be pursued, herd vaccination may be considered. All calves are vaccinated in the first week of life and management procedures to reduce the exposure of cattle to infection are implemented. Vaccination continues until no clinical Johne’s disease occurs for a period of at least 2 years.
\end{itemize}

\textsuperscript{40} \texttt{www.defra.gov.uk/fhp/index.htm} \textsuperscript{41} \texttt{www.fhpmodels.reading.ac.uk/}
At this point, vaccination can cease and progression towards Johne's Disease Accredited Free status can begin.

h. Blood samples can be either clotted or heparinised. Faeces samples should be of at least 5 gms submitted in a sample pot designed for the purpose.

i. In a herd where infection has not been identified previously, any animal that tests positive by the blood test must be placed in isolation and retained there until further testing has been carried out and the results known. The further tests required are examination for the infective organism in faeces by culture or if the animal is sent for slaughter, examination for the infective organism by culture or histological assessment of the ileo-caecal junction and drainage lymph node. If the animal is confirmed as shedding the infective organism, either by culture or by finding typical histological lesions in the intestine, that animal is defined as a reactor.

j. In herds where infection has already been confirmed, any animal that tests positive by blood test is defined as a reactor and isolation plus further testing are not required.

k. The option exists for herds to test the whole herd by faecal culture instead of the blood test. Faecal samples will be pooled in the laboratory and tested in batches of five.

l. Any disease condition in an animal 6 months of age or older that might be attributable to Johne's disease must be investigated by the supervising veterinary surgeon. This includes all animals that may have diarrhoea or weight loss or both. If the veterinary surgeon is satisfied that the condition is not Johne's disease, then no further action need be taken. If the veterinary surgeon cannot rule out Johne's disease, then a blood sample and faeces sample are to be collected from each affected animal. The affected animals should be isolated from the herd until the results of the laboratory tests are known. Animals that die before blood or faeces samples are collected must have the carcass or the intestinal tract or faeces examined at a participating laboratory.

m. Introduction of non accredited animals should not be added to the herd if at all possible. Where this cannot be avoided, it is preferable to blood sample and test them for antibodies to Johne's disease on the farm of origin. If positive, the animals cannot enter the herd. On entry to the herd, added animals must be placed in isolation and the general CHeCS rules on isolation and testing apply. The animals must be tested for Johne's disease using both blood and faeces samples. Only when the results are negative can the animals be introduced to the herd. In addition, they must also be re-tested every 12 months, notwithstanding any annual or biennial herd-screening program. Where a group of animals has been purchased from one source and one or more of them tests positive, none of that group of animals can enter the herd without loss of the herd's status.

n. With respect to shows and sales, because animals normally require prolonged exposure to large doses of the Johne's disease organism before becoming infected, if accredited cattle have been away from the herd at a show for a period not exceeding 7 days and have been prevented from having direct contact with other cattle, particularly their faeces and soiled bedding, Rule 21 of The Rules of CHeCS will not apply and the accredited cattle can rejoin their herd of origin without the need for isolation or testing.

A Johne’s Disease Risk Assessment Scheme was developed in 2005 by one of the health scheme operators (Biobest) directed at commercial herds where the official (CHeCS approved) scheme was too costly or impractical. The risk assessment involves a veterinary evaluation of the likelihood of disease presence. The evaluation encompasses purchasing policy, clinical/laboratory history and targeted testing including:

- blood samples from a total of ten animals selected for highest risk (cows aged 4-8 years that are thin, showing poor milk production or signs of scour or weight loss, plus cull cows and purchased breeding bulls)

- an environmental faecal sample for Johne’s PCR
a bulk milk sample to test for Johne’s antibodies (dairy herds only).

Herds are then classified as green, amber or red:

- For green classification (low risk Johne’s disease status), there have been no clinical cases in the last 10 years; there have been no purchases of breeding cattle of unknown Johne’s status in the last 10 years; and targeted laboratory tests were all negative.

