live export

Business plan

Registration of the aromatic attenuated salmonella vaccine in the live sheep trade

Project number LIVE.007B

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ISBN 174036 570 4

August 2004

MEAT & LIVESTOCK AUSTRALIA

LIVECORP

The livestock export program is jointly funded by the livestock exporters and producers of Australia

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Abbreviations used in this report

AMSA	Australian Marine Safety Authority
Aro	Aromatic (attenuated salmonella vaccine)
APVMA	Australian Pest and Veterinary Medicine Authority
AQIS	Australian Quarantine and Inspection Service
CIF	Cost Insurance Freight
CSL	Commonwealth Serum Laboratories
EMAI	Elizabeth Macarthur Agriculture Institute, Camden NSW
FOB	Free on Board (usually total value of cargo at point of embarkation
IM	intramuscular (referring to method of vaccine administration)
LEAP	Live Export Accreditation Program
MLA	Meat & Livestock Australia
NRA	National Registration Authority (now APVMA)
NVD	National Vendor Declaration Scheme

EXECUTIVE SUMMARY

- This document is a business plan for the registration of the aromatic attenuated salmonella vaccine for the live sheep trade. It was prepared to inform stakeholders of the costs and benefits of vaccine registration and assist with commercial negotiations between the vaccines manufacturer and the industry.
- Salmonellosis is a significant cause of sheep mortality during both the feedlotting and shipping stages of live sheep export. Much is not known about the risks of salmonellosis in intensive systems and the vaccines efficacy is based on informed estimates.
- A vaccine registration cost of $460,000 has been used in this analysis. Dose cost is between $0.05 and less than $0.10/dose. Promotion and distribution costs are minor. The cost of vaccination labour will be borne by either the sheep producer (scenario one – farmer vaccination) or the sheep exporter through a licensed vaccinator (scenario two).
- A decision will need to be made by MLA and LiveCorp as to whether these organisations will simply promote the use of the vaccine or initiate a more formal scheme to mandate its use. Administration and auditing costs will be driven by this decision.
- Vaccination benefits are estimated on the basis that only sheep shipped from east coast ports (Portland and Adelaide) are vaccinated. Direct benefits are reduced sheep mortality at both the feedlot and on board ship and fewer feedlot culls during salmonellosis 'spikes'. Indirect benefits may be public perception of a more sustainable and humane industry, and, for producers, a contribution to maintenance of this alternative market option, more stable, and possibly, higher prices for their sheep.
- The cost benefit analysis shows that a positive return from vaccination will occur if sheep producers provide vaccination labour at no cost. If licensed vaccination labour is required or sheep producers seek to recover the cost of their labour at a commercial rate, vaccination costs will exceed vaccination direct benefits.
- If MLA/LiveCorp funds vaccine registration and the vaccine producer charges only the direct costs of production and marketing (with a modest margin), then substantial returns will be available for exporters.
- The analysis confirms the vaccine's manufacturers proposition that their revenue from vaccine sales ($150,000 gross per annum or $30,000 per annum net assuming a 20% margin) will be modest and insufficient to justify registration costs.
- Sensitivity analysis shows, that vaccine efficacy would need to fall to 20% and the reduction in cull events during salmonella 'spikes' in eastern state feedlots fall from four to two events before vaccine registration costs equal vaccine registration benefits in scenario one (farmer vaccination).
- For the indirect, non-financial benefits of salmonella vaccination (animal welfare, mitigation of negative political impacts, environmental benefits, gains for domestic sheep feedlot industry) to be realised, a whole of industry regulatory/QA approach will probably be required. Vaccination for high-risk feedlots would need to be incorporated into the relevant live export QA standards. A revised LEAP program would include compulsory vaccination for all eastern state feedlots and a large-scale field trial vaccination for winter/spring 2004 is recommended.
- Vaccine registration next steps include (1) Industry considers the prospect of incorporating Salmonella vaccination (if it were to become available) into LEAP. (2) That representatives of the industry meet with Bioproperties and negotiate a MoU in relation to cost sharing for vaccine registration. (3) APVMA be approached regarding requirements for a large-scale field trial. (4) That the various departments of agriculture be enlisted to support the application for vaccine registration to ensure its fast tracking – in the event that industry takes the decision to proceed.

1. INTRODUCTION

1.1 Purpose of the Business Plan

This document is a business plan for the registration of the aromatic (aro) attenuated salmonella vaccine for the live sheep trade. The business plan is to assist in the negotiation of a satisfactory commercial agreement between the vaccines manufacturer (Bioproperties Pty Ltd) and stakeholders in the live sheep industry.

The business plan is required to:

1. Enable live sheep industry stakeholders to understand the costs and benefits of registering a vaccine for the live sheep trade; and
2. Provide a knowledge base to allow Meat & Livestock Australia (MLA) and LiveCorp to be able to negotiate with industry stakeholders and the vaccine manufacturer on the commercial supply and delivery of the vaccine.

Michael Clarke and Dr Bruce Standen prepared the cost benefit analysis and business plan for MLA and LiveCorp in July 2004.

1.2 Plan Preparation Methods

The cost benefit analysis and business plan was prepared using a five-stage process. The stages were:

- Document review and consultation in order to understand the nature of the vaccine and its potential market. A list of relevant reports and people consulted as part of the study is included in Chapters 7 and 8 of this document;
- Product and market scoping to determine a realistic set of projections of its likely/possible use and other parameters, for completion of project analysis;
- Financial and economic modelling;
- Preparation of a business plan, that was informed by the results of financial and economic analysis; and
- Formulation of conclusions, recommendations and vaccine registration ‘next steps’.

Draft and final reports were presented to MLA and LiveCorp for review.

2. VACCINE EFFICACY AND REGISTRATION PROCESS

2.1 Industry Background

Live Sheep industry

Historically, Australia has exported approximately six million live sheep per annum, which contributed around $300 million to the Australian economy. See Table 2.1 below. With the indefinite suspension of the export trade to Saudi Arabia, exports are forecast to fall to around 4.4 million sheep in 2004 before recovering to reach 5.2 million head in 2008 (MLA Industry Projections, 2004).

Table 2.1 Australian Live Sheep Exports

Year	Sheep Exported (million head)	FOB Value ($)
2000	5.5	260
2001	6.5	340
2002	6.1	409
2003	4.7	342
2004 forecast	4.4	
2008 forecast	5.2	

Source: LiveCorp website and MLA Projections

Live sheep are shipped from ports of Western Australia, Victoria and South Australia. Table 2.2 shows the relative importance of each state's exports in 2003.

