Cost of Diseases

Animal Health Alliance

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Executive Summary

Diseases of production animals cause major economic loss to Australian agriculture. Such diseases in beef cattle, dairy cattle, sheep, swine and poultry are usually controlled by the provision of nutritional supplements and/or the application of medicinal or biological agents to either prevent or alleviate the condition. Producers rely upon scientific advances to provide timely and cost effective solutions for the treatment of diseases and conditions, allowing downstream industries involved in the production of food and fibre to compete effectively in both domestic and international markets.

The disease landscape is ever changing, therefore any restriction or delay in the availability of modern animal health solutions will result in an economic impact for producers, as well as the competitiveness of downstream processing industries. This is especially true when such solutions are available in competitor countries, but are either not available or suffer delayed entry in the domestic market.

Animal Health Alliance (Australia) Ltd, ("the Alliance"), representing the majority of animal health companies present in the Australian market (by $ sales), wishes to more fully explore and understand the costs to Australian industry of major production animal diseases, as well as the additional costs incurred or opportunities foregone due to the absence or delayed entry of veterinary medicines/biological available elsewhere.

Menari Business Solutions (MBS) was commissioned to conduct a study evaluating the cost of disease in the Australian production animal industries. The major objective of the study was to fully analyse the costs associated in treating the major diseases of the beef, sheep, swine, poultry and dairy industries as well as understanding the associated production loss to farmers and producers when such diseases occur.

In light of this quantification, MBS was also asked to evaluate the current regulatory environment so as to understand the gaps and opportunities that exist in the products available to Australian farmers, particularly with respect to similar competitive markets such as New Zealand.

The study was conducted utilising existing data sources gained through extensive literature searches, recalibrated and updated where necessary. Where no data source existed in the literature, expert co-operators were sought who were asked to provide specific analyses regarding losses through various diseases.

MBS also extensively interviewed research and regulatory staff in the majority of Australian animal health firms, as well as representatives of industry bodies, research organisations and experts in private consultancy. To gain some perspective with regards the Australian regulatory environment, key staff from the New Zealand Food Safety Authority and Agcarm (NZ), were also personally interviewed.

Members of the Animal Health Alliance were also surveyed in order to understand the effect of regulatory delays or barriers to the introduction of innovative products to the Australian market. Measures of innovation were given as guidelines to classify products, and experienced personnel were asked to estimate reasonable timelines based on experience, risk and overseas standards.

Where losses and costs attributable to a condition arising from a disease or group of diseases have proven to be more quantifiable, then that condition is included.

Loss of production can often be attributable to nutritional, environmental or other non-disease causes. Such cases have been largely excluded from the study unless the data confirms such losses arise from primary disease. Infrequent or irregular catastrophic losses, especially in intensive industries, have also been excluded.

Quantification of Disease

Disease losses, prevention and treatment are major costs to the animal production and processing sector of the Australian farming community. Each year producers of beef, sheep, wool, pigs, eggs, chickens and dairy products face production losses of $936 million due to disease. They incur $819 million in additional expenses in an attempt to either prevent or treat disease outbreaks.

The most important industry from a disease perspective is sheep production which has a combined cost of loss and treatment of $761 million, followed by beef production at $509 million, dairy at $275 million, poultry at $109 million and pigs at $101 million.

The major diseases/conditions include external parasites of sheep and cattle ($562 million); gastro intestinal parasites in sheep and cattle ($328 million); mastitis in dairy herds ($141 million) and footrot in sheep ($109 million). Reduced income includes losses from both clinical and sub clinical manifestations of disease. Increased expenses include both preventative and corrective treatment, and where possible, associated costs such as labor and management.

Table 1 – Losses and Costs from Disease in Major Production Industries (2007 est)

	Reduced Income	**Increased Expenses**	**Total**
Industry	$	$	$
Beef Cattle	303,810,939	204,769,377	**$ 508,580,316**
Sheep	382,675,176	377,221,327	**$759,896,503**
Dairy Cattle	176,691,000	98,780,000	**$275,471,000**
Layer Poultry	9,192,300	25,800,000	**$34,992,300**
Broiler Poultry		73,902,600	**$73,902,600**
Swine	62,120,500	38,896,000	**$101,016,500**
Total	**$934,489,915**	**$819,369,304**	**$1,753,859,219**

Regulatory Environment

As evidenced above the cost of disease treatment and loss is significant in the national economy. Despite some 40 years of progress and scientific innovation, production losses from disease and pests still cost Australian farmers close to $1 billion per annum.