- For amber classification (medium risk), there have been no clinical cases in the last 5 years; there have been no purchases of breeding cattle of unknown Johne’s disease status in the last 5 years; and targeted laboratory tests were all negative.

- For red classification (high risk or unknown Johne’s disease status), the herd is of unknown status i.e. no veterinary risk assessment; and/or there have been multiple purchases of breeding stock of unknown status from multiple herds in the last 10 years; and/or there has been a confirmed clinical case of Johne’s in the last 5 years; and/or targeted laboratory tests produced at least one positive result.

Herds can progress to lower risk status if they purchase stock from herds with a higher health status and have consistently negative results from the targeted testing. Herds found to be infected are encouraged to develop a control program.

The Welsh Black Cattle Breed Society\textsuperscript{42} is an example of one of a number of cattle and sheep breed societies wishing to raise their profile that have encouraged their members to participate in health schemes. It initiated a Johne’s disease control scheme in 2000. Participating breeders throughout the UK are required to join the Premium Cattle Health Scheme run by the Scottish Agricultural Colleges and test by the scheme’s rules. The breed societies are increasingly running disease accredited sales and shows which have increased participation. Awareness campaigns in recent years have in particular increased participation by commercial herds wanting to control or eradicate Johne’s disease and pestivirus.

One health scheme provider, National Milk Laboratories\textsuperscript{43}, offers a HerdWise Johne’s Screening Program which is modelled almost exactly on the Danish Johne’s disease control program (see above) where milk samples collected for herd recording are tested using an individual milk ELISA. Cows are categorised as green, yellow or red depending on risk of infection with culling, hygiene and feeding of calves managed accordingly.

\subsection*{4.4.2 Multi-disease programs}

The cattle health schemes provide programs for monitoring, control and eradication of four diseases: bovine virus diarrhoea, Johne’s disease, infectious bovine rhinotracheitis and leptospirosis in beef and dairy herds. The government is highly supportive of such schemes because of the potential to create industry and farmer driven improvements in farm biosecurity, disease control and provision of accredited sources of disease-free, breeding cattle but remains at arm’s length from the system and provides no cash or in-kind support. Notably there is no reference to the health schemes on the DEFRA website.\textsuperscript{44} It is the private veterinarian, farmer and scheme operator that work in close partnership.

Producers participating in cattle health schemes can elect to test for one or more of the four diseases, each of the diseases having a set of management and testing rules which must follow the CHeCS rules and guidelines. Certification is provided by the scheme when a herd meets the

\begin{footnotesize}
\item [42] www.welshblackcattlesociety.org/
\item [43] www.nationalmilklaboratories.co.uk
\item [44] www.defra.gov.uk/
\end{footnotesize}
agreed national health standard. Certified cattle are expected to be allowed access to accredited sales and command a premium at sale.

The rules govern the frequency of testing and of which animals need testing. Samples are collected by private veterinarians. There are annual membership and laboratory testing fees paid to the laboratory and fees paid to the herd veterinarian. Herds are classified as Accredited Disease Free or Screening and Eradicating for each disease. Accreditation through bulk and individual milk testing is available for dairy herds.

The 

**HI Health scheme** \(^{45}\) is an example of a health scheme run by a farmer-led board with input from practising veterinary surgeons in conjunction with a private laboratory (BioBest). HI Health has two levels of participation. All members participate at Level 1. HI Health Level 1 requires one veterinary visit per year to advise on herd health including biosecurity measures, such as strategies for buying in disease free stock, and preventative management to control diseases of importance to that particular farm. This standardised approach to health planning has additional advantages: information is collected at the visit on the incidence of endemic diseases and is fed back to farmers so that they can benchmark their enterprises against others, and the disease surveillance information is of national benefit. HI Health Level 2 gives the option of adding on health schemes to control, eradicate or confirm freedom from specific diseases such as bovine viral diarrhoea, Johne’s diseases and infectious bovine rhinotracheitis.