Table 2.2 Live Exported Sheep by Port of Loading 2003

Port Loading	Sheep Exported (million head)
Fremantle, Western Australia	3.0
Port Adelaide, South Australia	0.8
Portland, Victoria	0.7
Other	0.2
Total	4.7

Source: LiveCorp

Live Sheep Losses Associated with Salmonellosis

Mortality rates in live sheep are low. For example, over the seven years to 2003, shipboard mortality in exported sheep was 1.38% (Norris, RT and Norman, GJ 2004).

There are two different syndromes of salmonellosis in the live sheep export trade. Firstly, problems during feedlotting are due to feedlot-related salmonellosis, which is a significant problem for many animal based industries following intensification. The second syndrome, the persistent inappetence-salmonellosis-inanition (PSI) complex, is the main cause of death in sheep during shipping (More 2002).

During a normal feedlotting period, paddock and shed-based feedlots suffer background losses of approximately 6 to 7 deaths per 10,000 sheep (0.067%). However, in approximately 20% of consignments each year, feedlot operators describe worrying, but sporadic, outbreaks of salmonellosis, which can result in an additional overall mortality rate of approximately 100 deaths per 10,000 animals (1%), and a much higher mortality rate in affected paddocks. Since early 2000, these outbreaks have occurred in each of the large paddock-based feedlots in Victoria, South Australia and Western Australia. Similar outbreaks have not been reported in the shed-based feedlots (More 2002).

In addition to economic losses caused by sheep death as a result of salmonella in feedlots, losses are also incurred due to mandatory culling. Current AQIS requirements are that once 30 cases of salmonella are observed in any one 1,200 head feedlot paddock, the whole paddock must be 'pulled' from the trade.

Salmonella outbreaks in feedlots are sporadic and unpredictable, but may be more common between the autumn break and early summer. All outbreaks are related to high throughput, and are believed to involve *Salmonella typhimurium* and/or *S. bovis-morbificans*. In all outbreaks of salmonellosis during feedlotting, deaths have been highly clustered in a small number of non-contiguous paddocks. However, 'problem' paddocks did not persist from one consignment to the next. Although not necessarily affected, high-risk lines include young animals, animals in poor conditions and long-haul and pastoral sheep. Risk of disease is substantially higher if animals arrive when the weather is cold, windy and wet (More 2002).

There has been a progressive decrease in the mortality rate attributable to salmonellosis during the shipboard phase for the Fremantle-loaded sheep. In contrast, for sheep loaded in Portland and Adelaide, this rate has been higher and progressively worsening in recent years (More 2002). Since More (2002) reported his findings, management changes and lower throughputs have eased this worsening trend (Norris, RT pers comm. 2004). See Table 2.3 below.

Table 2.3 Sheep Death Rates on Voyages to the Middle East (%)

Port	1997	1998	1999	2000	2001	2002	2003
Fremantle	1.28	1.57	1.31	1.24	0.96	0.87	0.77
Adelaide	1.16	1.18	1.25	1.41	1.48	1.29	1.20
Portland	1.70	1.58	1.62	1.73	2.15	2.10	1.01

Source: Norris, RT and Norman GJ (2004)

When analysed the causes of shipboard death included inanition (47%) and salmonellosis (27%). The proportion of total deaths attributable to salmonellosis is thought to be higher in sheep originating from the east coast and may be twice as high as the national average (Norris, RT pers comm. 2004).

In summary,

- Salmonellosis is a small but significant cause of sheep mortality during feedlotting and shipping;
- The literature does not comment on the impact of salmonellosis on sheep morbidity (i.e. percentage of sheep that become sick and consequently under perform). However, under current AQIS rules culling is required when salmonella spikes reach threshold levels;
- Much is still not known about the causes of salmonellosis in intensive systems;
- Salmonellosis is a minor problem in Western Australia where shed based feedlots are used;
- In Adelaide and Portland where paddock based feedlots are used salmonellosis is more significant;
- In Adelaide and Portland 20% of feedlot consignments are subject to a salmonella 'spike' which will kill 1% of the consignment; and
- On board ship losses vary between 1% and 2%, around one-quarter (27%) of which are attributable to salmonella. Shipboard salmonella is higher in sheep originating from east coast ports.

Industry's Need for a Salmonella Vaccine

The economic and political sustainability of the live sheep trade will be improved as mortality and morbidity continue to be improved. Salmonellosis and other causes of sheep deaths on ships (such as inanition and heat stress) can result in mortality 'spikes' which are reportable by the industry to the Australian Marine Safety Authority (AMSA). These reported incidents are noted by both the Australian government and the animal welfare lobby and generate community pressures to close the trade or result in further regulation that increases the industry's cost base. Control of salmonella 'spikes' is desirable from both a commercial and social perspective. LiveCorp and MLA are therefore continuing to seek ways to minimise mortality and morbidity in live export sheep due to salmonellosis.

In 2002, a review of best practice for the control of salmonellosis in live sheep export facilities (More 2002) concluded that a killed vaccine would not be efficacious. The review did not examine opportunities for a live salmonella vaccine.

At the request of the Live Export R&D Committee, Dr John House, University of Sydney, submitted a proposal (House *undated*) defining the procedures and tests/trials required to register for sheep an attenuated live salmonella vaccine that is currently used in the Australian poultry industry and is proposed for registration for use in the Australian cattle industry.

Recent discussions with Dr John House, NSW Agriculture and Bioproperties Pty Ltd (Portland 2004), have convinced LiveCorp and MLA that the live vaccine could be effective in helping to control salmonellosis in sheep.

Subsequently, the Live Export R&D Committee has endorsed the necessary R&D to enable registration of the live vaccine conditional upon a satisfactory commercial agreement between the vaccine manufacturer and stakeholders in the live sheep industry. This business plan is to inform the negotiations towards that agreement.

