

From: s.22(1)(a)(ii), s.47F(1)  
Sent: Tuesday, 26 July 2011 1:35 PM  
To: s.22(1)(a)(ii), s.47F(1)  
Cc:  
Subject: s.22(1)(a)(ii), s.47G(1) 4492 [SEC=UNCLASSIFIED]  
Attachments: Direction Letter - LSS.pdf

Dear Sir,

Please see the attached letter.

Please give me a call if you require any clarification.

Yours sincerely,

s.22(1)(a)(ii), s.47F(1)

**BVSc(Hons) MVS (Veterinary Surveillance)**

Live Animal Exports Program

Animal Division

Department of Agriculture, Fisheries and Forestry

s.22(1)(a)(ii), s.47F(1)

Fax: (02) 6272 5423

*Other related documents*



document 12  
Australian Government  
Australian Quarantine and Inspection Service

Sent by mail and e-mail  
26/07/2011 by

s.22(1)(a)(ii),  
s.47F(1)

s.22(1)(a)(ii), s.47F(1)

Livestock Shipping Services Pty Ltd  
PO Box 1441  
South Perth WA 6151

Dear s.22(1)(a)(ii), s.47F(1)

As the holder of a livestock export licence under the *Australian Meat and Live-stock Industry Act 1997* (AMLI Act), your company is required to comply with all the conditions of that licence.

One condition is that your company is required to comply with the *Australian Standards for the Export of Livestock* (version 2.3 April 2011) (**the Standards**). Section 5.11 of the Standards states that:

*If a notifiable incident occurs at any time, the relevant Australian Government agency must be advised as soon as possible and within 12 hours. In relation to a notifiable incident involving a mortality equal to, or greater than the reportable level, a report must be provided that includes the following:*

- (a) details of the mortalities (e.g. number, species, suspected causes)
- (b) factors that may have contributed to the deaths
- (c) the current location of the vessel and, if appropriate, its destination and estimated time of arrival.

A reportable level of mortality for a consignment of cattle on a long haul voyage (greater than or equal to 10 days) is one (1) per cent.

The details of LNC 4492 exported by Livestock Shipping Services Pty Ltd on 15 June 2011 are:

1. A consignment of 5022 cattle was exported from the port of Portland on 15 June 2011.
2. On 14 July, s.22(1)(a)(ii), s.47F(1) Livestock Shipping Services Pty Ltd, notified Animal Export Operations, Department of Agriculture, Fisheries and Forestry (DAFF) that mortality in the cattle exceeded the reportable level of one (1) per cent.
3. A master's report and veterinarian's end of voyage report are yet to be received by DAFF.

AQIS investigates any incident with a mortality level higher than the reportable level in the Standards.

Pursuant to section 17(1)(b) of the AMLI Act, Livestock Shipping Services Pty Ltd is directed to assist AQIS in conducting its investigation by 12 August 2011, by providing:

1. An end of voyage report from the on board veterinarian, as required under Section 5.12 of the Standards, including detailed information on the following:
  - a. the causes and locations of the mortalities
  - b. description of any clinical signs noted in the livestock
  - c. details of treatments given to cattle in the consignment including location of animals treated and response to treatments given

- d. details of the daily weather conditions during the voyage
  - e. details of dates and number of cattle unloaded at each port
  - f. any other relevant information.
2. The property of origin documentation for all the livestock in the consignment with LNC 4492.
  3. Registered premises documentation confirming date of entry, daily health records and daily mortality records.
  4. AQIS accredited veterinarian documentation.
  5. Documents confirming the weights of the livestock exported.
  6. The breakdown of the location of the different classes of livestock loaded on each deck including number and type.
  7. The final heat stress risk assessment for the [REDACTED] s.22(1)(a)(ii), s.47G(1)(a)
  8. Details of the feed loaded and the ration provided to cattle.
  9. Details of the watering system and water provided to cattle during the voyage.
  10. The actions your company has undertaken to investigate this incident.
  11. Your company's assessment of the cause of the mortalities with reference to the type (breed, sex, weight, age) of the animals that died.
  12. Your company's assessment of the vessel's performance, and whether any vessel factors may have contributed to the mortalities.
  13. Your company's explanation of why:
    - a. the voyage length was considerably longer than the length identified in the NOI (26 days)
    - b. the port of discharge, Port Bandirim, was changed without notifying DAFF.
  14. What procedures your company has put in place to reduce the likelihood of such an incident recurring.

I would like you to be aware that DAFF may consider, on a case by case basis, applying conditions to future consignments of cattle exported by Livestock Shipping Services Pty Ltd, at a minimum until the investigation is finalised and contributing causes are identified.

I request that you provide the documentation outlined above by 16 August 2011. I expect the report to be finalised two months after all the information has been supplied. Please contact [REDACTED] s.22(1)(a)(ii), s.47F(1) if you require further information or clarification. Please provide the report by fax to (02 6272 5423 or email [REDACTED] s.22(1)(a)(ii), s.47F(1)

Yours sincerely

[REDACTED] s.22(1)(a)(ii), s.47F(1)

Delegate to the Secretary  
General Manager (A/g)  
Animal Export Operations

26 July 2011

From: s.22(1)(a)(ii), s.47F(1)  
Sent: Monday, 26 September 2011 3:57 PM  
To: s.22(1)(a)(ii), s.47F(1)  
Subject: s.22(1)(a)(ii), s.47G(1)(a) [SEC=UNCLASSIFIED]

It is in closed

sent via BlackBerry® from Telstra

From: s.22(1)(a)(ii), s.47F(1)  
Date: Mon, 26 Sep 2011 13:50:06 +0800  
To: s.22(1)(a)(ii), s.47F(1)  
Subject: s.22(1)(a)(ii), [SEC=UNCLASSIFIED]  
s.47G(1)(a)  
Dear s.22(1)(a)(ii), s.47F(1)

I have started writing the report for the s.22(1)(a)(ii), s.47G(1)(a) based on the info that you have provided.

The part of report looks at the deck temperatures as were reported on the daily reports.

The daily reports listed Portland cattle as being on decks 3, 4, 5 and 6.

Could you please advise which of these decks are open and which are enclosed.

Please assume that deck 3 is lower in the vessel than 4, 5 and 6 as per all other vessels I have travelled on, if not, please let me know.

Give me a call if it is easier,

s. 22(1)(a)(ii), s. 47F(1)

s.22(1)(a)(ii), s.47F(1)

(WSP/IONS) MVS (veterinary surveillance)

Live Animal Exports Program  
Animal Division  
Department of Agriculture, Fisheries and Forestry  
s.22(1)(a)(ii), s.47F(1)

fax: (02) 6272 5423

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### Daily rainfall

Observations of Daily rainfall are nominally made at 9 am local clock time and record the total for the previous 24 hours. Rainfall includes all forms of precipitation that reach the ground, such as rain, drizzle, hail and snow. [About rainfall data](#)

Station: Woolsthorpe Number: 90084 Opened: 1884 Now: Open  
Lat: 38.18° S Lon: 142.47° E Elevation: 85 m

Key: Units = mm 12.3 = Not quality controlled. ↓ = Part of accumulated total

2011	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1st	0	0	2.4	0	8.0	0						
2nd	0	0	0	0	1.6	0						
3rd	0	0	0	0	5.4	0						
4th	0	0	0.6	0	0.4	0						
5th	0	6.2	0	2.8	1.4	0						
6th	0	0	0	0	0	7.2						
7th	0	0	0	0	0	4.2						
8th	1.2	0.4	0.4	0	0	4.4						
9th	0	0	20.2	0	2.2	1.4						
10th	1.0	0	10.6	0	0.3	1.6						
11th	7.8	3.0	0.4	71.8	12.2	0.4						
12th	53.8	0	0	2.2	10.2	0.8						
13th	0	1.3	0	2.4	9.2	0						
14th	32.4	0	0	2.6	0	0						
15th	0	0	0	0	0	0						
16th	0	0	0	0	2.6	0						
17th	0.4	30.4	0	0	0	8.8						
18th	1.2	0.6	0	1.2	0	0						
19th	0	3.3	0	0	0	0						
20th	0	2.0	0	11.4	0	7.0						
21st	0	0	0	0	0	26.8						
22nd	0	0	31.2	0	0	7.6						
23rd	0	0	0.4	4.4	7.2	4.6						
24th	0.6	0	10.0	0	4.0	1.2						
25th	0	0	4.8	0.6	1.0	0						
26th	4.8	2.2	0	0	0.4	0						
27th	0	0	0	0.6	0	0.6						
28th	0	0	0	0	0	0						
29th	0	0	0	0	3.4	0.4						
30th	0	0	0	0	0	0						
31st	0	0	0	0	0.2	0						
Highest Daily	53.8	30.4	31.2	71.8	12.2	26.8						
Monthly Total	103.2	49.4	81.0	100.0	69.7	77.0						

s.22(1)(a)(ii)

RP

8 / 16 days rain

### Summary statistics for all years

Statistic	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Mean	36.9	33.7	45.8	58.6	69.2	72.8	78.0	84.5	74.3	66.9	54.3	47.4
Median	28.5	24.0	37.5	55.0	64.4	69.4	73.2	81.7	70.1	63.2	50.8	44.0
Highest Daily	87.1 25th 1952	53.1 7th 1957	128.0 17th 1946	75.0 6th 1992	53.5 3rd 1983	42.0 25th 1990	47.8 8th 2008	42.7 29th 1893	49.0 2nd 1908	51.1 6th 1894	52.1 27th 1908	60.8 13th 2008

Product Code: IDCJAC0009 reference: 04932879

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#### LIABILITY

While every effort is made to supply the best data available this may not be possible in all cases. We do not give any warranty, nor accept any liability in relation to the information given, except that liability (if any), that is required by law.

### Daily rainfall

Observations of Daily rainfall are nominally made at 9 am local clock time and record the total for the previous 24 hours. Rainfall includes all forms of precipitation that reach the ground, such as rain, drizzle, hail and snow. [About rainfall data](#)

Station: Portland (Cashmore Airport) Number: 90171 Opened: 1982 Now: Open  
Lat: 38.31° S Lon: 141.47° E Elevation: 81 m

Key: Units = mm 12.3 = Not quality controlled. ↓ = Part of accumulated total

2011	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1st	0	0	0.8	0	18.2	0.6	0	0				
2nd	0	0	0	0.6	0.2	0.2	0	0.6				
3rd	0	0	1.0	0	0	0.4	21.6					
4th	0	0.2	0	1.2	1.4	9.6	5.8					
5th	0	0	0	0	1.8	0.2	15.0					
6th	0	0	0	0.4	0	16.0	8.8					
7th	0	0	0	0	0	6.0	9.0					
8th	0	0	0	0	4.4	4.0	0					
9th	3.8		3.4	0.4	0.8	2.6	1.2					
10th	0	0	0	7.6	0.4	2.4	0.8					
11th	0.8	4.6	0	15.0	9.8	0.4	2.4					
12th	63.0	2.2	0.4	14.8	5.2	1.0	0.4					
13th	0.4	0.2	0.2	2.8	2.8	0.4	3.0					
14th	72.0	0	0	2.6	1.8	1.2	0.4					
15th	0	0.2	0	0.2	0.8	0.4	0.2					
16th	0	0	0.8	0.4	0.6	0	0					
17th	0.2	0	0.4	0	0	5.8	0					
18th	0.2	7.8	0	0.2	0	2.8	17.4					
19th	0.2	38.4	0	0.4	0	1.0	4.2					
20th	0	2.2	0.2	5.6	0	6.6	0.4					
21st	0	0.6	19.4	1.6	0	28.8	0					
22nd	0	0.2	5.4	3.0	0.8	4.2	2.2					
23rd	0	0	1.6	0.4	14.0	3.2	0.4					
24th	2.4	0	9.0	1.8	10.6	2.2	17.0					
25th	0	0	1.8	0.2	1.6	2.4	0					
26th	6.4	0	0.2	0.2	2.8	0	3.0					
27th	0.2	0.4	0.2	0.2	4.2	0.6	0.4					
28th	0	0.2	0	0.4	7.8	1.0	0					
29th	0		0.4	0	1.6	0.2	0					
30th	0		1.8	1.4	0	0	0.2					
31st	0		0		0		0.2					
Highest Daily	72.0	38.4	19.4	15.0	18.2	28.8	21.6	0.6				
Monthly Total	149.6	57.2	47.0	61.4	91.6	104.2	114.0					