Farmers rely upon innovative products to tackle the challenge of disease. Timely availability of such products contributes to the competitiveness of industry, particularly when that industry is exposed to international competition. This is particularly true for our export

oriented industries such as beef, dairy, sheep, meat and wool, where competitors with access to more efficient means of production gain significant advantage.

A report into the animal health industry conducted by Business Decisions Ltd (2007) commissioned by the Alliance and the International Federation for Animal Health observed that the establishment of the Australian Pesticides and Veterinary Medicines Authority (APVMA) would provide an efficient process to implement the National Registration Scheme (NRS). The result was deemed positive at the time... "*This, combined with the emphasis on rapid science-based risk assessment by APVMA, created substantial benefits for companies, making market access easier and speeding up innovation.*".

More recent changes to the regulatory framework and its processes are perceived by member companies to have diminished these benefits, and in many cases market access is believed to be more difficult and innovation discouraged compared with other similar and competitive markets.

The Business Decisions Ltd study reported that the current regulatory environment increases both the time and cost of product development, elevates levels of uncertainty, and re-directs resources away from innovation. The effects of this are significant given the domestic R&D expenditures of animal health companies exceed A$50 million.

Significant insights into the Australian regulatory environment were gained through the member interview process and interviews with New Zealand regulatory personnel.

A measure of stagnation in the regulatory process was obtained through a survey of the majority of members companies in the Alliance. Qualified and experienced professionals within these organisations were asked to quantify the degree of delay (beyond reasonable expectations, based on science and data) in bringing innovative products to market. They were also asked to indicate the number of innovative products (available elsewhere) that could benefit Australian farmers but were not contemplated for launch due to regulatory barriers. Results were aggregated and rated to maintain commercial confidentiality issues.

<u>Products Delayed (Production Animal only)</u>

- *Over the last 4 years some 19 products of significant innovation (scaled 1-10) were delayed due to new difficulties in the regulatory process.*
- *The average delay period was 28 months over what would have been deemed reasonable by the regulatory professionals.*
- *APVMA issues concerning chemistry, safety or efficacy were evident in 11 cases.*
- *Delayed AQIS clearances were evident in 8 cases.*
- *APVMA trade issues delayed 3 cases.*

Products Available Elsewhere but not in Australia (Production Animals Only)

- *Some 20 major products of significant innovation (scaled 1-10) are available in other, competitive markets but are not contemplated for launch due to costs and idiosyncrasies in the Australian regulatory process.*
- *Some 17 products were relevant to the Beef and Dairy industries.*
- *5 products would be of significant benefit to the Pig and Poultry industries.*
- *AQIS policies on TSE and vaccines are preventing the introduction of at least 12 products.*
- *4 products have issues with regards the APVMA position on local efficacy or trade.*
- *Another 4 products relate to APVMA/NH&MRC positions on antibiotics.*

In every case these products are available in similar, competitive markets, often for many years. This is particularly the case for the New Zealand market where the regulatory environment allows farmers better access to innovative products. Many of the Alliance members operate in both markets.

Executive interviews conducted with the industry and regulatory officials in New Zealand illustrated the following:

1. The level of cooperation and more importantly, coordination, between the various stakeholders is high. This includes NZFSA, ERMA, Animal Health companies, processors and producers.
2. NZFSA has a strong risk management focus. It is able to address the major issues via policy and manages the minor risks by exception. The major policy and minor risk management processes are largely science and statistics based.
3. NZFSA readily accepts internationally recognised standards, such as Codex.
4. NZFSA readily accepts existing efficacy, safety and residue data, all other things being equal.
5. The New Zealand regulatory system appears to control risk at many points in the production and processing chain. Trade risk accountability is spread, as opposed to being focussed on the registration process.

1. Background

Diseases of production animals cause major economic loss to Australian agriculture. Such diseases in beef cattle, dairy cattle, sheep, swine and poultry are usually controlled by the provision of nutritional supplements and/or the application of medicinal or biological agents to either prevent or alleviate the condition. Producers rely upon scientific advances to provide timely and cost effective solutions for the treatment of diseases and conditions, allowing downstream industries involved in the production of food and fibre to compete effectively in both domestic and international markets.