2.2 Vaccine Efficacy

This business plan does not include a detailed assessment of the technical feasibility of the vaccine. However, the following points are relevant:

- An attenuated live vaccine like the aro attenuated salmonella vaccine is much more efficacious than known dead vaccines (House, *pers comm.*).
- The efficacy of aro attenuated salmonella vaccines has been demonstrated in numerous species including sheep (House, *undated*).
- The vaccine is used as a preventative and not a treatment.
- The vaccine can be delivered orally through drinking water or by intramuscular application.
- Oral delivery via drinking water has advantages in relation to cost (less 'washing' during manufacture of the vaccine and less labour during vaccination) and animal stress. However, the timeframe for protection is longer and less complete. Furthermore, not all sheep drink with the frequency required for inoculation.
- Intramuscular injection will provide maximum protection from salmonella infection 7 days after vaccination (David Tinworth *pers comm.*) with some protection as early as 24 hours after vaccination (Dr John House *pers comm.*)
- This means that vaccination will be required on farm and ideally up to 7 days before sheep arrive at the feedlot.
- Industry consensus (used in the absence of trial data) is that the proposed live vaccine may reduce sheep mortality from salmonellosis by up to 40%.

2.3 Registration Process

- It is a requirement of Australian law that all new vaccines for veterinary use are registered with the Australian Pest and Veterinary Medicine Authority (APVMA formally the National Registration Authority).
- The aro attenuated salmonella vaccine is already registered for use in poultry in Australia and this means that some of the requirements of registration (e.g. product stability) can be fast tracked.
- Registration of veterinary vaccines involves testing and trials to demonstrate (House, *undated*):
    - Stability (vaccine will be freeze dried and therefore its stability easy to demonstrate);
    - Safety (local reactions such as lumps on the sheep, systemic reactions such as fevers and interactions with other vaccines need to be tested);
    - Efficacy (will require both pen and field trials to provide reasonable evidence that the vaccine does work on sheep under trial and field conditions. Major source of effort and expenditure in achieving registration);
    - Meat withholding times; and
    - Market impacts.
- As proposed by House the registration process is anticipated to take between 12 and 18 months.

3. KEY DATA AVAILABLE TO THIS STUDY

3.1 Macro Data

Key data driving the benefit cost analysis and the business plan are:

- Australia will export an average of 4.5 million sheep per annum over the next five years (informed by MLA Industry Projections for 2004);
- Western Australia (WA) will export 3 million of these sheep, with the balance being drawn equally from Victoria (750,000) and South Australia (750,000) (based on recent historical market share between the states). Note however that in the three years prior to the closure of the Saudi market an average of only 1.1 million head of sheep were exported from the two eastern ports;
- The Free on Board (FOB) value of these sheep is $70/head and is based on price data supplied by LiveCorp and sourced from the ABS for the three years ending May 2004. The Cost Insurance Freight (CIF) value of these sheep is $105/head and is based on data sourced from Hassall & Associates 2000;
- Vaccination for salmonella using the aro attenuated salmonella vaccine will reduce current mortality rates associated with salmonellosis by 40%. The impact of a higher rate on the level of benefit from vaccination is explored.

3.2 Vaccine Usage and Size of the Market

Live Sheep Trade

- Unless made mandatory, vaccination is unlikely to be practiced in WA where feedlotting in raised sheds appears to have substantially reduced salmonella infection (NB one feedlot in Katanning does not have raised sheds). The case for compulsory vaccination of sheep fed in raised sheds is not compelling.
- If vaccination is not practiced in WA then the market for the vaccine will be limited to sheep sourced through Portland and Adelaide.
- For sheep loaded at these two eastern ports, vaccine use (particularly if mandated) could be either on a blanket basis (i.e. all sheep are vaccinated) or strategic basis (i.e. only high risk sheep sourced from high risk areas during high risk periods are vaccinated).
- The difficulty with a strategic approach to vaccination is that the parameters for high risk are not well understood (John House, *pers comm.*) so that rules/guidelines cannot be easily formulated.
- In the absence of guidelines for a strategic (i.e. selective) approach and allowing for the possibility of a mandatory requirement (or overwhelming commercial attraction) for vaccination at eastern ports only, usage is likely to have an upper limit of 1.5 million doses.
- The requirement to vaccinate could be built into the proposed new AQIS live export standards and made an export condition for sheep originating from east coast feedlots.
- Some voluntary use of the vaccine in WA might possibly boost usage to 2 million doses. Alternatively if the use of the vaccine were entirely voluntary annual usage might be 1 million doses or even fewer. This study uses a market of 1.5 million doses on which to base initial calculations.
- It is pertinent to note that the vaccine's manufacturer, Bioproperties has projected a maximum market size of 2 million doses per annum (David Tinworth, *pers comm.).*

Domestic Sheep and Lamb Feedlotting

- In addition to use in the live sheep trade, registration of the vaccine may facilitate its use in domestic sheep and lamb feedlotting. This sector has grown rapidly over the last few years, produces a premium product and is exposed to the same problem of intensification as live exports. The industry consists of six large players each with annual throughputs of 100,000 head and a large number or smaller 'opportunistic' players. Industry throughput is estimated at one million head per annum (Ian Ross, *pers comm.*).

3.3 Production, Application and Distribution

- If the vaccine is registered, Bioproperties will manufacture the vaccine in its Sydney based plant.
- The vaccine pack produced by Bioproperties will consist of a freeze-dried pellet in a 3 ml vile with an accompanying package of 400 ml of liquid for diluting the vaccine into a use ready form.
- Each pack will be suitable for vaccinating 200 sheep.
- While oral application of the vaccine is possible, the vaccine is likely to be most efficacious when applied intramuscularly. Intramuscular application is therefore assumed.
- Two alternatives present themselves for distribution and application of the vaccine.
- Under one scenario, live sheep buyers will source the vaccine from the manufacturer and pass it to the sheep producer at the time of selecting and purchasing the sheep on farm. The sheep producer will be required to vaccinate sheep on farm before they are delivered to the feedlot. Under this scenario the exporter pays for the vaccine pack but not vaccination labour.
- Under the alternative scenario, the exporter employs a licensed vaccinator and a trained operative vaccinates the sheep. This approach was adopted by the industry for vaccinating sheep against scabby mouth when the Saudi Arabian market was open. This approach addresses concerns expressed about use of an attenuated live vaccine by an untrained operator and the risk of any non-compliance (if vaccination were to be made mandatory) is greatly reduced. However it throws into sharp relief the questions of who bears the cost of a specialist vaccination service.
- Under scenario one, a low opportunity cost for sheep producer labour would mean little or no application cost is incurred. Under scenario two, accredited vaccinator charges, as for the scabby mouth program would incur labour costs of the order of $0.65/head.
- If vaccination becomes a requirement of the new AQIS quality control standards, then it is more likely that an accredited vaccinator will be required.