Annual total to Jul this year = 625.0 mm

### Summary statistics for all years

Statistic	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Mean	37.7	27.3	45.3	58.5	76.8	106.5	107.4	105.1	88.1	60.7	53.4	52.1
Median	33.6	22.0	38.8	57.0	67.0	105.1	107.3	99.0	82.8	55.8	45.2	42.8
Highest Daily	72.0	45.4	77.2	50.0	59.4	34.6	36.8	39.0	37.0	43.0	68.6	61.0
	14th	21st	22nd	6th	27th	6th	8th	26th	19th	9th	26th	13th
	2011	2003	1983	1992	2000	2003	1993	2001	1993	1992	2002	2005

Product Code: IDCJAC0009 reference: 04932873

### COPYRIGHT

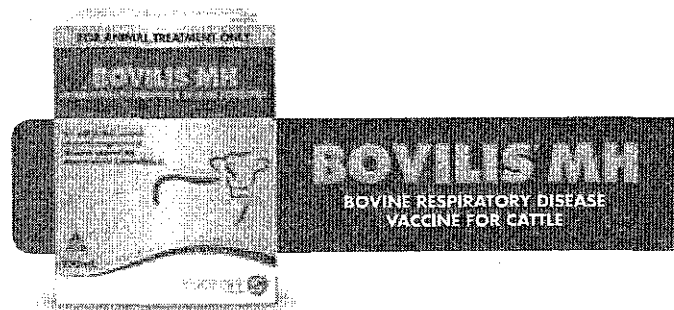
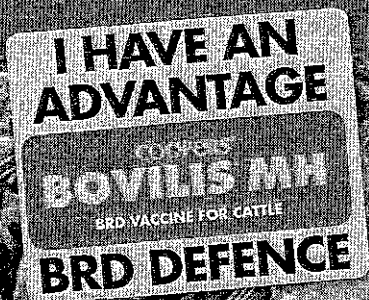
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### LIABILITY

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## SHOW THE BOVILIS MH ADVANTAGE FOR ALL TO SEE.

- Vaccinate your cattle and display the Bovilis MH advantage to feedlot buyers or agents.
- It's a chance to differentiate your cattle and increase demand.
- Talk to Coopers about branding your advantage at sale time.
- Talk to your livestock agent, vet or rural reseller about BRD and feedlot preference for vaccinated cattle.



### PACK SIZES AVAILABLE:

100 mL (50 dose) and 250 mL (125 dose)

### INDICATIONS:

Bovilis MH is used as an aid in the control of respiratory disease caused by the organism *Mannheimia haemolytica*.

### DOSAGE AND ADMINISTRATION:

2 mL subcutaneous injection. The recommended site of injection is that used for routine injection in cattle, i.e., under the skin on the side of the neck. Vaccinate cattle twice, approximately 3-4 weeks apart.

### WITHHOLDING PERIOD: NIL

### STORAGE:

Store between 2°C and 8°C (Refrigerate, DO NOT FREEZE). Discard if previously frozen.

For further information call Coopers Animal Health toll free 1800 226 511.

50912

\* registered trademark  
1. Controlling Bovine Respiratory Disease  
in feedlot cattle, MLA F106

# If you sell cattle to feedlots you MUST read this.

[www.bovilismh.com.au](http://www.bovilismh.com.au)

COOPERS<sup>®</sup>  
EST. 1843





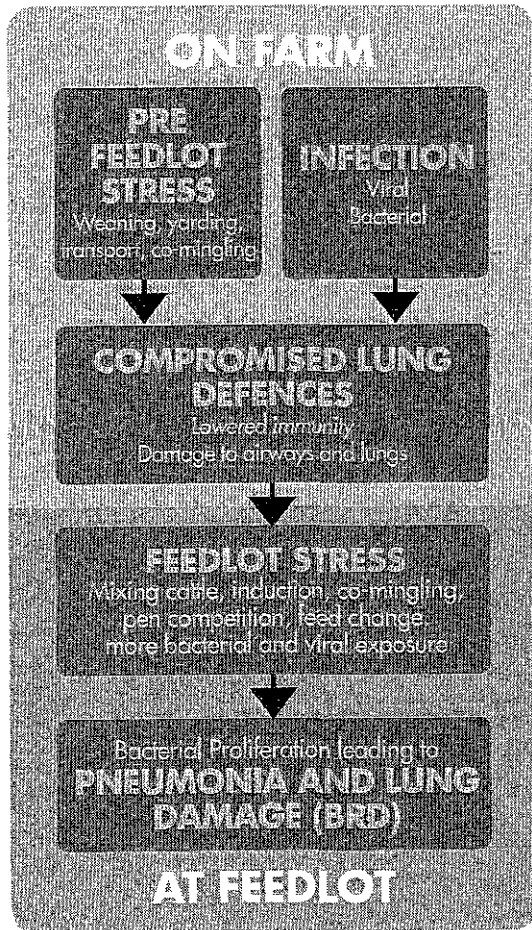
## BOVINE RESPIRATORY DISEASE (BRD)

Bovine Respiratory Disease (BRD) is the single most costly disease affecting feedlot cattle. In fact, it causes 50-90% of illness and death in Australian feedlots.

BRD is a complex disease involving many contributing factors, and usually occurs within four weeks of induction to the feedlot.

The bacteria *Mannheimia haemolytica* (MH) is a major cause of BRD in Australia.

Although BRD is mainly a disease of feedlot cattle, it's the management of these cattle in the months prior to arrival at the feedlot that is vital in protecting against *Mannheimia haemolytica* infection and BRD:



## VACCINATING AGAINST BRD

Bovilis MH requires a two dose vaccination program to achieve optimum protection from BRD and can be incorporated into other management programs:

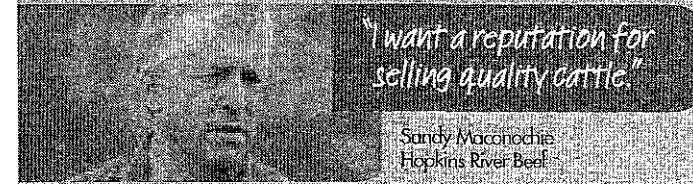
ON FARM BOVILIS MH VACCINATION PROGRAMS			
	1ST DOSE	2ND DOSE	
Weaner Program	4 weeks before weaning	At weaning	Re-vaccination required after 12 months if not sold prior
Calf Program	At marking	4 weeks post-marking	
Feeder Cattle Program	3-4 weeks prior to sale	At Feedlot induction	

By incorporating Bovilis MH into your cattle management program you can improve protection against BRD and gain the flexibility to market your cattle to feedlots to take advantage of favourable market conditions.

Feedlots prefer cattle that have been treated with Bovilis MH because they perform better. Whether you sell through saleyards or direct on farm, you can build a reputation for cattle that perform.



## CATTLE PRODUCERS THAT ARE ALREADY ON THE FRONT FOOT.



"Using Bovilis MH has certainly been better for our business in the long run. I've seen the benefits of using Bovilis MH at backgrounding. It's not just profitable, it has helped build a reputation."



"We see ourselves as backgrounders who try to differentiate ourselves from others. I'd say to other backgrounders that vaccinating with Bovilis MH is of a huge benefit. It's an opportunity to differentiate ourselves in the market. It's about creating the right product for our customers - the feedlots."

## FEEDLOTS THAT KNOW EXACTLY WHAT THEY WANT.



"Given the choice, we always prefer to buy and induct cattle treated with Bovilis MH. We always differentiate between treated and untreated cattle, and have to say, treated cattle get home first."



"We aim to build and maintain relationships with cattle producers. I encourage all cattle producers to use Bovilis MH, because as a feedlot manager, treated cattle are top of my list to buy."



"We want to differentiate our cattle over others."

"I want to buy cattle I know will perform"



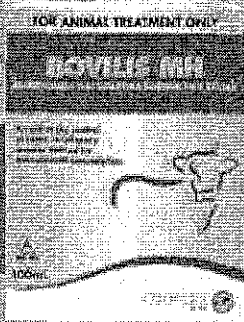
Sandy Macarochie  
Hopkins River Beef



Grant Carey  
General Manager - Livestock  
Cargill Beef Australia

They both want a healthy return on investment.

Give your cattle the advantage at sale time.



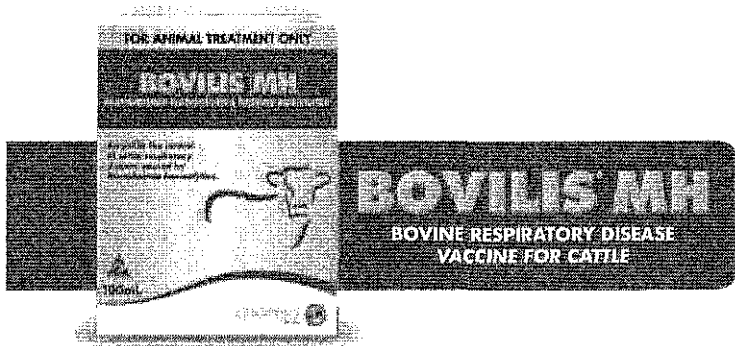
**BOVILIS MH**  
BOVINE RESPIRATORY DISEASE  
VACCINE FOR CATTLE

Bovilis MH vaccine minimises the costly effects of Bovine Respiratory Disease (BRD). Whether you sell through saleyards or direct on farm, you can give your cattle an advantage at sale time by vaccinating with Bovilis MH. Feedlots prefer to buy cattle that will perform, that's why producers who prime their cattle with Bovilis MH will increase market demand for their cattle. For further information call toll free 1800 226 511.

Now available from your local reseller.

® registered trademark

# Give your cattle the advantage at sale time.



## BOVINE RESPIRATORY DISEASE (BRD)

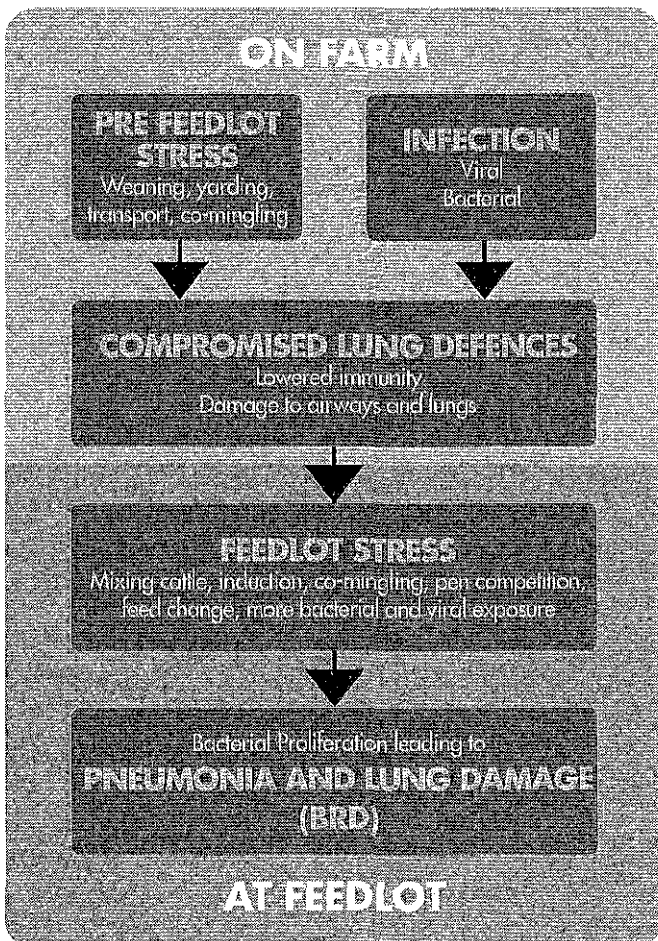
Bovine Respiratory Disease (BRD) is the single most costly disease affecting feedlot cattle.