The animal production industry in Australia is fragmented. Whilst the beef and sheep production sectors share some similarities in their producer base (diseases and centralised marketing of outputs, eg: red meat/Meat and Livestock Australia); the swine, poultry and dairy sectors represent a stronger degree of differentiation. As a consequence, there is little commonality in the disease importance profile, and even less in the understanding of the economic effects of these diseases. Many of the representative industry organisations and associated research bodies have not holistically quantified the economic effects of disease as most funding has been directed at marketing, production efficiency or the minimisation of a specific disease threat. An exception has been a 2006 study commissioned by MLA and Australian Wool Innovation and conducted by Sackett, Holmes et al. This report is a thorough assessment of the costs and losses associated with diseases in the Beef and Wool industry

The disease landscape is ever changing. Therefore any restriction or delay in the availability of modern animal health solutions will result in an economic impact for producers, as well as the competitiveness of downstream processing industries. This is especially true when such solutions are available in competitor countries, but are either not available or suffer delayed entry in the domestic market.

Animal health companies and regulatory authorities have therefore had to make many decisions on funding, priorities, resources and desired outcomes with no encompassing view of the economics of disease in production industries. Such an understanding becomes critically important in light of the tightly controlled and conservative regulatory environment in Australia.

The Australian regulatory environment is characterised by aversion to risk. This is understandably driven by the desire to minimise the threat from many exotic diseases or pests that are either not present in this country, or are adequately controlled. The consequences of failure are considered to include effects on trade, public safety, production and reputation. The major bodies that influence the regulatory and registration process include the APVMA (efficacy, chemistry, toxicology/residues, OH&S, registration and trade – directly or through federal or state bodies), NH&MRC (anti microbial resistance, public health), Biosecurity Australia (policy level disease and pest risk), AQIS (import risk). Other expert groups or interested parties are also often invited to give input regarding registration decision making although lack of transparency inhibits the ability to gauge their level of influence.

A particular source of complexity appears to the close association of trade issues with the regulatory process. The de facto regulation of trade compliance at the point of product

registration presents risks, costs and challenges to animal health companies that are not necessarily science based. Many Australian animal health firms struggle with this additional scope of activity, as well as question the efficiency and appropriateness of such controls.

2. Objectives

Animal Health Alliance (Australia) Ltd, ("the Alliance"), representing the majority of animal health companies present in the Australian market (by $ sales), wished to more fully explore and understand the costs to Australian industry of major production animal diseases, as well as the additional costs incurred or opportunities foregone due to the absence or delayed entry of veterinary medicines/biological available elsewhere.

Menari Business Solutions (MBS) was commissioned to conduct a study evaluating the cost of disease in the Australian production animal industries. The major objective of the study was to fully analyse the costs associated in treating the major diseases of the beef, sheep, swine, poultry and dairy industries as well as understanding the associated production loss to farmers and producers when such diseases occur.

The diseases/conditions considered were those identified as being –

- Optimally treated and of economic importance;
- Sub optimally treated and of economic importance;
- Currently subject to obligatory compliance treatment;
- Untreated but of present or future economic importance.

In light of this quantification, MBS was also asked to evaluate the current regulatory environment so as to understand the gaps and opportunities that exist in the products available to Australian farmers, particularly with respect to similar competitive markets such as New Zealand.

3. Methodology

The study was conducted utilising existing data sources gained through extensive literature searches, recalibrated and updated where necessary. Where no data source existed in the literature, expert co-operators were sought who were asked to provide specific analyses regarding losses through various diseases.

Various industries differ in the focus they have on disease or condition. The beef and sheep industries clearly target diseases in their research programs and are therefore easily measured and validated using common and consistent data. Other industries focus their research efforts on conditions, with the groupings largely driven by economics. Examples of this are pneumonia and scours in swine; or reproduction and lameness in dairy cattle. Where losses and costs attributable to a condition arising from a disease or group of diseases have proven to be more quantifiable, then that condition is included.

Basic disease models for each industry were constructed using data available from existing studies, industry bodies and literature searches. Where necessary, expert co-operators were then asked to provide input to each model to quantify costs, losses and incidence. In instances where a number of data sources were used these co-operators were asked to verify the validity and accuracy of estimates and assumptions.

Loss of production can often be attributable to nutritional, environmental or other non-disease causes. Losses estimated by Sackett et al in the beef and sheep industry but not included in this study include those from under nutrition (beef), heat stress (beef), post weaning mortality (sheep), various grass toxicities (sheep), peri-natal mortality (sheep). Similarly the losses to replacement chicks in broiler operations were also excluded due to the uncertainty associated with distinguishing between management and disease.