4. COSTS AND BENEFITS OF VACCINE REGISTRATION

Document review and consultation has identified the following potential costs and benefits to industry associated with vaccine registration and use.

Table 4.1 Costs and Benefits of Vaccine Registration and Use

Costs	Benefits
Vaccine Registration Cost	Mortality Avoided
Vaccine Production Cost and Manufacturers Margin	Morbidity Avoided
Vaccine Promotion Cost	Animal Welfare Benefits
Vaccine Distribution Cost	Political Benefits
Administration and Auditing	Marine Insurance Savings
Vaccination Labour	Additional Load Sizes
	Market Alternatives for Producers
	Environmental Benefits
	Benefits to Domestic Sheep and Lamb Feedlotting

Each of the cost and benefit items is described, and where appropriate quantified, in the sections below.

COSTS

4.1 Vaccine Registration Cost

- At the request of MLA and LiveCorp, Dr John House of the University of Sydney prepared a vaccine registration budget as part of a vaccine registration proposal. A summary of the budget is presented in Table 4.2 below. Dr John House estimates a total cost of $419,000 plus $90,000 in in-kind salary contributions. The budget is an approximation of registration costs.
- Advice from Bioproperties is that the budget is reasonable for the work described. Bioproperties advise that fast tracking of vaccine registration and truncating pen trials might shave a maximum of $100,000 off the budget prepared by Dr John House. Bioproperties contends that the total cost of registration will be double that shown in Table 4.2 if the cost of substantiating manufacturing methodology were added to the budget. The cost of substantiating manufacturing methodology will be borne by Bioproperties as part of registration of the vaccine for use in Australian cattle[1].

[1] The value of Bioproperties 'in-kind' contribution to vaccine registration, as estimated by Bioproperties, is shown in Appendix 1. Total in-kind contribution is estimated by Bioproperties at between $355,000 and $470,000. Of note is the inclusion in this cost estimate of Registration Documentation at between $30,000 and $50,000. This cost is currently budgeted by Dr John House in his submission to MLA as a cost to be borne by industry and is estimated at $22,000. Dr House has labelled this cost 'Preparation of Registration Packet'. This cost may therefore be saved from the estimates used in this plan if Bioproperties is offering this 'in-kind'. It was not possible to secure an independent estimate of these costs but a first 'low side' estimate prepared by Peter Claxton of Bioproperties was between $205,000 and $245,000. Advice from another animal health product provider was that $400,000 seemed on the high side but that the final cost would depend on the assumed cost of contract versus staff labour. This representative from another company also commented that his firm would not be interested in registering this small volume and therefore low profit vaccine. Also flagged but not explored is the possibility that registration costs incurred by Bioproperties may be eligible for R&D tax concessions.

- Alternatively, data collected in the sheep registration process may be of assistance to Bioproperties[2].
- For analysis purposes the cost of vaccine registration is assumed to be the total of Dr John House's cash costs plus a 10% contingency, i.e. $460,000. Most of this cost is occurred in the first year of registration trials.

Table 4.2 Vaccine Registration Budget – Summary of Dr John House Estimates

Item	Cost	Year Incurred/ Comment
In kind salary contribution	90,000	Non cash cost, split Yr 1 & 2
Graduate student scholarships	128,000	Split Yr 1 & 2
Salaries	115,000	Split Yr 1 & 2
Section Illa Safety	21,800	Yr 1
Experiment 2 Oral Vaccination	4,165	Yr 1
Section Illb Efficiency Homologous Salmonella Challenge	34,720	Yr 1
Heterologous Salmonella Challenge	34,720	Yr 1
Pre Field Trial Prevalence Determination	15,500	Yr 1
Field Trial	43,000	Yr 1
Preparation of Registration Packet	22,000	Yr 1
Total	418,925	

Source: Budget provided by MLA

4.2 Vaccine Production Costs and Manufacturers Margin

- The cost of vaccine production is dominated by the cost of the glass vile to contain the vaccine and vaccine packaging. The cost of vaccine replication, washing and production is relatively minor.
- Bioproperties have advised that vaccine production cost will be $12 to $15 per 3 ml glass vile
- This production cost is based on the cost of salmonella vaccine produced by Bioproperties for the poultry industry.
- The 3 ml glass vile used in the poultry industry is able to dose between 1,000 and 5,000 birds (normally 5,000 birds).
- The sheep industry requires a pack size of only 200 doses and the manufacturer has indicated that there will be a loss in production economies associated with this pack size. Cost of production for use in the sheep industry will therefore be at least $12 per vile.
- Bioproperties advise that margins in this business are typically 50% but that a margin of 10-15% will be acceptable in this instance if the industry were to fund the full cost of registration.
- Indications from Bioproperties are that, setting aside registration cost, retail price will be less than $0.10/dose and could be as low as $0.05/dose.
- Note: poultry vaccine sells for $0.02/dose. Bioproperties plan to market cattle vaccine for $1.00/dose. Vaccine volume per dose is not linked to animal size.
- A dose cost, inclusive of manufacturers margins of between $0.05/dose and $0.10/dose would appear to be consistent with the cost of other sheep vaccines, see Table 4.3 below. Key considerations when comparing retail prices are the strategic nature of the application, the need for annual boosters and the inclusion of a number of disease vaccines within a single vaccine product.

[2] Data collected for the sheep registration would assist the cattle registration in as much that it sets a precedent in a ruminant species in Australia. The testing of cattle registration would still be required. It is likely that the most important benefit to Bioproperties from registration for sheep is that it will improve the economy of scale. Quality control audits for vaccine production would also overlap. The in-kind contribution for sheep (documentation of manufacturing process, stability, etc) would also be used for the cattle registration.