In fact, it causes 50-90% of illness and death in Australian feedlots<sup>1</sup>.

BRD is a complex disease involving many contributing factors, and usually occurs within four weeks of induction to the feedlot.

The bacteria *Mannheimia haemolytica* (MH) is a major cause of BRD in Australia.

Although BRD is mainly a disease of feedlot cattle, it's the management of these cattle in the months prior to arrival at the feedlot that is vital in protecting against *Mannheimia haemolytica* infection and BRD:



## VACCINATING AGAINST BRD

Bovilis MH requires a two dose vaccination program to achieve optimum protection from BRD and can be incorporated into other management programs:

ON FARM BOVILIS MH VACCINATION PROGRAMS			
	1ST DOSE	2ND DOSE	
Weaner Program	4 weeks before weaning	At weaning	
Calf Program	At marking	4 weeks post-marking	Re-vaccination required after 12 months if not sold prior
Feeder Cattle Program	3-4 weeks prior to sale	At Feedlot Induction	

By incorporating Bovilis MH into your cattle management program you can improve protection against BRD and gain the flexibility to market your cattle to feedlots to take advantage of favourable market conditions.

Feedlots prefer cattle that have been treated with Bovilis MH because they perform better. Whether you sell through saleyards or direct on farm, you can build a reputation for cattle that perform.

## PRODUCT INFORMATION

### PACK SIZES AVAILABLE:

- 100 mL (50 dose)
- 250 mL (125 dose)

### INDICATIONS:

Bovilis MH is used as an aid in the control of Bovine Respiratory Disease caused by the bacteria *Mannheimia haemolytica*.

### DOSAGE AND ADMINISTRATION:

2 mL by subcutaneous injection, two doses to be given 3-4 weeks apart.

### WITHHOLDING PERIOD: NIL

### STORAGE:

Store between 2°C and 8°C (Refrigerate. DO NOT FREEZE).  
Discard if previously frozen.

For further information call Coopers Animal Health toll free 1800 226 511 or visit [www.bovilismh.com.au](http://www.bovilismh.com.au)



<sup>1</sup>Registered trademark. Controlling BRD in feedlot cattle, MLA F106.



## ADVICE SUMMARY

### APPLICATION FOR REGISTRATION OF A CHEMICAL PRODUCT

**Product name:** COOPERS BOVILIS MH & IBR RESPIRATORY DISEASE VACCINE FOR CATTLE  
**Applicant:** INTERVET AUSTRALIA PTY LIMITED  
**Product number:** 64608  
**Application number:** 48763

**Purpose of Application and Description of Use:** Registration of a immunobiological product containing  $1 \times 10^7$  cells/mL inactivated M.haemolytica isolate X387 Leucotoxin producing strain,  $1 \times 10^8$  cells/mL in activated M.haemolytica isolate X332 and  $1 \times 10^7$  TCID<sub>50</sub>/mL inactivated Bovine Herpes virus-type 1 antigen for cattle susceptible to respiratory disease.

**Active Constituent(s):** Mannheimia haemolytica Strain (x387) Leucotoxin producing strain  
Mannhemia haemolytica Strain (x332)  
Bovine herpesvirus-1.

#### Regulatory Decision:

To grant the application subject to the following conditions:

#### Standard Conditions of Registration/Approval

For full conditions, refer to [http://www.apvma.gov.au/advice\\_summaries/adv\\_summaries.shtml](http://www.apvma.gov.au/advice_summaries/adv_summaries.shtml).

#### Non-Standard Conditions of Registration/Approval

Add in full, any additional non-standard conditions that **will** appear on the Notice.

## External Chemistry Reviewer

Intervet Schering Plough has applied to the APVMA to register an inactivated vaccine Coopers Bovilis MH+IBR Respiratory Disease Vaccine for Cattle, containing Mannheimia haemolytica and Bovine Herpesvirus Type 1 (BHV-1) as its active constituents. Mannheimia haemolytica is contained in a currently registered product Coopers Bovilis MH Mannheimia Haemolytica Vaccine for Cattle (APVMA 55767) as its sole active constituent. The second component Bovine Herpesvirus Type 1 (BHV-1) virus is a 'new active constituent' in the sense that there is current no registered product containing inactivated BHV-1. However the APVMA has one product registered containing BHV-1 as live antigen. The proposed label claim for Bovilis MH+IBR is an aid in the control of Bovine Respiratory Disease (BRD) caused by Mannheimia haemolytica and Bovine Herpesvirus Type 1.

The Chemistry and manufacturing data was assessed by an external evaluator. The vaccine is manufactured locally in an APVMA licensed premises.

The vaccine consists of three antigens (active constituents), Mannheimia haemolytica Strain (x387) Leucotoxin producing strain, Mannheimia haemolytica Strain (x332) and Bovine herpesvirus-1. All three antigens were isolated from diseased cattle in Queensland.

The vaccine is to be marketed in PET bottles (100, 250 & 500mL) with siliconised nitrile rubber stopper and lacquered aluminum cap. The specifications of the bottles, rubber stopper the aluminum cap are all compliant with Ph.Eur standard.

Certificate of analysis were provided for all starting materials and were found to be satisfactory. Current AQIS biological import permit was also supplied. Gene technology was not used in the development of the antigens in the applicant formulation.

The MH master seed was identified to species level by the National E.coli reference laboratory. Both seeds were passaged (1-3x) and purified on trypticase soy broth. The seeds were tested for identity, freedom from extraneous agents, purity and viability and stored at -80°C. The working seed organisms (WSO) were thawed and sampled for purity, identity and viability. The WSO were initially inoculated into a broth, then into a growth media in a fermentation vessel. The culture was sampled for purity, leucotoxin (X387), and cell count. The culture was then inactivated with formalin at 0.3% v/v, for 36 hours. The inactivated MH antigen is sampled for inactivation, sterility and formalin, and then stored at 2-8 °C.

The Bovine herpesvirus-1 had one passage and some amplification passages, before the master seed was stored at -80°C. The master seed organism was tested for identity, and freedom from extraneous agents. It tested negative for all other bovine viruses present in Australia. The working seed was tested in accordance with Ph. Eur. for sterility and extraneous agents.

For the production of the Bovine herpesvirus-1, roller bottles were inoculated with MDBK cells and incubated at about 37°C until confluent. Confluent cells were inoculated with Bovine herpesvirus-1 and incubated a further 2 days. The culture was harvested and sampled for sterility, mycoplasma and virus titration. The resulting antigen was stored at -80°C.

The Bovine herpesvirus-1 (BHV1) harvest is inactivated by addition of Binary ethyleneimine (BEI) (10% v/v) at room temperature. The virus and BEI mixture is gently mixed in a vessel. The virus and BEI mixture is then aseptically transferred by means of a pump to a second inactivation vessel. BEI is neutralised with sodium thiosulphate solution. The inactivation kinetics showed that after 24 hours of exposure to BEI the Bovine herpesvirus-1 virus was totally inactivated.

Inactivated MH (X387 and X332) and inactivated Bovine herpesvirus-1 antigens are aseptically mixed with saline, thiomersal and adjuvants, pH is adjusted using NaOH or HCl to produce the final product. Batch release analysis included potency, sterility, safety, formalin, pH, thiomersal, extraneous agents, inactivation and homogeneity tests prior to release. The results were all found to be satisfactory.

The stability data provided for the final product supports a shelf life of 18 months when stored at 2-8°C. No in use stability data was provided, therefore the product must be used within 12 hours after broaching



## Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
46499	S	M McDermott, Elizabeth Hide	Infectious Bovine Rhinotracheitis Inactivation Kinetics Report.	21/10/2010	Chemistry and Manufacture	Active Constituent, Manufacturing/Quality Control	Applicant	
35794	S	Andrew Read & PD Kirkland	Screening for the presence of extraneous viruses in a bovine herpesvirus (BHV-1) vaccine master seed	24/06/08	Chemistry and Manufacture	Active Constituent, Manufacturing/Quality Control	Applicant	
35741	S	Intervet	2% w/v Thiomersal	Aug 09	Chemistry and Manufacture	Active Constituent, Stability	Applicant	
35769	S	Intervet	Procedure for measuring pH	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35770	S	Intervet	Preservative Efficacy	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35766	S	Intervet	Procedure for Formalin Assay	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35765	S	Intervet	Inactivation Test for Bacterial Cultures	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35772	S	Mike McDermott	Bovilis MH + IBR vaccine COA	29/6/09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35764	S	Intervet	Procedure for M.haemolytica Leukotoxin Testing	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35768	S	Intervet	Procedure for Bovine Vaccine Safety Testing	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35763	S	Intervet	Procedure for Viable Plate Counts	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35771	S	Mike McDermott	Bovilis MH + IBR vaccine COA	29/6/09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35767	S	Intervet	Test for Sterility by Method of Direct Inoculation	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35773	S	Mike McDermott	Stability Protocol - Bovilis MH/IBR	12/03/09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35762	S	Intervet	Procedure for Gram Stain	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	
35761	S	Intervet	Procedure for Purity Test	Aug 09	Chemistry and Manufacture	Product, Batch Analysis	Applicant	



Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
35750	S	Intervet	Veggie Medium	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35756	S	Intervet	BEI Solution	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35749	S	Intervet	Acetic acid (0.1M)	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35758	S	Intervet	M.haemolytica B3 (GM) Antigen	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35748	S	Intervet	Roller Bottle Coating Solution	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35760	S	Intervet	IBR Antigen Production	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35743	S	Intervet	0.9% w/v Saline	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35754	S	Intervet	Versene 100x	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35744	S	Intervet	2M Glucose	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35752	S	Intervet	Veggie Protease 100x	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35747	S	Intervet	Sodium Hydroxide (4 Molar)	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35757	S	Intervet	20% Sodium Thiosulphate	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	

Data No	Data Source	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
35746	S	Intervet	Yeast Extract	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35755	S	Intervet	Leupeptin 100x Stock Solution	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35745	S	Intervet	Kanamycin Solution 50 mg/mL	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35759	S	Intervet	Mannheimia haemolytica (X332) Concentrate	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35753	S	Intervet	PBS #1	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35751	S	Intervet	Pluronic F68 10% w/v	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35740	S	Intervet	1.5% w/v Quill-A	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	
35742	S	Intervet	1% Polymixin B	Aug 09	Chemistry and Manufacture	Product, Manufacturing/Quality Control	Applicant	

## External Efficacy Reviewer

An external reviewer evaluated the supporting efficacy and safety data.

An initial study confirmed the efficacy of the challenge model to be used in vaccinated animals as a single dose of 2mL live virus (BHV-1) 6.51 log<sub>10</sub> TCID<sub>50</sub> /mL.