Infrequent or irregular catastrophic losses, especially in intensive industries, have also been excluded. This is of particular significance to the swine industry as the prevention of such outbreaks is the focus of considerable resources allocated to both the veterinary and piggery management sectors. Many of the solutions to preventing such catastrophic events are found in various management innovations

Reduced income includes losses from both clinical and sub clinical manifestations of disease. Reductions are estimates based on current disease incidence and therefore allow for situations of minimal or no disease prevention. Increased expenses include both preventative and corrective treatment, and where possible, associated costs such as labour and direct/specific preventative management. Totals are derived from the mixed environment whereby animals are given a range of measures to prevent disease, a range of therapies to treat disease once encountered, and suffer production losses that vary according to the type of treatment they receive, if at all.

MBS also extensively interviewed research and regulatory staff in the majority of Australian animal health firms, as well as representatives of industry bodies, research organisations and experts in private consultancy. To gain some perspective with regards the Australian regulatory environment, key staff from the New Zealand Food Safety Authority and Agcarm (NZ), were also personally interviewed.

Members of the Animal Health Alliance were also surveyed in order to understand the effect of regulatory delays or barriers to the introduction of innovative products to the Australian market. Measures of innovation (1=generic copy to 10=new and innovative chemistry) were given as guidelines to classify products, and experienced personnel were asked to estimate reasonable timelines based on experience, risk and overseas standards.

Products were screened and those with low levels of innovation were excluded. As a guide those ranked 4 and above provided innovation ranging from delivery mechanisms and combined therapies (at the lowest level), to new and important indications (mid level), through to new chemistry and species (at the highest).

The survey was not conducted as an audit. It was a large sample (eight firms) consisting of the majority of major animal health companies in Australia. No attempt has been made to extrapolate, therefore all figures should be viewed as minimum actuals.

4. Results and Discussion

4.1 Beef Cattle

The beef cattle industry has three different production systems that are relevant from a disease perspective. Diseases/conditions such as cattle tick, tick fever and buffalo fly are significant contributors to loss in northern (sub tropical) systems; whereas bloat, gastro intestinal parasites and pinkeye prevail in southern (temperate) systems. A major cost to feedlot systems is the control of and losses from bovine respiratory disease. Many northern herds and some southern herds are at risk from bovine ephemeral fever.

Table 2 - Beef Cattle: Costs and expenses per annum by disease/condition

	Reduced Income	**Increased Expenses**	**Total**
Disease/Condition	$	$	$
Bloat	32,178,200	16,418,910	48,597,110
Gastro Intestinal Parasites	28,107,193	11,370,213	39,477,406
Pink Eye	19,495,482	3,725,546	23,221,028
Grass Tetany	969,407	10,553,466	13,522,873
Cattle Tick	44,019,065	99,776,546	143,795,611
Bovine Ephemeral Fever	64,319,058	35,732,810	100,051,868
Buffalo Fly	65,147,215	11,885,146	77,032,361
Tick Fever	928,199	6,749,590	25,677,789
Bovine Respiratory Disease	28,647,120	8,557,150	37,204,270
Total Beef	**$303,810,939**	**$204,769,377**	**$508,580,316**

Beef cattle data were largely sourced from a recent (April 2006) study commissioned by the Meat and Livestock Association, in association Australian Wool Innovation Ltd (Sackett et al). Data sets arising from the 2001 census were recalibrated at 2007 levels. Conditions arising from non disease sources were excluded.

4.2 Sheep

The sheep industry continues to suffer significant losses from both gastro intestinal and external parasites. The rapid development of resistance in the parasite population, coupled with the “niche” status of sheep products in major product development programs of research based companies, means that products quickly suffer reductions in efficacy and are not easily replaced. Of particular note is the large in balance between reduced income and treatment/prevention (increased expenses) for gastro intestinal parasites. No doubt anthelmintic resistance issues will have a significant effect on control strategies, as will the excessive demographic “tail” of sheep producers. Clearly this area provides one of the greatest opportunities to increase industry returns using pharmacological and management solutions. The aggregation of fly strike conditions presents a different challenge, that being to minimize preventative management expenses.