Table 4.3 Retail Price of Vaccine

Vaccine	Comment	Dose Volume	Retail Cost ($/dose inc GST)
Gudair™ OJD vaccine (Pfizer)	Lifetime single vaccination, used strategically and farmer administered. Killed vaccine. Some OH&S issues. 90% effective[2]	1 ml[1,4]	$1.80[1] - $2.00[4]
Ultravac™ 5-in-1 (Pfizer)	Used to prevent the major clostridial diseases in cattle and sheep. Two vaccines required followed by further boosters (annual) to confer lifetime immunity. Farmer administered.	1ml[4]	$0.12[3]
Scabigard™ (Pfizer)	Live vaccine requiring licensed vaccinators for administration associated with live export. Annual protection against scabby mouth diseases in sheep[4]	0.02 ml[4]	$0.20 [3]
Footvax (Coopers)	10 strain vaccine that assists in the control of footrot (together with management program). Used strategically. 2 does required. Farmer administered. Cures 60% of infected sheep and protects 80% from further/new infection. [5]	1 ml[1, 5]	$1.46[6]
Eweguard (Fort Dodge)	Moxidectin (worm protection) plus 6 in 1 vaccine for clostridial diseases and cheesy gland. 28 day withholding period. Farmer administered.	2-3 ml[1]	$0.49 - $0.73[8]
Weanerguard (Fort Dodge)	Moxidectin (worm protection) plus 6 in 1 vaccine for clostridial diseases and cheesy gland. 28 day withholding period. Farmer administered.	2-3 ml[1]	$0.35 - $0.53 [9]
Guardian 6-in-1 (Coopers)	Vaccine against five clostridial diseases plus cheesy gland. Initial 2 does, followed by annual boosters recommended. Farmer administered.	2 ml[5]	$0.16[6]
Guardian 6-in-1 plus Se (Coopers)	Vaccine against five clostridial diseases and cheesy gland, plus selenium for lambs. Initial 2 does, followed by annual boosters recommended. Farmer administered.	2 ml[5]	$0.18[6]
Ovastim (Virbac)	Fecundity stimulant, used strategically. Farmer administered.	2 ml[1]	$0.99[7]- $1.00[1]
Eryvac (Pfizer)	Vaccination against *Erysipelas* (sheep arthritis). Vaccination of lambs and annual boosters required. Used strategically. Not widely used	1 ml[1]	$0.33[1]

Various sources

[1] MLA 2004a

[2] http://www.dpi.vic.gov.au/dpi/nreninf.nsf/LinkView/CD35A8409F777CB5CA256C8400037CDBF1CB7E555D17189F4A256DEA00274543

[3] per communication, Agritech Rural Pty Limited, Horsham, 20 July 2004.

[4] www.pfizeranimalhealth.com.au

[5] Coopers© Animal Health (2004) Effective vaccination programmes for sheep, cattle and goats. http://www.coopersanimalhealth.com.au. Accessed 20 July 2004.

[6] personal communication (2004) Coopers Animal Health 20 July 2004

[7] www.farmsupplies.com.au, accessed 20 July 2004

[8] personal communication, Purkiss Seeds CRT, Armidale, 19 July 2004.

[9] personal communication, Hamilton Farm Supplies, Hamilton, 19 July 2004.

4.3 Promotion Cost

- Bioproperties anticipate that vaccine promotion costs will not be incurred. The live sheep market is small, exporters will be informed through LiveCorp, exporters will instruct their buyers (typically stock and station agents) and stock and station agents will simply order the vaccine as part of their regular inventory.
- MLA and LiveCorp will incur costs to inform their constituents about the vaccination program, the reasons it is being implemented and advise where the vaccine may be purchased. This cost will be included as part of these organisations normal contact with constituent groups and no additional cost will be incurred.

4.4 Distribution Cost

- Distribution costs will include delivery costs associated with dispatching product to stock and station agents and distribution of the vaccine by agents.
- Distribution to agents is assumed to occur as part of normal inventory delivery with a corresponding low to zero marginal cost.
- Delivery of vaccine to the farm will be via a simple in car esky to ensure the vaccine remains at a stable temperature.
- No separate cost estimate is made for these items.

4.5 Administration and Vaccination Auditing Costs

- A decision will need to be made by MLA and LiveCorp as to whether these organisations will simply promote the use of the vaccine or initiate a more formal scheme to mandate its use.
- Any mandatory scheme will involve a level of administration, monitoring and auditing.
- Salmonella vaccination could become a requirement of the new AQIS live export standards (a proposed regulatory system to sit over the top of LEAP) and if this is the case there will need to be a set of standards for vaccination and a vaccination audit system.
- The scabby mouth vaccination scheme was run as part of the Saudi Livestock Export Program (SLEP) and its administration was funded with a $0.01 levy on compulsory ear tags.
- A much lower cost of administration and auditing could be incurred with a voluntary scheme that had widespread support from exporters, buyers and producers. Producers could provide a statutory declaration via the National Vendor Declaration Scheme that vaccination had been carried out and spot checks could be done by exporters at feedlot using blood samples. The level of participation in such a voluntary scheme is problematical.
- An ear tag will be a requirement under NLIS[3] and information on salmonella status could be added to an existing tag at low or no marginal cost.
- Auditing would be facilitated by the addition of a dye to the vaccine[4].

[3] NLIS will almost certainly be mandatory by July 2005. Its implementation prior to this date is being encouraged.

[4] The dye would be apparent on the skin of non-pigmented sheep following inoculation. Most sheep in the trade are non-pigmented. The length of the fleece would impact observation of the skin. Most sheep entering the live sheep trade are shorn and this will assist with observation.

4.6 Vaccination Labour

- The cost of vaccination labour will be borne by either the sheep producer (scenario one – farmer vaccination) or the exporter through a licensed vaccinator (scenario two).
- Scenario two costs are drawn from program costs associated with the second scabby mouth vaccination. See Table 4.4 below. A labour cost of $0.65/head accredited vaccinator charge is assumed.
- Zero cost is assumed for vaccination equipment and use of sheep yards on farm.

Table 4.4 Total Cost of Second Scabby Mouth Vaccination

Item	Cost ($/dose)
Vaccine Cost	$0.11
Accredited Vaccinator Charge	$0.65
Ear Tag Cost	$0.11
GST	$0.09
Total	$1.00

Source: Tony Brightling pers comm.