A successful take of challenge strain, allowed clinical and serological parameters to be established. The parameters determined as useful criteria in further trials were virus excretion (nasal and conjunctival), and clinical score. Rectal temperature did not prove effective as predictive of infection in this trial but was deemed a suitable parameter for further trials as it is a non invasive method and may be more useful in larger group sizes.

Dose titration studies were conducted with 5 groups of seven calves between the ages of 6-7 months. The calves were vaccinated twice four weeks apart. The doses of inactivated IBR included in the vaccine were 6.0 log<sub>10</sub> TCID<sub>50</sub> /mL, 7.0 log<sub>10</sub> TCID<sub>50</sub> /mL and 8.0 log<sub>10</sub> TCID<sub>50</sub> /mL. As control a group of animals were vaccinated with a IBR only vaccine and an additional group received a placebo only. The study established the optimal concentration of inactivated IBR virus to be included in combination vaccine for further evaluation as 7.0 log<sub>10</sub> TCID<sub>50</sub> /mL or 8.0 log<sub>10</sub> TCID<sub>50</sub> /mL.

Several challenge studies were carried out by the applicant to support the claim that Bovilis MH+IBR, aids in the control of cattle respiratory disease caused by *Mannheimia haemolytica* and Infectious Bovine Rhinotracheitis. A summary of the studies are given below.

#### **Assessment of the efficacy of a Bovine Herpesvirus 1 (BHV-1) and Mannheimia haemolytica combined vaccine, and a BHV-1 only vaccine**

Three groups of 8 calves were used in this study. Bovilis MH+IBR Vaccinate Group, IBR only Vaccinate Group and Non Vaccinate Group. Vaccinated animals were challenged intra-nasally with 2 ml of wild virus containing approximately 6.5 log<sub>10</sub> TCID<sub>50</sub> /ml.

Clinical scores were collected from 2 days prior to the challenge and then daily for 14 days post challenge. Rectal temperatures were taken at the same time points. The conjunctiva and nostrils were swabbed daily from one day pre-challenge until 14 days post challenge for the determination of virus titres. Blood was collected 7, 14 and 21 days post challenge for determination of antibody titres.

While not statistically significant there were strong trends towards reduced severity and frequency of clinical signs and reduced shedding of live virus from animals vaccinated with IBR containing vaccines.

#### **Assessment of the efficacy of a bovine herpesvirus (BHV-1) and Mannheimia haemolytica combined vaccine, and a BHV-1 only vaccine**

A total of 30 calves were equally allocated to one of two vaccine treatments or the control group. Bovilis MH+IBR and Bovilis IBR each vaccine containing 7.0 log<sub>10</sub> TCID<sub>50</sub>/mL of BHV-1 were given twice 4 weeks apart. The control group of animals were given no vaccine but were kept in the same area as the vaccinates.

Observations of clinical signs and injection sites occurred on the day of vaccination (day 0), four hours later and then daily on days 1, 2, 3, 4, 7, 14, 21, 28 (twice), 29, 30, 31, 32, 35, 42, 47 and days 48 through 61.

Rectal temperatures were determined on the same days as the clinical observations.

Swabs of the conjunctiva and nasal cavities were taken just prior to challenge and daily following challenge until day 14 post challenge.

Blood samples were collected on the day of the first vaccination (day 0), days 28 and 42, the day of challenge and then at days 7, 14, 21 and 28 post challenge.

Vaccinated animals showed reduced clinical signs and reduced virus shedding compared to non-vaccinates. Animals vaccinated with Bovilis IBR had lower average total clinical score than the animals vaccinated with Bovilis MH+IBR or those not vaccinated. The differences between the treatment groups based on clinical score were not significant however it is possible that, with larger numbers of animals in each treatment group, a statistical difference will be evident.

All vaccinated animals showed tissue reactions; however the lesion size was not statistically different between groups. The reactions lasted for approximately three weeks following the first dose of vaccine. Following the second dose of vaccine lesions were still present 14 days later but were reduced in total area

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## Assessment of the efficacy of a bovine herpes virus (BHV-1) and *Mannheimia haemolytica* combined vaccine

A total of 24 animals were used in the trial. Eight were vaccinated with Bovilis MH+IBR. The second group of eight animals received the Bovilis MH the existing *Mannheimia haemolytica* vaccine currently produced by the applicant. The remaining animals received no vaccine. All animals were screened for antibodies against leucotoxin produced by *Mannheimia haemolytica*. Only sero-negative animals were used.

The challenge involved the intra-tracheal injection of 100ml of log phase growth of Benalla strain of *Mannheimia haemolytica*.

Observations of clinical signs, injection sites reaction and collection of blood samples followed the same protocol as the above trial.

Following challenge the animals were monitored from day 43 to day 50. Clinical signs were monitored on a daily basis and any moribund animal was euthanized. Surviving animals were euthanized on days 50 and 51. Blood was collected at this time and the lungs scored for degree of pneumonia. Tissues were collected for attempted bacterial isolation. No tissues were collected for evaluation of the injection by histology.

All animals vaccinated with the combined vaccine survived the experiment challenge; 7/8 animals vaccinated with *Mannheimia haemolytica* alone survived and only 4/8 control animals survived the challenge with *Mannheimia haemolytica*.

*Mannheimia haemolytica* was recovered from the lungs of all animals used in the trial at the time of autopsy examination. The total lung scores for the control animals were numerically higher than for the vaccinated animals; but no statistics were used in this report to compare the differences.

Numerical differences between the vaccinated and control animals with respect to anti-leucotoxin titres were assessed as being significant without statistical analysis. At the time of euthanasia there appeared to be a negative correlation between the level of anti-leucotoxin antibodies and the lung lesion score. Increased numbers of control animals compared to vaccinated animals were destroyed or died prior to the end of the trial.

## Assessment of the efficacy of a bovine herpesvirus (BHV-1) and *Mannheimia haemolytica* combined vaccine, and a BHV-1 only vaccine

The objective of this trial was to evaluate the differences in clinical signs, maximum virus titres and the duration of virus excretion following challenge with a live virulent IBR virus in animals vaccinated with Bovilis IBR vaccine, and a Bovilis MH+IBR

Thirty-eight 7 month old IBR sero-negative animals were used in the trial. Group A received two doses of Bovilis IBR vaccine four weeks apart, Group B received two doses of Bovilis MH+IBR four weeks apart, Group C received a single dose of the Bovilis IBR only vaccine and Group D received no vaccine (placebo). All animals were challenged with two ml of approximately  $6.5 \log_{10}$  TCID<sub>50</sub> /ml of live IBR virus strain Y146.

An observer blinded to the treatments given did the recording of the clinical signs of the challenged animals. Observations of clinical signs, injection sites reaction and collection of blood samples followed the same protocol as the above trial. Swabs for viral isolation of the conjunctiva and nasal cavities were taken daily from just prior to the challenge until 12 days post challenge.

This trial showed that animals immunised twice with the Bovilis IBR (Treatment group A) had clinical signs of reduced severity and frequency, and reduced virus shedding, in terms of peak virus titres and duration of excretion, when compared to naive animals. Animals immunised twice with the Bovilis MH+IBR (Treatment group B) also showed clinical signs of reduced

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severity and frequency, and reduced virus shedding when compared to naive animals, though not to the same extent as Treatment Group A. This result indicates that both the Bovilis IBR vaccine and the Bovilis MH+IBR vaccine when given in two doses 4 weeks apart are suitable for use in cattle to reduce the clinical signs of IBR and decrease shedding of the virus. Bovilis IBR vaccine appears to be more efficacious compared to Bovilis MH+IBR. Bovilis IBR given as a single dose did result in a slight reduction in clinical signs and virus shedding. This result was inferior to the result obtained in either Treatment Group A or B. The areas of injection site tissue reactions were not statistically different between the treatment groups.

The results appear to indicate that both the Bovilis IBR vaccine and the Bovilis MH+IBR vaccine when given in two doses 4 weeks apart are suitable for use in cattle to reduce the clinical signs of IBR and decrease shedding of the virus.

No field efficacy studies were provided in support of this application. The applicant expressed the view that studies demonstrating efficacy of vaccines against natural challenge with infectious agents responsible for bovine respiratory disease (BRD) in feedlot animals should not be considered critical for registration of vaccines against BRD. It is common knowledge that a wide range of predisposing causes or contributing factors may be involved in BRD with the contribution of any one or combination of factors varying between occurrences of disease. Examples include viruses, bacteria, stress, animal age, immune status and capacity, dehydration, nutritional stress, inadequate passive immunoglobulin transfer, climate, ambient temperature, dust particles, , stocking density, humidity etc.

Intervet Schering Plough argued that the complexity of the causal web, means that it is difficult to design a field study to provide effective control of the many potential biases that may occur. The applicant also raised the issue of how to assess the contribution of various causal factors including challenge with other infectious agents, the unpredictable and variability in exposure to infectious agents and the impact of other modifying causal factors.

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The applicant explained that whilst field trials may provide data to support claims of safety and efficacy there is a high likelihood that field trials may return equivocal evidence of efficacy not because of failure of protection by the vaccine but because of the unpredictability in the level of challenge, duration of effect and interaction between the complex range of causal factors including infectious agents that are known to be involved in the aetiology of BRD. The applicant argued that these are the major reasons why field trials to demonstrate efficacy of BRD vaccines should not be mandatory for registration of these vaccines.

BRD is an important disease in beef cattle in Australia particularly cattle in feedlots and in many intensive dairy operations in Australia. Antimicrobials used for treatment of BRD in Australian cattle include tulathromycin, tilmicosin, ceftiofur, oxytetracyclines. It is believed that considerable amount of antimicrobials are used in feedlots to treat BRD.

Vaccination of cattle against BRD has substantial health benefits. Vaccination reduces numbers of cattle contracting BRD and reduces antimicrobial use in feedlots. Reduction in antimicrobial use has the benefit of slowing antimicrobial resistance and reduces the risk of antimicrobial residues in meat.

There is no indication that the product is not efficacious. The evaluator is of the view that Bovilis MH+IBR used as directed on the label is likely to be safe and efficacious and has a place in the control of BRD and therefore recommends registration of this product.



## Safety studies

A double dose safety study, repeat administration safety study was conducted by a Specialist Pig Veterinarian Victoria Department of Primary Industries Bendigo using Bovilis MH+IBR, and Bovilis IBR. No adverse physical or systemic effect was observed with either vaccine.