Table 3 – Sheep: Costs and expenses per annum by disease/condition

	Reduced Income	Increased Expenses	Total
Disease/Condition	$	$	$
Gastro Intestinal Parasites	242,894,560	46,117,189	289,011,749
Body Fly Strike	23,258,349	57,675,043	80,933,392
Breech Fly Strike	19,932,656	95,087,613	115,020,269
Pizzle Fly Strike	21,571,667	1,831,547	23,403,214
Lice	30,509,564	65,534,521	96,044,085
Bacterial Enteritis	18,203,797	4,878,460	23,082,257
Arthritis	20,321,796		20,321,796
Footrot	3,973,367	104,652,210	108,625,577
Ovine Johnes Disease	2,009,420	1,444,744	3,454,164
Total Sheep	**$383,988,808**	**$377,221,327**	**$761,210,135**

Sheep data were largely sourced from a recent (April 2006) study commissioned by the Meat and Livestock Association, in association Australian Wool Innovation Ltd (Sackett et al). Data sets arising from the 2001 census were recalibrated at 2007 levels. Conditions arising from nutrition related causes were excluded.

4.3 Dairy Cattle

Dairy production in Australia has largely been concentrated in the south eastern temperate zone over the last 20 years and as a consequence most of the disease profile has been standardised. This is illustrated by the decline in sub tropical herds as a proportion of national milk production, thereby minimizing the role of cattle tick and buffalo fly in production loss. Whilst dairy cattle will suffer similar health issues to beef herds under like conditions, the key contributors to loss in dairy systems are those associated with mastitis, lameness and reproduction. A number of factors can contribute to these conditions and as such the industry tends to measure and treat these conditions rather than the specific disease. The Count Down Downunder program is a joint funded (Dairy Australia, State Departments of Primary Industry/Agriculture) to improve mastitis control and minimize associated loss. Significant data has been collected over the last 10 years to measure losses associated with mastitis.

Table 4 – Dairy Cattle: Costs and expenses per annum by disease/condition

	Reduced Income	Increased Expenses	Total
Disease/Condition	$	$	$
Mastitis Clinical	102,821,000		102,821,000
Mastitis Cell Counts	37,950,000		37,950,000
Mortality- Metabolic and Disease	35,920,000		35,920,000
Disease Treatment and Prevention		98,780,000	98,780,000
Total Dairy	**$176,691,000**	**$98,780,000**	**$275,471,000**

Dairy cattle data were not available from the industry body or from any centralised study. Indicative data was gained from health professionals within the industry. Specific mastitis information was sourced from the Count Down Downunder program. Mastitis cell counts were used as a measure of sub clinical loss. General disease treatment and prevention was aggregated under general veterinary costs. ABS data from 2007 was used to calibrate.

4.4 Layer Poultry

The layer industry is characterised by intensive production, significant potential for disease outbreak and therefore high costs in prevention. This is due to the longer lifespan of the layer, a high incidence (80%) of intensive cage production and some specific diseases of increased relevance to layers production (Egg Drop Syndrome). Production systems are similar across the industry. Considerable research appears to be targeted at the prevention (or worst case, control) of outbreaks of exotic diseases. Endemic disease is well controlled through a combination of prevention and treatment.

Table 5 – Layer Poultry: Costs and expenses per annum by disease/condition

	Reduced Income	**Increased Expenses**	**Total**
Disease/Condition	$	$	$
Coccidiosis	97,500	600,000	697,500
Necrotic Enteritis	16,800	900,000	916,800
Fowl Pox	96,000	1,200,000	1,296,000
Mareks Disease	720,000	2,400,000	3,120,000
Infectious Bronchitis	1,200,000	1,800,000	3,000,000
Newcastle Disease		3,000,000	3,000,000
ILT		840,000	840,000
Egg Drop Syndrome (EDS)	1,440,000	1,200,000	2,640,000
Mycoplasma	612,000	2,400,000	3,012,000
Infectious Coryza	294,000	2,880,000	3,174,000
Fowl Cholera	1,386,000	2,880,000	4,266,000
Spotty Liver	2,070,000	900,000	2,970,000
Salmonella	1,260,000	4,800,000	6,060,000
Total Layer	**$9,192,300**	**$25,800,000**	**$34,992,300**

Layer poultry data were not available from the industry body or from any centralised study. Indicative data was gained from health professionals within the industry. Disease prevention, incidence, treatment and loss data were compiled by industry co-operators and validated by cross referencing. Costs and losses were separated for both barn and cage production systems. ABS data from 2007 was used to validate. Catastrophic event data were excluded.