The Scottish Agricultural Colleges run the **Premium Sheep and Goat Health Scheme**. \(^{46}\) It is the only such scheme in Great Britain and there is no licensing or oversight body as there is for the cattle health schemes. Diseases include maedi-visna, caprine arthritis encephalitis, enzootic abortion, scrapie and caseous lymphadenitis. Uptake is generally low and confined to the pedigree sector. Most flocks participate to gain maedi-visna monitored free accreditation.

The **Maedi Visna (MV) Accreditation Scheme** provides an example of the types of incentives for farmers to join the scheme and the accreditation process. Some of the advertised benefits of the MV accreditation scheme include:

- reducing the risk of a flock contracting the disease
- enables attendance at shows and sales from which animals would otherwise be barred
- allow export to certain countries free from MV
- gives the opportunity to advertise to potential purchasers that a flock is MV accredited
- gives added value to a flock by enabling supply of replacements to purchasers who demand MV accredited stock

A flock can become MV accredited when it passes two qualifying blood tests between 6 and 12 months apart and has certification from a veterinarian that the holding can comply with scheme rules and conditions. \(^{47}\) Once accredited, a proportion of the flock is blood tested either every 2 years or every 3 years depending on the situation. The member is then issued with certificates of status for selling or moving scheme sheep. Shows and sales are licensed to provide space for accredited sheep.

**Bibliography**

- a CHeCS at [www.checs.co.uk](http://www.checs.co.uk/)

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\(^{45}\) [www.hi-health.co.uk](http://www.hi-health.co.uk)

\(^{46}\) [www.sac.ac.uk/consultancy/services/i-r/sghs/](http://www.sac.ac.uk/consultancy/services/i-r/sghs/)

\(^{47}\) [www.sac.ac.uk/mainrep/pdfs/mvrules](http://www.sac.ac.uk/mainrep/pdfs/mvrules)
4.5 United States of America (USA)

4.5.1 Bovine Johne’s disease programs

In 1998, the Federal Government and the United States Animal Health Association approved the Voluntary Johne’s Disease Herd Status Program for Cattle (VJDHSP) which relied heavily on testing of animals and removal of positive cattle from herds and separately classifying test positive herds from test negative herds. The VJDHSP is a model program designed to guide USA states wanting to develop a program of their own for classifying test positive and test negative herds. Each state is free to adopt it as is or to make modifications. Progress has been slow with high attrition rates of participating herds because of high costs, lack of progress in reducing prevalence and decreased funding from the USA government.

The program has education, management, herd testing and classification elements. Concerns about the implications of a positive test result are a strong deterrent to joining the program particularly for beef farmers because federal regulations prevent test positive cattle from being moved interstate except direct to slaughter with an owner declaration identifying animals as infected. Some states therefore encourage wary producers to limit their involvement to the management level of the program and avoid testing.

In the testing and classification element there are four test positive levels and four test negative levels. The four test positive levels are A, B, C or D. Level A indicates a very low prevalence (0 test positivity) and Level D indicates a very high prevalence (>15% herd test positivity). Herds at Level A without a recent history of infection may enrol in the test negative component of the program. In some states such as Wisconsin with large dairy industries that have invested considerably in Johne’s disease control, state regulations require herd classification to be disclosed to a buyer at the time of sale of any animal in the herd. And any herd that is not tested or does not annually renew the herd classification by testing becomes classified Maximum Risk for Johne’s disease by default.

The four test negative levels are 1, 2, 3 and 4 with each step indicating an increased probability of freedom from Johne’s disease in the herd ie. Level 1 < 85%; Level 2 <95%, Level 3 <98%, Level 4 < 99%. Levels must be attained successively.

An initial test determines whether a herd participates in the test positive or test negative component of the program. Herd additions must be from an equivalent or higher level herd.

Testing requirements to reach each test negative level are as follows:

Level 1 – negative serum ELISA, pooled faecal culture or environmental sampling
Level 2 – negative serum ELISA
Level 3 – negative pooled faecal culture or individual faecal culture plus environmental sampling
Level 4 – negative individual serum ELISA and faecal culture

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Cattle must be >36 months unless herd size is small when animals >24 months are tested.