### Data relied on to provide the advice

Data No	Data Source*	Author(s)	Title	Date	Data Type	Data Sub-type	Authorising Party	Inherited Application No.
35779	S	Andrew Read	Assessment of the efficacy of a bovine herpesvirus (BHV-1) and mannheimia haemolytica combined vaccine and a BHV-1 only vaccine trial 3	25/08/09	Efficacy and Safety	Efficacy	Applicant	
35780	S	Andrew Read	Supplementary Report on Experiment 155/07 and 900/08	25/08/09	Efficacy and Safety	Efficacy	Applicant	
35778	S	Dr Mark Ford & Dr Chris Prideaux	Assessment of the efficacy of a Mannheimia haemolytica and bovine herpesvirus (BHV-1) combined vaccine	Aug 09	Efficacy and Safety	Efficacy	Applicant	
35776	S	Andrew Read	Assessment of the efficacy of a bovine herpesvirus (BHV-1) and mannheimia haemolytica combined vaccine and a BHV-1 only vaccine trial 1	25/08/09	Efficacy and Safety	Efficacy	Applicant	
35777	S	Andrew Read	Assessment of the efficacy of a bovine herpesvirus (BHV-1) and mannheimia haemolytica combined vaccine and a BHV-1 only vaccine trial 2	25/08/09	Efficacy and Safety	Efficacy	Applicant	
35781	S	Dr Leigh Callinan	Bendigo Scientific Data analysts - Assessment of the efficacy of a mannheimia haemolytica and bovine herpesvirus (BHV-1) combined vaccine	27/06/09	Efficacy and Safety	Efficacy	Applicant	
35784	S	Nigel Perkins	Report on vaccine efficacy and safety trials for Bovilis vaccine products	17/09/09	Efficacy and Safety	Efficacy	Applicant	
35783	S	Dr leigh Callinan	Bendigo Scientific Data analysts - The experimental design for a field trial to evaluate bovilis MH & IBR (Mannhemia Haemolytica + IBR) vaccine for cattle	15/11/08	Efficacy and Safety	Other Information	Applicant	
35782	S	Dr Tony Fahy, Karen Moore and Patrick Daniel	Evaluation of the safety of a combined infectious bovine rhinotracheitis mannheimia haemolytica vaccine (IBR MH)	25/8/09	Efficacy and Safety	Target Animal Safety Studies	Applicant	
35775	S	Andrew Read	Bovine Herpesvirus-1 (BHV-1) inactivated vaccine dose response trial	25/08/09	Efficacy and Safety	Target Animal Safety Studies	Applicant	
35774	S	Andrew Read	Assessment of Bovine Herpesvirus type 1 (BHV-1) Challenge model in calves	25/08/09	Efficacy and Safety	Target Animal Safety Studies	Applicant	

\* *S* = Data submitted with the application  
*I* = Data inherited (that is, referenced) from another application



**FACSIMILE**

TO:	s.22(1)(a)(ii), s.47F(1)		
ORGANISATION:	Livestock Shipping Services Pty Ltd		
FACSIMILE NO.:	s. 22(1)(a)(ii), s. 47G(1)(a)		
FROM:	s.22(1)(a)(ii), s.47F(1)		
SECTION:	Live Animal Exports		
FACSIMILE:	(02) 6272 5423	PHONE:	s.22(1)(a)(ii), s.47F(1)
DATE:	9 June 2011	PAGES TO FOLLOW:	10

Dear s.22(1)(a)(ii), s.47F(1)

In accordance with section 2.44 of the *Export Control (Animals) Order 2004* (the Order), I am writing to notify you of AQIS' approval of the notice of intention (NOI) and consignment risk management plan (CRMP) ID LNC-4492.

This letter provides approval for you to prepare the livestock for export in accordance with the information supplied to AQIS in the NOI and CRMP. If any relevant circumstances change, you must inform AQIS ACT in writing and receive approval from AQIS ACT of the changes before proceeding any further with the preparation of the livestock for export.

I have attached the approved export programs (AEPs) for this consignment. In accordance with subsection 2.47(4) of the Order, you must give the AQIS accredited veterinarians (AAVs), Dr s.22(1)(a)(ii), s.47F(1)

complete the activities and provide declarations that the activities have been completed. The shipboard AEP is to be given to s.22(1)(a)(ii), s.47F(1)

You should contact AQIS Vic with an application for a health certificate and permission to leave for loading using the standard form (available on the AQIS webpage at [www.aqis.gov.au](http://www.aqis.gov.au)) when the consignment has been prepared. This application must be signed by a person in management control for LSS. You will need to attach the following documentation to the application for the livestock.

**For all livestock in the consignment**

1. Import permit(s) with an accredited English translation.
2. Travel and load plan (the plan must describe how the livestock will be transported to the place of loading, loaded, and carried on the voyage including feed and water requirements and stocking densities).
3. Confirmation of date of departure and vessel name.
4. An updated HSRA reflecting the anticipated load out weights.

5. Declaration from the AQIS accredited veterinarians (AAVs) that the approved export programs were completed including dates of actions and supporting documentation to detail the treatments given, products used, and examinations undertaken.

#### **For the slaughter sheep**

1. List of properties of origin and PIC numbers for the properties the sheep were resident on for the last 60 days prior to dispatch to the registered premises.
2. Documentation from the State or Territory Government Veterinary Authority confirming that all properties listed in point 1 and the registered premises are in the bluetongue free zone.
3. Property of origin disease documentation from the State or Territory Government Veterinary Authority for the notifiable diseases listed in the sheep import conditions into Turkey.
4. Documentation from the State or Territory Government Veterinary Authority confirming that the sheep are not animals to be killed under a national program for the eradication of disease.
5. National Vendor Declaration or vendor declaration:
  - indicating that the animals have been resident on the property for at least the last 60 days prior to delivery to the registered premises or if less than 60 days the animals have been resident on the property for at least the last 40 days prior to delivery to the registered premises and additional vendor declarations are provided to cover the period to 60 days.
  - indicating that each animal has an ear tag that can be identified to the property of origin.
  - indicating that the sheep have not received any stilbene or thyrostatic substances
  - indicating that the sheep have not received oestrogenic, androgenic, gestagenic or  $\beta$ -agonist substances for purposes other than therapeutic or zootechnic treatment
  - indicating that no hormones and antibiotics treatments has been applied for the animals to be exported within 30 days prior to export.
6. Declarations from the registered premises operator:
  - stating that the sheep did not come into contact with other cloven-hoofed animals not complying with the health requirements for Turkey.
  - stating that the sheep were held in the registered premises for a minimum of five clear days immediately prior to export.
  - indicating that no hormones and antibiotics treatments has been applied for the animals to be exported during quarantine.
7. Declaration that during transport from the property of origin to the registered premises and from the registered premises to the vessel, the animals did not come into contact with other cloven-hoofed animals not complying with the health requirements for Turkey.
8. Declaration that any transport vehicles or containers in which the sheep were loaded were cleaned and disinfected before loading, with a registered disinfectant.

**For the feeder cattle**

1. A pregnancy declaration in accordance with the ASEL.
2. List of properties of origin and PIC numbers for the properties the cattle were resident on for the last 60 days prior to dispatch to the registered premises.
3. Documentation from the State or Territory Government Veterinary Authority confirming that all properties listed in point 2 and the registered premises are in the bluetongue free zone.
4. Property of origin and regional disease documentation from the State or Territory Government Veterinary Authority for the notifiable diseases listed on the cattle import conditions into Turkey.
5. Documentation from the State or Territory Government Veterinary Authority confirming that the cattle are not animals to be killed under a national program for the eradication of disease.
6. National Vendor Declaration or vendor declaration:
  - indicating that the animals have been resident on the property for at least the last 60 days prior to delivery to the registered premises or if less than 60 days the animals have been resident on the property for at least the last 30 days prior to delivery to the registered premises and additional vendor declarations are provided to cover the period to 60 days.
7. Declarations from the vendor:
  - for non- notifiable diseases listed on the cattle import conditions into Turkey.
  - stating that the cattle have not received any stilbene or thyrostatic substances.
  - stating that the cattle have not received any oestrogenic, androgenic, gestagenic or  $\beta$ -agonist substances for purposes other than therapeutic or zootechnic treatment.
  - stating that the animals were born and raised in Australia after 1997.
  - stating that the animals were isolated from all other animals on the property of origin for at least the last 20 days prior to delivery to the registered premises.
8. Declarations from the registered premises operator:
  - stating that the cattle did not come into contact with other cloven-hoofed animals not complying with the health requirements for Turkey.
  - stating that the cattle were held in the registered premises for a minimum of ten clear days immediately prior to export.
9. Declaration stating that the cattle have been treated for endo and ectoparasites using a registered antiparasitic drug at least 10 days prior to export.
10. Declaration stating that the cattle have been vaccinated for leptospirosis using a registered vaccine.



11. Declaration from a registered veterinarian stating that:

- the cattle have been tested for Enzootic Bovine Leukosis (EBL) with negative results, using the AGID or ELISA test within 30 days prior to shipment.
- cattle have been tested for bluetongue by ELISA with negative results.
- treated with long acting oxytetracycline within 14 days prior to shipment.

12. Laboratory test results including methods used.

13. List of ear tag numbers to cross reference with laboratory results.

14. Declaration that during transport from the property of origin to the registered premises and from the registered premises to the vessel, the animals did not come into contact with other cloven-hoofed animals not complying with the health requirements for Turkey.

15. Declaration that any transport vehicles or containers in which the cattle were loaded were cleaned and disinfected before loading, with a registered disinfectant.

16. An identification list of eligible animals in the format below.

No.	Property of Origin PIC	Visual Tag No.	RFID No.
1			
2			
3			
4			

17. A list of ineligible animals and reason for rejection.

Once the document examination is completed, an AQIS inspection of the livestock can be arranged. Part of the inspection process is checking the property of origin identification of the livestock.

Conditions for this approval are:

- That livestock are not permitted to leave the registered premises until AMSA and AQIS (sea ports) has undertaken the pre-loading inspection and determined that the s.22(1)(a)(ii), s.47G(1)(a) is in a fit state for the proper carriage of the livestock
- Only male sheep are eligible for export to Turkey.
- LSS must provide a declaration to AQIS Vic stating that the cattle have been prepared in accordance with the information provided to AQIS in the NOI/CRMP submission for management of BRD. The declaration must state that in addition to the requirements in the AEPs the cattle were vaccinated once with Bovilis MH ®.
- The onboard veterinarian and the accredited stockmen may not be changed from those listed in the NOI without prior approval from AQIS ACT.
- The travel and load plan supplied to AQIS Vic must include the number and class of livestock to be loaded in each pen on each deck.
- The load plan supplied to AQIS Vic must clearly show that the feeder cattle and slaughter sheep will be penned separately.
- Seven days additional fodder must be loaded (4 extra days over and above the normal 3 additional days specified in ASEL).
- Permission to leave for loading will not be granted until:

- all the cattle have been identified by confirmation of both visual tag and RFID number at final inspection, and
  - ineligible cattle have been segregated from the cattle which are being exported, and
  - an identification list of eligible and ineligible cattle has been provided to AQIS.
  - **AQIS approves the updated HSRA after inspection and weighing of cattle (if required)**
- LSS must provide a final packing list for cattle including only the visual tag prior to issuance of the export permit.
  - When the ship has been loaded to approximately 85% of the estimated capacity for sheep or cattle, loading ceases until the weight of the loaded sheep or cattle is calculated and the load plan and HSRA are updated. Once AQIS Vic have determined that the load plan and HSRA are in accordance with the ASEL requirements, an AQIS representative would give approval for loading to continue.
  - During loading, AQIS will direct animals that have not been loaded in accordance with the ASEL to be unloaded. Any compromise to animal welfare or commercial loss that results from such action will be at the exporter's risk and responsibility.
  - The end of voyage report must specify the number of deaths that occurred on each deck and the number of deaths in each class of livestock.

Please note that as per conditions on the Livestock Shipping Services Pty Ltd licence for export of cattle:

1. Sufficient antibiotics to provide appropriate treatment in the event of an outbreak of pneumonia over and above the drugs specified in the ASEL are to be loaded on the vessel.
2. An additional accredited stockman is required to accompany the cattle.

You must also arrange for the livestock to be examined as they are being loaded onto the vessel to remove all animals unfit for travel.