4.5 Broiler Poultry

The broiler industry is characterised by the production of large volumes of relatively short lived birds by highly concentrated industry operators under shed conditions. The emphasis is on prevention of disease and whilst major disease outbreaks are rare, the effect is generally catastrophic in nature. Production systems are highly similar across industry. Again, control of potential outbreaks of exotic disease is high on the research agenda.

Table 6 – Broiler Poultry: Costs and expenses per annum by disease/condition

	Reduced Income	Increased Expenses	Total
Disease/Condition	$	$	$
Coccidiosis		16,422,800	16,422,800
Mareks Disease		16,422,800	16,422,800
Fowl Pox		8,211,400	8,211,400
Infectious Bronchitis		12,317,100	12,317,100
Newcastle Disease		20,528,500	20,528,500
Total Broiler		**$73,902,600**	**$73,902,600**

Broiler Poultry data were not available from the industry body or from any centralised study. Indeed this industry had the least amount of information available, due to the concentration of production and consequent confidentiality issues. Industry co-operator information was used to estimate disease treatment costs. Losses were not estimated as overall mortality in this industry is low (adequate disease prevention and short animal lifespan), and mortality is often attributable to environmental/management causes. Catastrophic event data were excluded.

4.6 Swine

The swine industry, along with most other intensive industries has a significant body of research available on specific diseases and conditions but little on the overall cost. This is largely due to many of the diseases/conditions having significant management components in both their cause and eradication. Given the fact that this industry is also characterised by fragmentation of producer base as well as a high degree of variation in production systems, there is little chance of finding a typical or representative production unit. Indicative information is available from health and production professionals within the industry, usually with the caveat of “if there is an outbreak”. The fact that many well managed units do not have outbreaks is often due to the low disease status and risk profile of their production system.

In the model below an overall health treatment cost was separated from agreed losses per sow by disease /condition. Specific treatment costs for leptospirosis and atrophic rhinitis were stripped out and the remainder of the table “solved” against a total treatment cost to get a measure of income loss vs increased expenses.

Table 7 – Swine: Costs and expenses per annum by disease/condition

	Reduced Income	Increased Expenses	Total
Disease/Condition	$	$	$
Mycoplasma	20,020,000		20,020,000
Pleuropneumonia	18,304,000		18,304,000
Swine Dysentery	28,600,000		28,600,000
Atrophic Rhinitis		10,420,000	10,420,000
Mange	17,160,000		17,160,000
Leptospirosis		6,512,500	6,512,500
(Health Cost)	(21,963,500)	21,963,500	
Total Pigs	**$62,120,500**	**$38,896,000**	**$101,016,500**

Swine data were not available from the industry body or from any centralised study. Indeed much of the research was focussed on individual diseases rather than overall incidence. A body of reports by Cutler et al, starting in 1985 and continuously updated through to 2001 were used extensively and recalibrated to 2007 data. Differing data sets provided by industry co-operators were used to triangulate costs and losses and allow separation of diseases within the category of respiratory diseases. The costs attributable to the different causes of swine dysentery were impossible to separate and are therefore aggregated. Catastrophic event data were excluded.

4.7 Member Regulatory Audit

Significant insights into the Australian regulatory environment were gained through the member interview process and interviews with New Zealand regulatory personnel.

The report by Business Decisions Ltd illustrated the degree of frustration experienced by member companies of the Alliance, and well as conveying sense of disappointment that the efficiencies sought through the creation of the APVMA had not eventuated or had been eroded.

The key issues raised by member companies were:

1. Delays due to underfunding, understaffing, or a failure to retain skilled and experienced staff at the APVMA. Particular emphasis was placed on recent delays in the Chemistry section, however members were strongly of the view that delays due to funding, training and staff turnover were endemic.

2. Failure in overall coordination and consistency between, and transparency of, decision making bodies such as Biosecurity Australia (BA), AQIS, APVMA and NH&MRC.

3. Reduced emphasis on science in the decision making process, in particular, the issue of TSE (Transmissible Spongiform Encephalopathies). Members believe the current nil risk approach by both BA and AQIS is unsupported by science, inconsistent with other similar markets (eg: NZ), costly to comply with, a barrier to innovation and a disincentive to maintain even older generation products in registration.

4. Continued reluctance to recognise international data. Whilst the members continue to support local efficacy, safety and residue studies when appropriate, it appears that the regulatory process has made little progress in recognising offshore data when the risk is low.