Recognised limitations to the program include:

- Test-negative herd status is often interpreted as uninfected, yet classification of herds as free from Johne’s disease infection is not part of the program.
- The reluctance by many producers to have their herds included in the Management component without tools to rapidly move into the test-negative component. This limits herd testing and producer participation in the current herd testing and classification program.
- Infected herds with Johne’s disease control programs cannot currently participate in the test-negative component until they become test-negative (usually after many years of control efforts), despite making marked progress in control of the disease. A single positive test removes herds from the test negative component of the program.
- Restriction of animal movement for herds in the existing test negative component is a constraint on producer participation.

The classification aspects of the program are under review to try to identify ways to increase producer participation particularly by reducing testing costs, reducing stigma attached to positive herds, increasing flexibility in animal movements and faster movement to upper levels of the program.

Some of the proposed changes to the program include:

- easy entry to Level 1 by testing minimum number of animals
- making greater use of vaccination
- making greater use of milk ELISA, pooled faecal culture, and environmental sampling to reduce testing costs
- removing requirement to confirm positive ELISA tests
- simplifying the classification scheme by removing the test positive A, B, C and D classification levels and renaming test negative levels as risk levels. This would destigmatise test positive herds by classifying them at various risk levels in the Level 1-4 system and remove the misleading concept of freedom from disease.

  Level 1: Based on 95% confidence that the true within-herd prevalence is <15%
  Level 2: Based on 95% confidence that the true within-herd prevalence is <10%
  Level 3: Based on 95% confidence that the true within-herd prevalence is <5%
  Level 4: Based on 95% confidence that the true within-herd prevalence is <2%

These categories indicate high confidence of increasingly low risk of Johne’s disease positivity but provide no direct indication of the probability the herd is not infected.

- minimising animal movement restrictions for Levels 1-3.
- continued high level of rigour at Level 4 to ensure scientific credibility.
- herds must achieve Level 3 and implement movement restrictions before eligible for testing to reach Level 4.
- herd testing using individual faecal culture to reach Level 4.
4.5.2 Other Johne’s disease programs

There is no national program for control of Johne’s disease in sheep and goats; two states have Johne’s disease control programs for goats. In Wisconsin\(^49\), the Johne’s disease control program for goats classifies herds based on the percentage of the herd that is test-positive by faecal culture. Herds are classified A (no test-positive animals) through D (more than 15% of the herd tests positive). This herd classification must be disclosed to a buyer at the time of sale of any animal from the herd. Any herd that is not tested, or does not annually renew the herd classification by testing, becomes classified “Maximum Risk for Johne’s disease” by default.

The US has considered including in the VJDHSP testing for other diseases such as enzootic bovine leucosis, bluetongue and pestivirus but the idea lost traction and has now been dropped. New York State (NYS) implements a multi-disease certification program (see below) although it has slowed in recent years. There are no multi-disease certification programs for sheep in the USA.

4.5.3 Multidisease programs

The New York State Cattle Health Assurance Program\(^50\) (NYSCHAP) started in 1998 is a voluntary quality assurance program for cattle herds sponsored by the New York State government (Department of Agriculture and Markets) and managed by Cornell University. Its goals are to formulate and implement integrated preventive intervention strategies that will enhance production and product quality. The program is based on a contract between the producer, their private veterinarian and the state veterinarian. Support is provided by nutritionists and other personnel with the expertise to address specific problems on the farm. Since inception, 1300 farms have enrolled, 900 remaining active in the program, representing 14% of the state’s dairy cattle herds.

All participating NYSCHAP farmers must first complete a Core Module which focuses on biosecurity and Best Management Practices to improve the overall health status of the herd. The Core Module requires a baseline survey and risk assessment be performed by a NYSCHAP-certified veterinarian, followed by the development of a herd action plan for the coming year and then an annual review of the progress of the herd plan. Depending on the specific problems and goals identified for each individual farm, there are several additional disease specific modules that the producer can choose to implement as well. These include Johne’s disease, bovine virus diarrhoea, enzootic bovine leucosis, salmonellosis, mastitis, lameness and neosporosis. There are also drug residue, animal welfare, herd expansion and market cow and bull beef quality assurance modules.