BENEFITS

4.7 Sheep Mortality Avoided, A Vaccination Benefit

- The simplest calculation of the sheep mortality avoided would be to assume all sheep exported live are vaccinated. With this assumption the benefit from vaccination is calculated on the following basis:
    - Feedlot spikes: vaccination will arrest salmonellosis spikes in 20% of feedlot consignments where it will result in an annual reduction in mortality of 3,600 head (4.5 million sheep X 20% of feedlot consignments X 1% loss X 40% reduction due to vaccination).
    - Feedlot background levels: vaccination will reduce salmonellosis in the 80% of feedlot consignments where 6 to 7 deaths per 10,000 sheep are attributable to salmonella. This reduction will amount to 965 head (4.5 million sheep X 80% of feedlot consignments X 0.06% loss X 40% reduction due to vaccination).
    - Shipboard loss: vaccination will reduce losses due to salmonellosis on board ship by 4,860 head (4.5 million sheep X total losses of 1% X 0.27% attributable to salmonella X 40% reduction due to vaccination).
    - The total value of mortality avoided is therefore 4,565 sheep saved pre loading at an FOB value of $70/head plus 4,860 sheep saved on route with a CIF value of $105/head. This total 'mortality avoided' benefit amounts to $830,000 per annum.
- Alternatively if vaccination is confined to sheep exported from east coast ports, mortality avoided will relate to a population of 1.5 million sheep and the resultant benefit will be:
    - Feedlot spikes: 1,200 head (1.5 million sheep X 20% of feedlot consignments X 1% loss X 40% reduction due to vaccination).
    - Feedlot background levels: 322 head (1.5 million sheep X total losses of 80% feedlot consignments X 0.06% loss X 40% reduction due to vaccination).
    - Shipboard loss: 1,620 head (1.5 million sheep X total losses of 1% X 0.27% attributable to salmonella X 40% reduction due to vaccination).
    - The total value of mortality avoided is therefore 1,522 sheep saved pre loading at an FOB value of $70/head plus 1,620 sheep saved on route with a CIF value of $105/head. This total 'mortality avoided' benefit amounts to $277,000 per annum. Some data

suggests the on route losses from eastern ports are higher than the industry average. If the losses are double the industry average, and the reduction attributable to vaccination commensurately higher, then the 'mortality avoided' benefit increases to $447,000.

- No value is assumed for salvage of sheep killed by salmonellosis.

4.8 Feedlot Culling Avoided, A Vaccination Benefit

- In addition to losses associated with mortality AQIS require that sheep held in the feedlot paddock where a salmonella outbreak occurs be culled (or pulled) as a preventative measure and the paddock quarantined for a period of four weeks.
- Current AQIS requirements are that once 30 cases of salmonella are observed in any one 1,200 head feedlot paddock, the whole paddock must be 'pulled' from the trade. Sheep are sold to an abattoir at a salvage price of $20/head (rather than their $70/head value FOB).
- Advice from David Peddie Cape Nelson Feedlot Portland (pers comm. 2004) is that salmonella cases typically trigger this threshold twice per year. At the same time he notes that Cape Nelson has not had a trigger event for two years.
- Quantification of the benefit of avoided sheep losses was completed assuming vaccination averted one of two events per annum at each of four east coast feedlots where 1,200 sheep are culled incurring an economic loss of $50/head. The total loss avoided is $240,000.

4.9 Animal Welfare Benefits

- The welfare of sheep exported live will be improved through salmonella vaccination, not just through fewer deaths but also through reduced illness and a reduction in stress in surviving animals.
- These animal welfare benefits associated with vaccination are qualitative and in addition to financial benefits from the reduction in sheep mortality and morbidity. Although of real value, it is difficult to place a dollar value on this benefit and this has not been attempted in the analysis.

4.10 Reduction in Political Pressures

- Salmonella outbreaks in feedlots and onboard ship can occur in 'spikes' (see Chapter 3). A key benefit to industry from vaccination will be a reduction in the incidence and severity of these 'spikes' with a corresponding reduction in notifiable events. (A notifiable event is triggered when sheep voyage mortality is greater than 2%)
- Notifiable events generate public criticism of the trade and, potentially, a government policy response that either increases the cost structure of the exporter or, at the extreme, closes the trade completely.
- Industry costs in responding to these pressures are substantial. Personnel can be preoccupied for many weeks after an incident, dealing with the media, animal welfare organisations and government agencies. Indirect costs also of concern include a perception of higher risk and this translates into costs such as industry financing.
- These avoided costs are identified and noted but not quantified in this analysis

4.11 Marine Insurance Savings

- Marine insurance costs are linked to losses associated with the voyage. Marine insurance currently costs 0.5% of consignment value. At least in principle, an argument could be advanced that fewer deaths and less political pressure should result in lower insurance costs. The benefit is noted but not quantified.

4.12 Additional Load Sizes and Improved Feedlot Utilisation

- Additional load sizes at Portland – exporters were previously able to load 50,000 head per feedlot but AQIS have restricted this to 20,000 head per feedlot, the limitation of each feedlot's roofed area between July and October. . If vaccination were to result in the removal of this restriction the benefit of once again being able to load larger shipments would be transport cost savings associated with fuller ships. This potential benefit has been considered but is not included in the analysis.
- Salmonella spikes result in the quarantining of feedlot paddocks for four-week periods after stock have been removed. When the trade is buoyant, loss of feedlot capacity can constrain feedlot operation. Once again, this potential benefit of vaccination is considered but not included in the analysis.

4.13 Market Alternatives for Producers

- Benefits to producers are the maintenance of alternative market options, more stable, and possibly, higher prices for their sheep. Long term analysis of producer returns 'with' and 'without' the operation of live export buyers shows returns are higher and more stable when live exporters are present in the market place.

4.14 Environmental Benefits

- Environmental costs are incurred from disposal of carcases at both the feedlot and at sea. Sheep lost to salmonella must be disposed of to either landfill or in the ocean. While every endeavour is made by the industry to minimise any environmental costs of disposal, a reduction in sheep mortality is a positive for both terrestrial and marine environments.

4.15 Domestic Sheep and Lamb Feedlotting

- Salmonellosis is associated with intensification of animal production systems. In addition to the live export trade, sheep are intensively managed in feedlots during drought and for premium wool and lamb production. A registered salmonella vaccine will be of benefit to these sectors. Potentially, there are one million head in the lamb feedlotting industry that may benefit from availability of this vaccine.

4.16 Benefit Cost Analysis and Conclusions

The cost benefit analysis of registering the aro attenuated salmonella vaccine for the live sheep trade is completed using the following data. All costs are net of GST.

Costs

- Vaccine registration cost of $460,000 is recovered over a 5-year period, an annual cost of $92,000.
- 1.5 million sheep are vaccinated at a cost of $0.10/dose, an annual cost of $150,000.
- Administration and auditing cost is $0.01/head, or $15,000 per annum.
- Vaccination labour under scenario one – sheep producer vaccination is zero and under scenario two – licensed vaccinator, is $0.65/head or $975,000 per annum.