5. Trade compliance at point of regulation. Australia continues to minimise much of its trade risk at the product registration level through ensuring that products export slaughter intervals (ESI) comply with overseas market requirements. Unfortunately a nil risk philosophy ensures that Australian animal health companies also incur significant costs and delays preparing their products for registration, particularly for minor use markets. More pragmatic and practical solutions related to mitigation of risk, product segregation, harmonization with Codex and LoD/LoM are generally not considered. The result at best is increased costs to companies, often a product withdrawal, and worst case from an Australian producers' perspective, a termination of vital research programmes.

A measure of stagnation in the regulatory process was obtained through a survey of the majority on members companies in the Alliance. Qualified and experienced professionals within these organisations were asked to quantify the degree of delay (beyond reasonable expectations, based on science and data) in bringing innovative products to market. They were also asked to indicate the number of innovative products (available elsewhere) that could benefit Australian farmers but were not contemplated for launch due to regulatory barriers. Results were aggregated and rated to maintain commercial confidentiality issues.

<u>Products Delayed (Production Animal only)</u>

- *Over the last 4 years some 19 products of significant innovation (scaled 1-10) were delayed due to new difficulties in the regulatory process.*
- *The average delay period was 28 months over what would have been deemed reasonable by the regulatory professionals.*
- *APVMA issues concerning chemistry, safety or efficacy were evident in 11 cases.*
- *Delayed AQIS clearances were evident in 8 cases.*
- *APVMA trade issues delayed 3 cases.*

<u>Products Available Elsewhere but not in Australia (Production Animals Only)</u>

- *Some 20 major products of significant innovation (scaled 1-10) are available in other, competitive markets but are not contemplated for launch due to costs and idiosyncrasies in the Australian regulatory process.*
- *Some 17 products were relevant to the Beef and Dairy industries.*
- *5 products would be of significant benefit to the pig and poultry industries.*
- *AQIS policies on TSE and vaccines are preventing the introduction of at least 12 products.*

- *4 products have issues with regards the APVMA position on local efficacy or trade.*
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In every case these products are available in similar, competitive markets, often for many years. This is particularly the case for the New Zealand market where the regulatory environment allows farmers better access to innovative products. Many of the Alliance members operate in both markets.

4.8 New Zealand Regulatory Evaluation

Feedback from Alliance member companies illustrated significant differences in the regulatory outcomes in New Zealand compared to Australia.

The New Zealand animal production industry is one of the most export oriented in the world. Its products compete strongly in overseas markets with Australian beef, lamb, dairy and wool and it generally enjoys similar benefits to Australia with regards to its disease and pest free status.

Most Alliance members quoted the comparative smoothness and transparency that they experienced in the New Zealand regulatory process, clearly evidenced by the greater range of new and innovative products available for New Zealand producers.

A strong point of difference between Australia and New Zealand is illustrated by the approach to TSE/BSE. The NZFSA recognises assessments made, among others, by bodies such as the OIE (World Organisation for Animal Health) through its Terrestrial Animal Health Code. Such assessments allow many advanced biological products to be marketed in New Zealand, products that are not allowed into Australia due to local provisions.

Executive interviews conducted with Alliance members in Australia and industry and regulatory officials in New Zealand illustrated the following:

1. The level of co-operation and more importantly, co-ordination, between the various stakeholders is high. This includes NZFSA, ERMA, Animal Health companies, processors and producers.
2. NZFSA has a strong risk management focus. It is able to address the major issues via policy and manages the minor risks by exception. The major policy and minor risk management processes are largely science and statistics based.
3. NZFSA readily accepts internationally recognised standards, such as Codex.
4. NZFSA accepts existing efficacy, safety and residue data, all other things being equal.

The New Zealand regulatory system appears to control risk at many points in the production and processing chain. Trade risk accountability is spread, as opposed to being focussed on the registration process. Other risks are recognised as manageable and are addressed using a multilayered approach.