The NYSCHAP is promoted as a powerful educational tool that producers can use to improve both the overall health status of their herds as well focus on specific diseases to control. NYSCHAP certification provides a certain level of health assurance to consumers of the products of the participating farm. The NYSCHAP model has been adopted by a number of other US states including New Jersey, Maine, Vermont, Pennsylvania, Utah and Mississippi.

Some key features are:

- The program is sponsored by the New York State government
- No enrolment fee for participation.
- Herd veterinarians must attend training to become accredited.

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\(^{49}\) [www.johnes.org/goats/certification.html](http://www.johnes.org/goats/certification.html)

\(^{50}\) [www.nyschap.vet.cornell.edu/](http://www.nyschap.vet.cornell.edu/)
- Herd veterinarians are compensated for their time in the planning process by the Department of Agriculture and Markets.
- Herd plans are herd specific and are customized to the goals and resources of the farm operation. Some plans incorporate just changes in management practices while other plans may include disease testing or even construction of facilities.
- Testing is subsidized for Johne’s disease and culture of bulk milk in the mastitis module.
- Herd owners are given internet access to their herd test results.

The Johne’s disease module is consistent with the VJDHSP, however, most producers limit themselves to the Management element and don’t enter into a regular testing program with culling of all positive animals. There are 35 farms in the test negative program.

**Bibliography**

- Johne’s disease information centre. University of Wisconsin – School of Veterinary Medicine.

### 4.6 Less relevant programs in other countries

#### 4.6.1 Austria

Johne’s disease is widespread in cattle and a major problem in the Limousin breed; the disease is less widespread in sheep and goats. In 2006, Austria made Johne's disease a notifiable disease and introduced a government coordinated compulsory control program for Johne’s disease in cattle, sheep, goats and farmed deer. However, no official herd classification or certification program exists.


#### 4.6.2 Czech Republic

The Czech Republic has had a strong regulatory approach to Johne’s disease control since 1992 in a range of domesticated livestock species based on testing individual animals with faecal culture and culling of positive animals. The program ceased in 2008 after it was judged a failure because of high costs, lack of satisfactory progress in controlling the disease and low motivation of farmers. Dairy farmers were unwilling to notify disease as milk from infected herds was refused by processing plants. A certification program based on milk examination by PCR is being considered.

#### 4.6.3 France

France apparently operates two industry coordinated national voluntary Johne’s disease programs including a market assurance program however detailed information was unobtainable.
4.6.4  Finland

Johne’s disease is not considered a problem in Finland’s 3000 beef breeder herds and 22,000 dairy herds with clinical cases occurring in beef cattle occasionally (cases were detected in five herds between 1992-2000) and no cases have been reported in dairy cattle since 1918. However, Johne’s disease is not a reportable disease. No certification program exists.


4.6.5  Germany

Johne’s disease is widespread in cattle in Germany. A voluntary control program operates in the federal state of Thuringia using faecal culture and serum ELISA as diagnostic tools.

4.6.6  Ireland

In 2006 the government in Ireland was actively encouraging industry organizations (through offers of financial support for training and laboratory costs in initial stages) to work together to develop and implement herd health programs that included Johne’s disease. A coordinated national program is apparently in the advanced stages of development but detailed information was unobtainable.

4.6.7  Israel

The Israel Johne’s disease control program is voluntary and began in 2003. It consists of a management program and whole herd testing using milk or serum ELISA followed by faecal culture of positive cows.

4.6.8  Japan

Japan has a strong regulatory approach to Johne’s disease control in cattle – it has had a national eradication program since 2007. Targeted herds, mainly dairy herds, are tested every 5 years and positive animals culled with compensation at 80% of market value. Infected herds are subject to an intense program of repeated testing and must adopt legislated control measures including introduction of cattle with disease-free certification.