If you require any additional information please do not hesitate to contact

s.22(1)(a)(ii), s.47F(1)

s.22(1)(a)(ii), s.47F(1)

Yours sincerely

s.22(1)(a)(ii), s.47F(1)

Delegate to the Secretary



Australian Government  
 Department of Agriculture,  
 Fisheries and Forestry  
 Australian Quarantine and  
 Inspection Service

# Approved Export Program

Section 2.47 of the Export Control (Animals) 2004

NOI/CRMP ID  
 LNC-4492.  
 1/3

Consignment Description			
Species:	Bovine	Importing Country:	Turkey
Class:	Feeder	Est. Departure Date:	15/06/2011
Breed:	Mixed	Vessel Name:	s.22(1)(a)(ii), s.47G(1)(a)
		Port of Loading:	Portland

s.22(1)(a)(ii), s.47F(1)

Activities in the registered premises	Date(s)
AAVs to directly supervise Triangle 4 or Bovilis MH / IBR vaccination	In the registered premises and within 30 days of export.
AAVs to individually examine cattle at the registered premises - only those cattle that: <ul style="list-style-type: none"> <li>- are free from signs of disease and external parasites,</li> <li>- fit to travel,</li> <li>- are free from the symptoms listed in the cattle rejection criteria,</li> <li>- showed no clinical signs of notifiable diseases during the isolation period in the registered premises,</li> <li>- show no clinical signs of infectious keratoconjunctivitis, ringworm, warts, scabies and cow pox,</li> </ul> qualify for export.	Within 48 hours prior to loading

The AAVs must provide a declaration that the activities have been completed as part of the exporter's application for a health certificate and permission to leave for loading.

s.22(1)(a)(ii), s.47F(1)

Name of Authorised Officer

s.22(1)(a)(ii), s.47F(1)

Signature of Authorised Officer

09/06/2011  
 Date



# Approved Export Program

Section 2.47 of the Export Control (Animals) 2004

NOI/CRMP ID

LNC-4492

1/3

## CATTLE REJECTION CRITERIA

The AQIS accredited veterinarian must reject any animal found with the following signs. Any other condition that could be defined as an infectious or contagious disease, or would mean that the cattle or buffalo's health would decline or that the cattle or buffalo would suffer distress during transport would also mean rejection from export.

CATEGORY	DETAILS
General requirements	<ul style="list-style-type: none"> <li>• Fail to meet requirements of protocol/import permit, such as sex, type, breed, tag number.</li> <li>• Lactating animals with calves at foot</li> <li>• Pregnancy status not confirmed as appropriate for journey</li> </ul>
Systemic Condition	<ul style="list-style-type: none"> <li>• Emaciated or overfat</li> <li>• Anorexia (inappetence)</li> <li>• Uncoordinated, collapsed, weak</li> <li>• Unwell, lethargic, dehydrated</li> <li>• Ill-thrift</li> </ul>
Musculoskeletal System	<ul style="list-style-type: none"> <li>• Lameness or abnormal gait</li> <li>• Abnormal soft tissue or bony swellings</li> </ul>
Gastrointestinal System	<ul style="list-style-type: none"> <li>• Dysentery or profuse diarrhea</li> <li>• Bloat</li> </ul>
Nervous System	<ul style="list-style-type: none"> <li>• Nervous signs (e.g. head tilt, circling, incoordination)</li> <li>• Abnormal or aggressive behaviour/intractable or violent</li> </ul>
External/skin	<ul style="list-style-type: none"> <li>• Generalised papillomatosis or generalised ringworm, dermatophilosis</li> <li>• Generalised and extensive buffalo fly lesions</li> <li>• Generalised skin disease</li> <li>• Visible external parasites</li> <li>• Significant lacerations</li> <li>• Discharging wound- or abscesses</li> <li>• Blood/discharge from reproductive tract (vulva/prepuce)</li> </ul>
Head	<ul style="list-style-type: none"> <li>• Blindness in one or both eyes</li> <li>• Cancer eye</li> <li>• Keratoconjunctivitis (pink eye)</li> <li>• Excessive salivation</li> <li>• Nasal discharge</li> <li>• Severe coughing</li> <li>• Respiratory distress — difficulty breathing</li> <li>• Horns causing damage to head or eyes</li> <li>• Uninjured sharp horns</li> <li>• Cattle: horns longer than 12 cm, except in approved NOI and CRMP</li> <li>• Bleeding horn stumps</li> </ul>
Other	<ul style="list-style-type: none"> <li>• Mobs with unusual mortalities or mortalities of more than zero point five (0.5) per cent over the whole period of pre export preparation</li> <li>• Large disparities in sizes or ages (Re-draft animals in this case)</li> </ul>



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Consignment Description			
Species:	Ovine	Importing Country:	Turkey
Class:	Slaughter	Est. Departure Date:	15/06/2011
Breed:	Mixed	Vessel Name:	s.22(1)(a)(ii), s.47G(1)(a)
		Port of Loading:	Portland

s.22(1)(a)(ii), s.47F(1)

Activity	Date(s)
AAV to inspect sheep at the registered premises –only those sheep free from evidence of infectious or contagious disease, external parasites and fit to travel consistent with the rejection criteria qualify for export.	Within 72 hours prior to loading
AAV to directly supervise individual examination of sheep - only those animals free of clinical signs of infectious or contagious diseases, external parasites and are fit to travel qualify for export.	On the day of export at the registered premises

The AAVs must provide a declaration that the activity has been completed as part of the exporter's application for a health certificate and permission to leave for loading.

s.22(1)(a)(ii), s.47F(1)

Name of Authorised Officer

s.22(1)(a)(ii), s.47F(1)

Signature of Authorised Officer

09/06/2011

Date





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# Approved Export Program

Section 2.47 of the Export Control (Animals) 2004

NOI/CRMP ID

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## SHEEP REJECTION CRITERIA

The AQIS accredited veterinarian must reject any animal found with the following signs. Any other condition that could be defined as an infectious or contagious disease, or would mean that the sheep health would decline or that the sheep would suffer distress during transport would also mean rejection from export.

CATEGORY	DETAILS
General requirements	<ul style="list-style-type: none"> <li>• Fail to meet requirements of protocol/import permit, such as sex, type, breed, tag number</li> <li>• Lactating animals with young at foot</li> <li>• Lactating ewes and does</li> <li>• Pregnancy status not confirmed as appropriate for journey</li> </ul>
Systemic Condition	<ul style="list-style-type: none"> <li>• Emaciated or overfat</li> <li>• Anorexia (inappetence)</li> <li>• Uncoordinated, collapsed, weak</li> <li>• Unwell, lethargic, dehydrated</li> <li>• Ill-thrift</li> </ul>
Musculoskeletal System	<ul style="list-style-type: none"> <li>• Lameness or abnormal gait</li> <li>• Abnormal Soft tissue or bony swellings</li> </ul>
Gastrointestinal System	<ul style="list-style-type: none"> <li>• Dysentery or profuse diarrhea</li> <li>• Bloat</li> </ul>
Nervous System	<ul style="list-style-type: none"> <li>• Nervous signs (e.g. head tilt, circling, incoordination)</li> <li>• Abnormal or aggressive behaviour/intractable or violent</li> </ul>
External/skin	<ul style="list-style-type: none"> <li>• Generalised skin disease</li> <li>• Visible external parasites</li> <li>• Cutaneous myiasis (flystrike)</li> <li>• Significant lacerations</li> <li>• Discharging wounds or abscesses</li> <li>• Wool longer than 25 mm, unless approved by the appropriate Australian Government agency based on agreed heat stress risk assessment model</li> <li>• External skin cancer</li> <li>• Ballanitis (pizzle rot in sheep)</li> <li>• Blood/discharge from reproductive tract (vulva/prepuce)</li> </ul>
Head	<ul style="list-style-type: none"> <li>• Blindness in one or both eyes</li> <li>• Cancer eye</li> <li>• Keratoconjunctivitis (pink eye)</li> <li>• Excessive salivation</li> <li>• Nasal discharge</li> <li>• Respiratory distress — difficulty breathing</li> <li>• Horns causing damage to head or eyes</li> <li>• Sheep: long horns greater than one curl, except in approved NOI and CRMP</li> <li>• Bleeding horn stumps</li> <li>• Coughing</li> <li>• Scabby mouth</li> </ul>
Other	<ul style="list-style-type: none"> <li>• Mobs with unusual mortalities or mortalities of more than zero point five (0.5) per cent over the whole period of pre-export preparation</li> <li>• Large disparities in sizes or ages (Re-draft animals in this case)</li> </ul>



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# Approved Export Program

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NOI/CRMP ID

LNC- 4492

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Consignment Description			
Species:	Bovine / Ovine	Importing Country:	Turkey
Class:	Feeder/ Slaughter	Est. Departure Date:	15/06/2011
Breed:	Mixed	Vessel Name:	s.22(1)(a)(ii), s.47G(1)(a)
		Port of Loading:	Portland

AQIS accredited shipboard veterinarian: s.22(1)(a)(ii), s.47F(1)

The live-stock are to be accompanied on their export voyage by s.22(1)(a)(ii), s.47F(1)

The AAV must remain on the vessel until the last animal has disembarked.

s.22(1)(a)(ii),  
s.47F(1)

must provide:

- A daily report to AQIS in accordance with Appendix 5.1 of the Australian Standards for the export of livestock (ASEL).
- An end of voyage report to AQIS within 5 days of the end of voyage in accordance with Appendix 5.2 of the Australian Standards for the Export of Livestock (ASEL).
- **The daily and end of voyage reports must include:**
  - the mortalities in each class of livestock, i.e. the number loaded and the number of mortalities must be reported separately for each line of feeder cattle and slaughter sheep,
  - the number of livestock and the number of mortalities on each deck,
  - details of the suspected causes of mortality (based on post mortem examination findings where possible).
- If heat stress mortalities occur the daily and end of voyage report must specify the deck on which the heat stress mortalities occurred.
- Written notification to AQIS if a notifiable incident occurs. This notification must be provided to AQIS as soon as possible (within 12 hours of occurring). Definition of notifiable incident and reportable levels of mortalities are provided below.
- If incidents (eg. disease or mortalities etc.) occur in particular lines provide details, including identification, to allow trace backs.

**Notifiable incident** means an incident that has the potential to cause serious harm to the health and welfare of animals. A notifiable incident includes, but is not limited to:

- a shipboard mortality rate equal to or greater than a reportable level;
- disablement of ventilation, feeding and/or watering systems on a vessel carrying livestock, causing a serious adverse effect on animal welfare;
- rejection of livestock at an overseas port;
- diagnosis or strong suspicion of an emergency disease in a consignment of livestock;



# Approved Export Program

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- marine casualty of a vessel carrying livestock;
- disablement of a vessel carrying livestock, such that assistance is required for return to port;
- an act of terrorism or piracy; and/or
- any other incident that has a serious adverse effect on animal health and welfare.

**Reportable level** means, in respect of any species, the percentage listed below or three (3) animals, whichever is the greater number of animals:

- sheep and goats: two (2) per cent;
- cattle and buffalo, voyages  $\geq 10$  days: one (1) per cent;
- cattle and buffalo, voyages  $< 10$  days: zero point five (0.5) per cent;
- camelids: two (2) per cent;
- deer: two (2) per cent;

Shipboard mortality rate refers to any species, and means the percentage determined by dividing the number of deaths of that species occurring while on the vessel (including during loading and unloading) by the total number of that species loaded, and multiplying the resulting figure by 100.