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6. Appendices

6.1 Interviews Conducted (number)

Agcarm – Graeme Peters (1), Jan Quay (1)

Australian Farm Institute – Michael Keogh (2)

Bayer Australia Ltd – Neil Cooper (2)

Boehringer Ingelheim Pty Ltd – Ian Douglas (2), Jillian Walker (2)

Elanco Animal Health – Lisa Wade (2), Kim Agnew (1), Darryl Meaney (1)

Fort Dodge Australia Ltd – David Chudleigh (2)

Intervet Schering Plough – Rebecca Halligan (3), Mark Albrecht (1)

Meat and Livestock Australia Ltd – Michael Goldberg (1)

New Zealand Food Safety Authority – Debbie Morris (1), Warren Hughes (1)

Novartis Animal Health Australasia Pty Ltd – Stephen Neutze (1), Harry Collins (1)

Pfizer Animal Health – Mike Van Blommestein (3), Domenic Dell'Osa (2), Les Cooper (2), Ross Henderson (1)

Virbac (Australia) Pty Ltd – Paul Martin (2)

6.2 Industry Sources and Co-operators

Australian Chicken Meat Federation – Vivian Kite

Australian Egg Corporation – James Kellaway

Australian Pork Ltd – Darryl De Souza, Patricia Mitchell, Andrew Spencer

Australian Poultry CRC – Mingan Choct

Countdown Down Under Program – John Craven

Dairy Australia Ltd – Helen Dornom, Sandy McKendrick

Golden Cockerel Pty Ltd – Rod Jenner

IAS Management Services/ UQ – Kit Parke

Pork Journal – Peter Bedwell

Ross Cutler and Assoc – Ross Cutler

Scolexia Pty Ltd – Peter Scott

6.3 Advice from NZFSA regarding BSE and SPF Eggs

<Email communication 2nd Oct 2008 (Reproduction permission granted)>

John - we have followed up on the queries you raised in the meeting with Warren and me.

1. Eggs / Vaccines - we know it is a general requirement to use SPF eggs but we have no knowledge of why this would be limited to SPF from a specific country and there are no requirements over and above the general ones in relation to New Zealand

2. BSE / Milk - Trish talked to our New Zealand expert (who is also one of the international leading lights in this area) and his advice was as follows:

Milk and milk products pose no BSE risk. See the following clip from the 2008 Terrestrial Animal Health Code:

Article 11.6.1. General provisions and safe commodities

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1. When authorising import or transit of the following *commodities* and any products made from these *commodities* and containing no other tissues from cattle, *Veterinary Authorities* should not require any BSE related conditions, regardless of the BSE risk status of the cattle population of the *exporting country*, *zone* or *compartment*:
a) *milk* and *milk products*;
b) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;
c) hides and skins;
d) gelatine and collagen prepared exclusively from hides and skins;
e) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;
f) dicalcium phosphate (with no trace of protein or fat);
g) deboned skeletal muscle meat (excluding mechanically separated meat) from cattle 30 months of age or less, which were not subjected to a stunning process prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which passed ante-mortem and post-mortem inspections and which has been prepared in a manner to avoid contamination with tissues listed in Article 11.6.14.;
h) blood and blood by-products, from cattle which were not subjected to a stunning process, prior to *slaughter*, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process.

Hope this answers your queries
Regards

Debbie Morris
Director (Approvals and ACVM)
New Zealand Food Safety Authority

6.4 Listing by member company (blind) of delayed or absent products

Company	Delayed - Number of Products			Not Available - Number of Products		
	Innovation Ranking			Innovation Ranking		
	(4-5)	(6-7)	(8-10)	(4-5)	(6-7)	(8-10)
A	3	2			2	
B	1					2
C	3			1		
D			1		1	1
E	1		2	1		7
F	1					
G		1	1	4		1
H	1	1	1			
Total	**10**	**4**	**5**	**6**	**3**	**11**

6.5 Listing by type of delayed and absent products

Product Type	Delayed - Number of Products			Not Available - Number of Products		
	Innovation Ranking			Innovation Ranking		
	(4-5)	(6-7)	(8-10)	(4-5)	(6-7)	(8-10)
Anti-Coccidials	2		1			
Anthelmintics	3	1				
Other Vaccines and Antibiotics	3	2	3			
Ecto Parasiticides	2	1	1			
Vaccines				4	3	7
Antibiotics				2		3
Other						1
Total	**10**	**4**	**5**	**6**	**3**	**11**

6.6 Listing by species of delayed or absent products*

Species	Products Delayed				Products Unavailable			
	Innovation Ranking				Innovation Ranking			
	(4-5)	(6-7)	(8-10)	Tot	(4-5)	(6-7)	(8-10)	Tot
Beef**	2	2	2	**8**	4	1	10	**15**
Sheep	3	1	1	**5**				
Dairy**	1	1		**2**	2		2	**4**
Swine	1		1	**2**			2	**2**
Poultry	4	1	2	**7**	1	2	2	**5**

*Products may have more than one species application

**Many beef products will have common application in dairy but are not recorded as such