4.6.9  New Zealand

Johne’s disease is not notifiable in New Zealand – it is widespread in a range of domestic and wild animals including sheep, goats, deer and cattle. There are no control or quality assurance programs for Johne’s disease in New Zealand in any species. The deer industry has however prepared a set of draft voluntary protocols for the advertisement of Johne’s disease status of deer presented to the live sale market. The risk statuses proposed are: Low Risk, Confirmed Infected and Unconfirmed. Low Risk status is based on the results of on-farm testing and abattoir surveillance. Work is ongoing to refine and gain consensus approval on the protocols.

The New Zealand dairy industry has decided not to implement control programs because it is considered that control measures currently available are too costly and insufficiently effective for application in the New Zealand situation. Considerable research is being done to identify cost-effective methods for control in New Zealand in case food safety and market access issues arise. Vaccination and selection of resistant cattle are considered likely components of any future control program given herd prevalence, multispecies involvement and wildlife reservoirs.

There are a number of national coordinated single disease control programs (managed by different non-government entities) including for enzootic bovine leucosis, pestivirus, leptospirosis, ovine brucellosis and tuberculosis in cattle and deer. Trading rules apply...
according to the testing-based herd classification and certification system used for the program. The New Zealand government has no involvement in management of endemic diseases except for tuberculosis.

### 4.6.10  Sweden

Johne’s disease is a notifiable disease in Sweden and a strong regulatory approach is taken - infected herds are stamped out. Johne’s disease is rarely detected in beef cattle and has not been detected in dairy herds, sheep and wildlife despite extensive surveillance. A voluntary control program has been in place since 1998 based on faecal sampling of all adult animals and trade is restricted to herds with the same status in the program.


### 5.  Conclusions and recommendations

No country appears to have formally evaluated its Johne’s disease programs to identify if the program’s stated objectives have been met. This may be because the programs have not been running long enough or because it was obvious that low attractiveness to farmers, lack of progress in controlling the disease or excessive costs were reasons why programs were failing. Nonetheless, a number of countries have developed or transformed their programs as a result of lessons learned from their own or others’ programs. The modifications have mostly focused on increasing farmer participation with surprisingly little attention paid to increasing assurance of low disease risk in herds.

The International Dairy Federation's 2nd ParaTB Forum will be held on August 7-8, 2009 in St. Paul - Minneapolis, Minnesota, USA. The theme for the 2nd ParaTB Forum will be “Monitoring success of paratuberculosis programmes”, hence, there may be some revelations of interest to Australia. The aim of the ParaTB Forum is to provide representatives of national Johne’s disease programs around the world with a platform for discussions specifically on challenges and experiences with Johne’s disease control, surveillance and certification programs. Australia should be represented at the Forum.

Gauging the success of programs in other countries via the methodology used here is difficult. A study tour of selected countries by a group of Australian experts to better gauge the success of programs and their modifications should be considered. The countries of most interest are Canada, Denmark, the Netherlands, UK and USA and possibly France, Ireland and Israel. A number of ideas have emerged from programs developed overseas that may have application in Australia – these might become the terms of reference for any study tour. Some of these ideas are as follows:

1. **To reduce testing costs**, culture of pooled faecal samples from beef herds and environmental samples from dairy herds, and antibody ELISA on individual milk samples collected for herd recording in dairy herds should be considered. Bulk milk testing might be very useful for Johne’s

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51 [www.fil-idf.org/WebsiteDocuments/AHNewsletter2.pdf](http://www.fil-idf.org/WebsiteDocuments/AHNewsletter2.pdf)

52 For more information about the 2nd ParaTB Forum, the contact is: Søren Saxmose Nielsen, University of Copenhagen e-mail:ssn@life.ku.dk. The meeting precedes the 10th International Colloquium on Paratuberculosis (10ICP), which is August 9-13, 2009 in Minnesota, USA.
disease control and certification programs. Developments in this area in overseas programs should be monitored closely however accepting diagnostic tests of reduced sensitivity with the aim of increasing producer participation should be done with caution if it is at the expense of providing adequate levels of assurance of low disease risk.