Mortalities which occur after arrival in the port but before the animal can be discharged must be included in the daily and end of voyage reports.

s.22(1)(a)(ii), s.47F(1)

Name of Authorised Officer

s.22(1)(a)(ii), s.47F(1)

Signature of Authorised Officer

Date


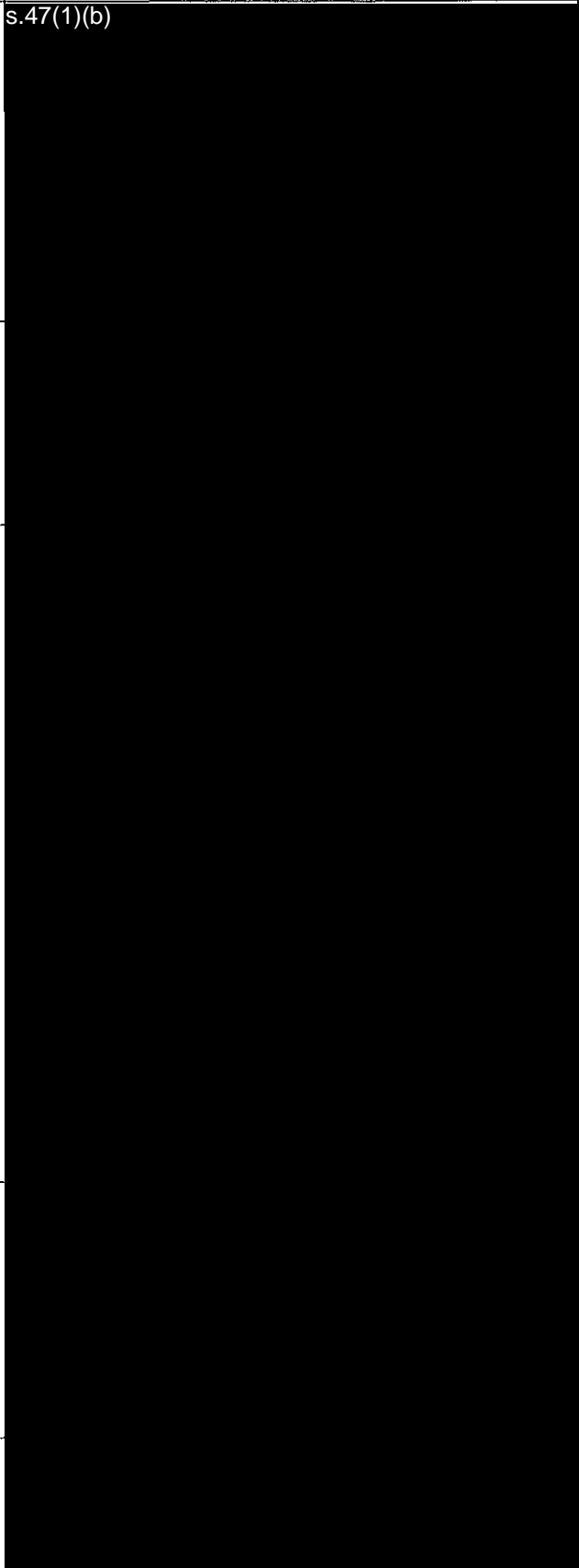
09/06/2011

CONSIGNMENT RISK MANAGEMENT PLAN

	Turkish requirements	Risk management procedure
1.	<p><b>Property of origin health status</b></p> <p>The cattle come from holdings which are not subject to official quarantine restrictions on animal health grounds for anthrax, paratuberculosis, enzootic bovine leucosis, or any other notifiable disease of cattle.</p>	<p>s.47(1)(b)</p>
2.	<p><b>Non-notifiable diseases on property of origin</b></p> <p>The cattle come from holdings which have no confirmed clinical cases of IBR/IPV, BVD, PI-3, epizootic haemorrhagic disease or leptospirosis during the previous 12 months.</p>	
3.	<p><b>HGPs</b></p> <p>The cattle have not received any stilbene or thyrostatic substance, nor any oestrogenic, androgenic, gestagenic or <math>\beta</math>-agonist substances for purposes other than therapeutic or zootechnic treatment.</p>	
4.	<p><b>Country disease freedom</b></p> <p>Australia is free from foot-and-mouth disease, rinderpest, contagious bovine pleuropneumonia, heartwater, bovine brucellosis (<i>Brucella abortus</i>), bovine tuberculosis, lumpy skin disease, rabies, Rift Valley Fever and vesicular stomatitis.</p>	
5.	<p><b>Vaccination against exotic diseases</b></p> <p>During the last 12 months there has been no vaccination against foot-and-mouth disease, rinderpest, contagious bovine pleuropneumonia, heartwater, bovine brucellosis (<i>Brucella abortus</i>), bovine tuberculosis, lumpy skin disease, rabies, Rift Valley Fever, vesicular stomatitis, bluetongue or epizootic haemorrhagic disease and importation of cattle vaccinated against these diseases has not been permitted.</p>	

6.	<p><b>BSE</b></p> <p>The cattle come from a country in which BSE has not occurred and is recognized as a country with 'negligible' BSE risk.</p>	<p>ocument 12U s.47(1)(b) 173</p>
7.	<p><b>Born after meat and bone meal banned</b></p> <p>The animals for export were born after the date from which the ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants was effectively enforced.</p>	<p>s.47(1)(b)</p>
8.	<p><b>BSE surveillance</b></p> <p>Australia has an effective and permanent surveillance and monitoring program against BSE within the framework laid down in the BSE Chapter in the OIE Terrestrial Animal Health Code.</p>	
9.	<p><b>Identification of selected cattle</b></p> <p>Each animal selected for export to Turkey has been marked individually.</p>	
10.	<p><b>Animal identification to herd of origin</b></p> <p>The animals are identified by a permanent identification system enabling them to be traced back to the herd of origin.</p>	

11.	<b>Bovine Brucellosis &amp; Bovine Tuberculosis</b> The cattle originated from herds of origin free from bovine brucellosis ( <i>Brucella abortus</i> ) and bovine tuberculosis.
12.	<b>Johne's Disease</b> The cattle originate from herds of origin which are free from Johne's Disease at least 5 years.
13.	<b>Herd of Origin Clearance</b> The cattle originated from herds of origin which have been clinically free of Enzootic Bovine Leucosis (EBL), and bovine pasteurellosis for 24 months and Trichomoniasis, Vibriofetus, Leptospirosis, Bovine Herpes Virus type 1 (BHV 1), IBR/IPV, Bovine Viral Diarrhea/Mucosal Disease (BVD/MD), Neosporosis and Para Influenza-3 (P13) for the last 12 months.

<p>14. <b>Diseases around registered premises</b></p> <p>During the previous 60 days, within a 100 km radius of the AQIS approved registered premises, there has been no clinical case/outbreak of bluetongue in cattle and within a 10km radius there has been no clinical case/outbreak of bovine brucellosis (<i>Brucella abortus</i>) and bovine tuberculosis.</p>	<p>Document ID: s.47(1)(b)</p> 
<p>15. <b>Diseases around property of origin</b></p> <p>During the previous 60 days within a 100 km radius of the property of origin there has been no clinical case/outbreak of bluetongue in cattle; and within a 10 km radius there has been no clinical case/outbreak of any of bovine brucellosis (<i>Brucella abortus</i>) and bovine tuberculosis.</p>	<p>s.47(1)(b)</p> 
<p>16. <b>Residency in bluetongue-free zone</b></p> <p>The cattle were kept in a bluetongue free zone for at least 60 days prior to shipment.</p>	
<p>17. <b>Isolation</b></p> <p>The cattle to be exported have been kept in isolation (3) (in the origin holding or assembly centre or isolation centre) for at least 30 days prior to export, with at least the last ten days in as AQIS approved premises under the control of an official veterinarian, and showed no clinical signs of any notifiable disease.</p>	
<p>18. <b>Inspection</b></p> <p>At the time of export the cattle showed no clinical signs of infectious keratoconjunctivitis, ringworm, warts, scabies and cow pox.</p>	
<p>19. <b>Treatment</b></p> <p>The cattle were treated against endo and ectoparasites using registered antiparasitic</p>	



20. **Testing & Treatments**

The cattle have been tested for the following animal diseases with negative results:

- a) IBR/IPV; (using the serum neutralization test or Elisa within 30 days prior to export) Note: This is only applicable to unvaccinated animals.
- b) Leptospirosis; (using the micro agglutination test, (sero types: pomona, grippotyphosa, icterohaemorrhagia, hardjo, canicola – titre <1;100) withing 30 days of export).

or

They were injected once with 20mg per kg of body weight of long acting oxtetracycline within 14 days of shipment.

and

There were vaccinated with a vaccine registered for use in Australia against leptospirosis.

Enzootic Bovine Leucosis (EBL); (using the agar gel immunodiffusion (AGID) test or ELISA within 30 days prior to export).

Blue Tongue test (using ELISA) within 60 days of export.

21. **Vaccination**

The cattle have been vaccinated against the following animal diseases:

- a) The cattle were vaccinated against IBR/IPV at 4 months of age or younger in full accordance with vaccine label directions and revaccinated at least annually to maintain vaccination status. All vaccines used were approved by Australia.
- b) or: The cattle were vaccinated against IBR/IPV using a killed vaccine approved by Australia within 30 days prior to export.

22. **Examination prior to Shipping**

The cattle have been examined clinically

s.47(1)(b)

	before shipped and showed no clinical signs of any infectious or contagious disease.	s.47(1)(b) 177
23.	<p><b>Disease control programs</b></p> <p>The cattle are not animals to be killed under a national program for the eradication of disease.</p>	s.47(1)(b)
24.	<p><b>Dispatch to the registered premises</b></p> <p>The cattle are dispatched from the property of origin to the registered premises without coming into contact with other cloven-hoofed animals not complying with the requirements for export of slaughter cattle to Turkey.</p>	
25.	<p><b>Isolation at the registered premises</b></p> <p>The cattle are held at a registered premises immediately prior to export to Turkey and until dispatched to Turkey do not come in contact with other cloven-hoofed animals not complying with the requirements for export of slaughter cattle to Turkey.</p>	
26.	<p><b>Cleaning and disinfection of vehicles</b></p> <p>Any transport vehicles or containers in which the cattle are loaded are cleaned and disinfected before loading with a registered disinfectant.</p>	
27.	<p><b>Final inspection</b></p> <p>The cattle were examined by an official veterinarian within 48 hours of loading and show no clinical signs of disease.</p>	

	Australian requirements	Risk management procedure <span style="float: right;">178</span>
23.	Cattle selection	s.47(1)(b)
24.	Land transport of cattle	
25.	Management of registered premises	
26.	Cattle type	
27.	Bovine respiratory disease	
28.	Heat stress	
29.	Vessel preparation and loading	
30.	On-board management	

		s.47(1)(b)	
		ocument 12	179
31.	Shipboard fodder	s.47(1)(b)	
32.	Sawdust		

Date of this CRMP: 27<sup>th</sup> May, 2011





Australian Government

Australian Quarantine and Inspection Service

**3. CONSIGNMENT SUMMARY - Details of the intended export consignment must be supplied**

Transport Vessel Name: s.22(1)(a)(ii), s.47G(1)(a)

Transport Route: - list all departure, transit and arrival ports in date order (eg. Portland, Adelaide, Fremantle, Muscat, Kuwait)  
Portland, Fremantle, Mersin

Port of Loading: Portland Departure Date: 15/06/2011

Description					Registered Premises: Name & Registration #	Proposed Arrival Date	Proposed Departure Date	Importing Country	Import Country Port/s	Import Permit Required (Y/N)	Proposed Arrival Date
Species	Class (Breeder, Feeder, Slaughter and sex)	Breed	Age	Quantity							
Cattle	s.47(1)(b)	Mixed	N/A	2,800	s.22(1)(a)(ii)	31/05/2011 to 04/06/2011	15/06/2011	Turkey	Mersin	Y	11/07/2011
Cattle		Mixed	N/A	3,000		02/06/2011 to 04/06/2011	15/06/2011	Turkey	Mersin	Y	11/07/2011
Sheep		Mixed	N/A	5,000		09/06/2011	15/06/2011	Turkey	Mersin	Y	11/07/2011