Benefits

- Mortality savings of 3,142 head valued at $277,000 per annum (NB: some data suggests that on route losses from eastern ports are higher than the industry average, if the losses are double the industry average, then mortality savings increase to $447,000)
- Cull savings valued at $240,000 per annum

Results

Table 4.5 Industry Returns from Vaccine Registration – Scenario One

Annual Costs		Annual Benefits	
Vaccine Registration	92,000	Mortality Savings	276,640
Vaccine cost	150,000	Cull Savings	240,000
Admin and Auditing	15,000		
Labour	0		
Total	257,000	Total	516,640
Per head	$0.17	Per head	$0.34

Table 4.6 Industry Returns from Vaccine Registration – Scenario Two

Annual Costs		Annual Benefits	
Vaccine Registration	92,000	Mortality Savings	276,640
Vaccine cost	150,000	Cull Savings	240,000
Admin and Auditing	15,000		
Labour	975,000		
Total	1,232,000	Total	516,640
Per head	$0.82	Per head	$0.34

- The net present value (NPV) for scenario one is $15,500 (6% real interest rate and 10 year analysis period). The NPV for scenario two is strongly negative.

Cost Benefit Analysis Comments and Conclusions

- A positive return from vaccination is possible if sheep producers provide vaccination labour at no cost. Producers were willing to meet the cost of the first scabby mouth vaccination under the two dose Saudi Livestock Export Program but this did not require an additional labour operation and vaccination was mandatory.
- If licensed vaccination labour is required or sheep producers seek to recover the cost of their labour at a commercial rate, vaccination costs will exceed vaccination benefits (Table 4.6 – scenario two).
- Administration and auditing costs of $15,000 per annum appear to be low. Costs of this level may be consistent only with a voluntary scheme.
- It is possible that the vaccine will be less effective when administered by the sheep producer and the reduction in mortality less than 40%. Sensitivity analysis shows, that vaccine efficacy would need to fall to 20% and reduction in cull events during salmonella 'spikes' in eastern state feedlots fall from four to two events prevented before vaccine registration costs equal vaccine registration benefits in scenario one (farmer vaccination).
- Vaccine benefits associated with avoided mortality have been conservatively estimated at $277,000 per annum. Some data suggests the on route losses from eastern ports are higher than the industry average. If the losses are double the industry average, and the reduction attributable to vaccination commensurately higher, then the 'mortality avoided' benefit increases to $447,000. This data further strengthens the case for vaccination registration in scenario one (farmer vaccination). Net per head benefit increases from $0.17 ($0.34 less $0.17) to $0.29 ($0.46 less $0.17). It is insufficient to justify vaccine registration in scenario two.
- The cost benefit analysis has been completed on the basis of a dose cost of $0.10/head. If dose cost was $0.05/head then net benefit in scenario one would increase from $0.17 ($0.34 less $0.17) to $0.22 ($0.34 less $0.12). It is insufficient to justify vaccine registration in scenario two.
- If MLA/LiveCorp funds vaccine registration and the vaccine producer charges only the direct costs of production and marketing (with a modest margin), then reasonable returns will be available to exporters from its use.
- Benefits to producers from vaccine use will only come from the opportunity to sell their sheep in the event that exporters uniformly require it or its use is mandated. Potentially there are costs for vaccine labour.
- The analysis confirms Bioproperties proposition that their revenue from vaccine sales ($150,000 gross per annum or $30,000 per annum net assuming a 20% margin) will be modest and insufficient to justify registration costs. If Bioproperties were to fund 100% of the $460,000 in registration costs their return on capital would be negative (minus 11%). If Bioproperties were to fund 50% of registration costs their return on capital would be 1%. If Bioproperties were to fund 25% of registration costs their return on capital would be 16%.

5. COMMERCIAL CONSIDERATIONS

5.1 Vaccine Registration SWOT Analysis

A 'strengths, weaknesses, opportunities and threats' analysis is provided in Table 5.1 for the scenario in which industry funds the costs of registration in return for an agreement with Bioproperties to produce and market the vaccine at a concessional price.

Table 5.1 Vaccine Registration SWOT Analysis

Strengths	**Weaknesses**
▪ Favourable cost sharing – registration costs will be met as R&D and therefore split ¼ producer, ¼ exporter and ½ government ▪ 'Cheap insurance' – provided it is widely used the vaccine is a low cost means of avoiding mortality spikes, additional poor publicity and adverse regulatory responses	▪ Vaccine efficacy data is not yet available ▪ The economics of its use depends on low or no costs for vaccination labour ▪ Much is not known about the causes and risks of salmonella – a lower cost strategic vaccination regime, as apposed to blanket east coast vaccination, may prove to be appropriate ▪ Returns, even assuming no cost for vaccination labour are modest and widespread (even significant) usage may require a mandatory industry scheme ▪ Sourcing of sheep from eastern ports may decline in medium/long term
Opportunities	**Threats**
▪ Opportunity to demonstrate industry animal welfare credentials through a proactive initiative ▪ Opportunity to head off higher cost policy interventions such as compulsory feedlot shedding ▪ Opportunity to make a case for larger load sizes and lower insurance premiums	▪ A superior or lower cost product is identified after industry is locked into a long term agreement with Bioproperties ▪ AQIS impose vaccination in association with a high cost labour and admin regime ▪ Portland is closed

- Returns, even assuming no cost for vaccination labour, are modest. This has an advantage in that there is a strong incentive for the manufacturer to keep the vaccine price at a low level. Risks and threats are associated with vaccine efficacy, the agreement with Bioproperties and changes in the operating environment at Portland and Adelaide.

5.2 Bioproperties as a Commercial Partner

Company Profile

- Established 1989 by David Tinworth and James Judd, privately held small to medium sized enterprise.
- 30 full time equivalent employees and turnover in excess of $10 million.
- Claim to be profitable, financially conservative and have minimal borrowings.
- Offices in Melbourne and a Sydney based vaccine manufacturing plant
- Joint R&D projects with RMIT
- Claimed strategic niche is 'novel live vaccines for the intensively farmed food animal industry'
- Seven vaccines registered for the Australian market and a further two on the cusp of registration
- Currently in discussions with NSW Government in relation to development of an alternative Ovine Johnes vaccine
- Currently working towards registration of aro attenuated salmonella vaccine for use in Australian cattle industry
- Domestically, Bioproperties manufactures in Australia and sells direct
- Internationally, Bioproperties has established distribution channels via major pharmaceutical companies
- 50% of the company's revenue is earned through exports

Table 5.2 Bioproperties as a Commercial Partner

Strengths	**Weaknesses**
▪ Proven capacity to supply an effective live salmonellosis vaccine to the intensive animal industry in Australia ▪ Specialist in live vaccines ▪ Shown some empathy with sheep industry need for the vaccine despite modest returns for Bioproperties	▪ Relatively small operation without the financial 'reach' of a major international pharmaceutical company ▪ Are the only known source of the vaccine i.e. are in a strong negotiating position

On balance Bioproperties appears to be a reputable commercial partner capable of negotiating a reasonable deal with industry, but more systematic 'due diligence' will need to be undertaken if a contractual relationship extending over a number of years is to be negotiated.