2. To increase the incentive to participate in Johne’s disease prevention or control programs, milk (or meat) processors collectively could insist that suppliers participate as occurs in the Netherlands. Imposing penalty deductions or bonus payments for meat and milk such as occurs in Denmark’s salmonella program could be considered. In the UK many breed societies insist on members participating in a health scheme’s disease certification programs. In Australia, more breed societies, farmer associations and other focused groups including catchment or district groups could consider insisting on participation by members.

Vigorous promotion of the cost-benefits of disease control and prevention using farmer friendly communication and targeting the commercial sector as occurs in the UK could be considered as a means of increasing participation in Australia. Industry ownership, not just support, is recognized as important to give credibility to programs and promote participation. Government involvement in programs may deter participation.

3. To reduce stigma associated with having an infected herd or flock, management programs without testing such as occurs in the management components of the Canadian and USA programs could be considered. Credit is given for the number of years in the program. A single system of classifying herds based on a limited number of risk levels and removing labelling references to positive or negative status as is proposed in the US program and occurs in the Wisconsin Johne’s disease control program for goats is worth considering as a destigmatising measure. The National Dairy BJD Assurance Score may do this to a certain extent in Australia already.

4. To prevent relegation to program start for herds or flocks testing positive where no recognition was given to years of progress in control, consideration should be given to a model similar to the two level system such as the Status Pathway in the proposed Canadian program where culling of positive animals is sufficient to maintain Level 1 status and regaining Level 2 after a positive test can be achieved with one clean test. A similar principle applies in the Paratuberculosis Program Netherlands. The Ontario Sheep Health Program’s classification by a veterinarian without testing into low, moderate and high risk for certain diseases is possibly an interesting attempt to avoid stigmatisation.

5. To maximize disease control with minimal culling (if the JDMAPs were to be extended to include statuses and risk categories for infected herds) for those farmers that cannot afford to cull all positive animals) there are lessons learned from the Danish program with its conservative approach to culling. Cows are categorised into different risk levels based on serial individual milk ELISA scores - culling, hygiene and calf feeding are managed according to risk. The system has stigma management advantages of no black and white classification of results as positive or negative plus farmers can make their own decisions on culling of cows. A “risk likelihood” system such as operated by the Danish may become important if tests of increased sensitivity are developed resulting in more animals in herds and flocks being found positive but unable to be culled.

6. To increase practicality there may be options in Australian programs to ease rules on agisting cattle to herds of lower status (as the Dutch do in their Intensive Paratuberculosis Program because they view the risks of introducing Johne’s disease by this means as low). The practicality of not having to confirm positive ELISA tests as is proposed in the USA program and not having to cull all positives (as already discussed) would also increase the attractiveness to some farmers. As farmers, particularly dairy farmers, increase their herd sizes and have less time and labour to pay attention to management components (ie hygiene and segregation of
young stock), the potential role for vaccination in control and quality assurance programs becomes greater, a role recognized by the USA and New Zealand.

7. To increase general biosecurity awareness and the discretionary buying of cattle with respect to disease risk, ready public access to internet sites bearing herd and flock risk statuses as occurs in Denmark for the salmonella program could be considered. And making it a legal requirement to disclose herd or flock status to prospective buyers as occurs in Wisconsin could be considered.

The NYSCHAPs, the UK’s health schemes for cattle, sheep and goats, the Ontario Sheep Health Program and the Healthier Goat program in Norway provide models of multi-disease quality assurance programs. They appear good in theory and the testimonials from those running the programs are glowing, however to be sure of their success and effectiveness, let alone their application to Australia, would require a study tour.

The common theme of having in place a core biosecurity program to which disease modules can be added as required is certainly attractive. In Australia there is scope for similar multi-disease quality assurance programs to be run by private veterinary laboratories in conjunction with universities, breed societies and farmer organizations. In addition to Johne’s disease, diseases included in such programs might include for cattle: pestivirus, salmonella, neospora, vibriosis and trichomoniasis; for sheep: footrot, lice, CLA and campylobacter; and for goats: CAE, footrot and lice.
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