Name of AQIS Accredited Vet: s.22(1)(a)(ii), s.47F(1)

Name of LiveCorp accredited stockman:

Method of transport in Australia:

Road

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Area from which live-stock are to be sourced: Victoria

Document 12

Document 12

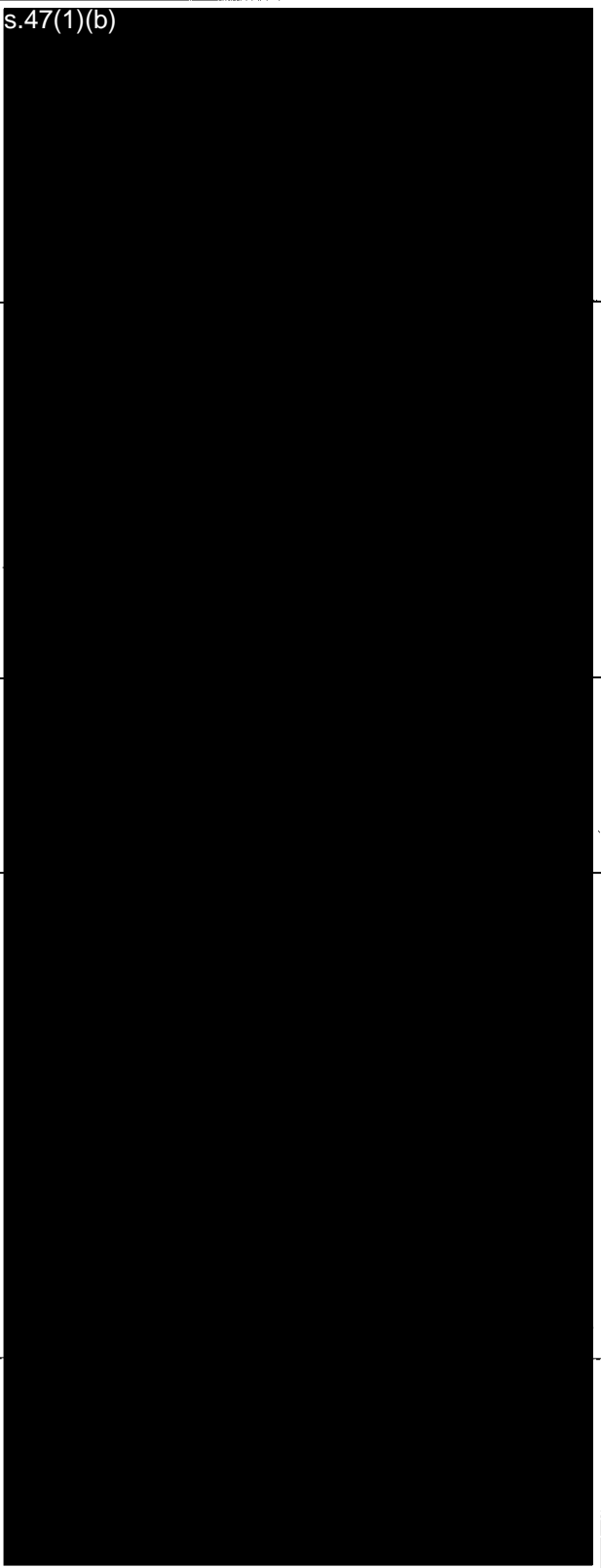
181

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s.22(1)(a)(ii),  
s.47G(1)(a)

Slaughter Sheep

CONSIGNMENT RISK MANAGEMENT PLAN

	Turkish requirements	Risk management procedure
1.	<p><b>Property of Origin Health Status</b></p> <p>The sheep come from properties of origin which has been free from any official prohibition on health grounds for the last 30 days in the case of anthrax and have not been in contact with animals from properties which did not satisfy these conditions.</p>	<p>s.47(1)(b)</p> 
2.	<p><b>HGPs &amp; Antibiotic Treatments</b></p> <p>The sheep have not received any stilbene or thyrostatic substance, nor any oestrogenic, androgenic, gestagenic or β-agonist substances for purposes other than therapeutic or zootechnic treatment.</p> <p>No hormone or antibiotic treatments have been applied to the animals for export within 30 days prior to export.</p>	
3.	<p><b>Born After Meat and Bone Meal Banned</b></p> <p>The ban on the feeding of ruminants with meat-and-bone meal and greaves derived from ruminants has been in place since 1997.</p>	
4.	<p><b>Identification</b></p> <p>Each animal for export has an ear tag that allows the identification of the property of origin.</p>	
5.	<p><b>Country Disease Freedom</b></p> <p>Australia has been free for 24 months from foot and mouth disease, classical scrapie, clinical bluetongue, contagious agalactia of sheep or goats, pulmonary adenomatosis,</p>	



	<p>Maedi/visna, bovine tuberculosis, Brucella abortus and Brucella Melitensis and rabies; for 12 months from Rinderpest, Rift valley fever, peste des petits ruminants, sheep pox, goat pox and contagious caprine pleuro-pneumonia and for 6 months from vesicular Stomatitis.</p>	
<p>6.</p>	<p><b>Vaccination Against Exotic Diseases</b></p> <p>During the last 12 months, no vaccination has been carried out against the diseases listed (foot and mouth disease, classical scrapie, clinical bluetongue, contagious agalactia of sheep or goats, pulmonary adenomatosis, Maedi/visna, bovine tuberculosis, Brucella abortus and Brucella Melitensis, rabies, Rinderpest, Rift valley fever, peste des petits ruminants, sheep pox, goat pox and contagious caprine pleuro-pneumonia and vesicular Stomatitis) or against bluetongue or epizootic haemorrhagic disease, in domestic cloven hooved animals.</p>	<p>s.47(1)(b)</p>
<p>7.</p>	<p><b>Residency on Property of Origin</b></p> <p>They have remained since birth or at least 40 days before dispatch in the property of origin</p>	
<p>8.</p>	<p><b>Residency in Bluetongue-free Zone &amp; Other Diseases</b></p> <p>The sheep were kept in a bluetongue free zone for at least 60 days prior to shipment.</p> <p>Australia has been free of the other diseases (foot and mouth disease, classical scrapie, clinical bluetongue, contagious agalactia of sheep or goats, pulmonary adenomatosis, Maedi/visna, bovine tuberculosis, Brucella abortus and Brucella Melitensis, rabies, Rinderpest, Rift valley fever, peste des petits ruminants, sheep pox, goat pox and contagious caprine pleuro-pneumonia and vesicular Stomatitis) for at least 40 days prior to shipment.</p>	
<p>9.</p>	<p><b>Disease Control Programs</b></p> <p>The sheep are not animals to be killed under a national programme for the eradication of disease.</p>	

<p>10.</p>	<p><b>Johne's Disease</b></p> <p>The sheep do not come from a property of origin in which the following diseases have been clinically detected:</p> <p>a) Paratuberculosis, within the last 12 months.</p>	<p>s.47(1)(b)</p>
<p>11.</p>	<p><b>Dispatch to the Registered Premises</b></p> <p>They were dispatched from the property of origin to the export assembly centre(s) without coming into contact with other cloven-hoofed animals not complying with the health requirements of Turkey.</p>	
<p>12.</p>	<p><b>Isolation at the Registered Premises</b></p> <p>They were held in the officially authorised assembly centre(s) immediately prior to export to Turkey, and until dispatched to Turkey did not come in contact with other cloven-hoofed animals not complying with the health requirements of Turkey.</p>	
<p>13.</p>	<p><b>Transport vehicles to Registered Premises</b></p> <p>Any transport vehicles or containers in which they were loaded were cleaned and disinfected before loading, with a registered disinfectant.</p>	
<p>14.</p>	<p><b>Final Inspection</b></p> <p>The sheep were examined by an official veterinarian within 72 hours of loading and showed no clinical signs of disease.</p>	
<p>15.</p>	<p><b>Cleaning and Disinfection of Vehicles</b></p> <p>The sheep were loaded for dispatch to Turkey in the means of transport that was cleaned and disinfected before loading in accordance with Australian quarantine requirements.</p>	

	Australian requirements	Risk management procedure
16.	Sheep selection	s.47(1)(b)
17.	Land transport of Sheep	
18.	Management of registered premises	
19.	Sheep type	
20.	Heat stress	
21.	Vessel preparation and loading	
22.	On-board management	
23.	Shipboard fodder	

Date of this CRMP: 20<sup>th</sup> May, 2011

s.22(1)(a)  
(ii),

Portland

s.22(1)(a)(ii), s.47G(1)  
(a)

s. 47G(1)(a)

Vessel Name	
Last Port of Departure	Portland
Departure Date	15/06/2011
First Port of Arrival	Mersin_Suez
Arrival Date	11/07/2011

	head	area	tonnes
Cattle	5800	6278.33	1512.64
Sheep	5000	1475.01	210
Goats	0	0	0
Total	10800	7753.34	1722.64

Livestock:      Weight:      Wet Bills      Minimum      Actual Area      Loading Density      5% Mortality      Exp'd      Req'd Gross      Port of      Destock'd

s. 47G(1)(a), s. 47(1)(b)

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s.22(1)(a)  
(ii), s.47G(1)

Portland

s.22(1)(a)(ii), s.47G(1)  
(a)

s. 47G(1)(a)

Vessel Name	
Last Port of Departure	Portland
Departure Date	15/06/2011
First Port of Arrival	Mersin_Suez
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	head	area	tonnes
Cattle	5800	6278.33	1512.64
Sheep	0	0	0
Goats	0	0	0
Total	5800	6278.33	1512.64

Exporter	Deck Level	Deck Area	ID	Type	Breed Name	Weight (kg)	Quantity	Fat Score	Description	Acc. zone	Temp	Wet Bulb Minimum	Actual Area	Loading Density	5% Mortality	Exp'd	Reprod Cross	Port of	Destocking					
													(m <sup>2</sup> )	(m <sup>2</sup> )	(m <sup>2</sup> /head)	Risk	Mortality	Wind (knots)	Comment	Livestock	HSRA No.	Discharge	Qty	Port Risk
s. 47(1)(b), s. 47G(1)(a)																								

require extra space to get below 2%

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**3. CONSIGNMENT SUMMARY - Details of the intended export consignment must be supplied**

Transport Vessel Name: s.22(1)(a)(ii), s.47G(1)(a)

Transport Route: - list all departure, transit and arrival ports in date order (eg. Portland, Adelaide, Fremantle, Muscat, Kuwait)  
 Portland, Fremantle, Mersin

Port of Loading: Portland Departure Date: 15/06/2011

Description					Registered Premises: Name & Registration #	Proposed Arrival Date	Proposed Departure Date	Importing Country	Import Country Port/s	Import Permit Required (Y/N)	Proposed Arrival Date
Species	Class (Breeder, Feeder, Slaughter and sex)	Breed	Age	Quantity							
Cattle	s.47(1)(b)	Mixed	N/A	2,800	s.22(1)(a)(ii)	31/05/2011 to 04/06/2011	15/06/2011	Turkey	Mersin	Y	11/07/2011
Cattle		Mixed	N/A	3,000		02/06/2011 to 04/06/2011	15/06/2011	Turkey	Mersin	Y	11/07/2011
Sheep		Mixed	N/A	5,000		09/06/2011	15/06/2011	Turkey	Mersin	Y	11/07/2011

Name of AQIS Accredited Vet: s.22(1)(a)(ii), s.47F(1) Method of transport in Australia: Road

Name of LiveCorp accredited stockman:

Area from which live-stock are to be sourced: Victoria

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