5.3 Options for a Commercial Agreement with Bioproperties

Six alternative models for a commercial agreement are suggested. Features of each of these models are presented in the table below.

Table 5.1 Commercialisation Models

Model	Features of the model
Do Nothing	• Continue to minimise salmonella losses through improvements in animal husbandry
Bioproperties fund the full cost of vaccine registration	• Bioproperties position is that registration for use in sheep is not a financially attractive proposition, and the calculations of this study tend to support this position This conclusion ignores any benefit Bioproperties will realise from use of sheep registration data for cattle registration.
Industry funds registration costs	• MLA/LiveCorp fund registration • Bioproperties charges price to cover only production and marketing costs for agreed period • This price is between $0.05 and $0.10/dose
Industry seeks recovery of its investment in registration costs	• MLA funds registration and seeks a charge from manufacturer to recuperate registration costs when sales exceed an agreed threshold • Bioproperties unfettered in pricing but constrained by limited demand if use not mandatory
R&D Committee Proposal	• Bioproperties and MLA go halves in registration cost • Pricing policy complex
Vaccine is used 'off-label'	• An alternative is not to register the vaccine for sheep but to use it legally 'off-label'. • This involves veterinary prescription and sourcing vaccine registered for cattle at $1 dose (NB: poultry vaccine is $0.02 dose)

5.4 Features of a Preferred Commercial Agreement

If Bioproperties persists with its position that production and marketing of the vaccine will only be undertaken if industry funds the trials/tests required to achieve registration then industry, represented by MLA/LiveCorp, will need to negotiate a formal agreement that has the following features:

- Clauses that specify an agreed starting price for the vaccine and circumscribe and clearly define the conditions for any vaccine price rise for a period of, say, 5 or 10 years

5.5 Opportunities to Fast Track Commercialisation

- Typically registration takes between twelve and eighteen months with most registrations requiring eighteen months to complete.

- According to Bioproperties, a large-scale field trial is the most obvious method for fast tracking vaccine registration. A permit to conduct a large-scale field trial takes as little as 6 weeks to secure and the first year's vaccination program could be justified as a field trial. APVMA will need to be convinced of the merit of a large-scale field trial and it is essential that field trial data be submitted to APVMA for their review.

- Fast tracking can also be assisted if state government views the application for registration as a priority. If the registration application includes endorsement from each of the Western Australian, Victorian and South Australian as well as the Australian Chief Veterinary Officers, it will receive priority attention from APVMA.

- In addition, state governments can indicate to APVMA that they have a technical reviewer available who will give priority to completing the necessary peer review of trial data. Normally a nine-month period is allowed for the technical reviewer to respond to the application and commonly all of this time elapses before the reviewer responds to APVMA. By lining up a reviewer prior to lodging the registration application six to eight months can be shaved off the registration application period.

6. CONCLUSIONS AND RECOMMENDATIONS

6.1 Gaps in Knowledge

- Better data on salmonella risk factors, losses and vaccine efficacy
- Whether farmers can apply vaccine or licensed vaccinators required
- Whether use of the vaccine will be mandatory or voluntary
- If mandatory, what will be the rules of application

6.2 Preliminary Conclusions

- Benefit cost analysis has shown that the commercial returns to individual exporters are reasonably attractive and the inconvenience/effort to farmers is likely to impede its widespread voluntary use.
- For the non-financial benefits of salmonella vaccination (animal welfare, mitigation of negative political impacts) to be realised, a whole of industry regulatory/QA approach will be required.
- The case for compulsory vaccination of shipments out of WA is not compelling.
- Vaccination of only individual high-risk consignments from the eastern ports cannot yet be incorporated into the relevant live export QA standards because the parameters defining risk are not yet clear.
- A revised LEAP program could include compulsory vaccination for all eastern state feedlots and a large-scale field trial vaccination, as soon as possible, is recommended.

6.3 Recommendations and Next Steps

- That industry considers the desirability/practicality of incorporating Salmonella vaccination (if it were to become available) into LEAP, making vaccination mandatory for all sheep shipped from Portland and Adelaide.
- That representatives of the industry meet with Bioproperties and negotiate a MoU in relation to cost sharing for vaccine registration.
- APVMA be approached regarding requirements for a large-scale field trial.
- Should a decision be made to proceed with registration, that the various departments of agriculture be enlisted to support the application to ensure its fast tracking.

7. PERSONS CONTACTED

Peter Stinson LiveCorp
Jane Cleeve LiveCorp
David Tinworth, Bioproperties
Keith Walker EMI NSW Agriculture
Tony Brightling (practical knowledge)
David Peddie (Cape Nelson Feedlot Portland)
Bruce Christie, Chief Veterinarian NSW Agriculture
Richard Norris, WA Department of Agriculture
Ian Ross, MLA

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APPENDIX 1 ESTIMATE OF IN-KIND BY BIOPROPERTIES

The following estimate of in-kind contribution was prepared by Peter Claxton and David Tinworth of Bioproperties.

Cost Item	Justification	Cost ($'000)
Registration documentation	This is a new presentation and will require a full dossier	30 to 50
Manufacturing documentation	A different manufacturing protocol is required for the injectable FD product	30 to 50
Stability studies	This is a different presentation to the poultry vaccine	25 to 35
Quality control documentation	Evaluation of endotoxin is a major issue – not significant with poultry product	50 to 75
Production of three trial batches	High cost per dose of pilot batches because of smaller batch size	150
Review of trial protocols/reports	To ensure stability for product registration dossier	20 to 30
Trial monitoring	To ensure compliance with protocols and cGCP	20 to 30
Other regulatory input	Meetings with MLA, APVMA, sheep exporters and others	30 to 50
	Total	**355 to 470**