Import Risk Analysis: Cattle germplasm from all countries & Live cattle from Australia, Canada, the European Union,

and the United States of America.

REVIEW OF SUBMISSIONS

13 February 2009

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Policy and Risk MAF Biosecurity New Zealand



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Approved for general release

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Contents

Executive Summary 1		
1.	Introduction	4
2.5. 2.6. 2.7.	Review of Submissions DAVID BURT, FEDERATED FARMERS OF NEW ZEALAND ROBERT COURTNEY, AMBREED KEN COTTIER, LIVESTOCK IMPROVEMENT (LIC) NEIL & ROSE SANDERSON, ADVANCED GENETICS LTD ALLEN DONALD, GENETIC ENTERPRISES LTD LINDSAY BURTON, FONTERRA JOHN R CLIFFORD, USDA TRACY GALLAND, MEAT & WOOL NEW ZEALAND, THE MEAT INDUSTRY ASSOCIATION, AND DEER INDUSTRY NEW ZEALAND	6 12 14 18 19 21 22 23
3.3. 3.4. 3.5. 3.6. 3.7.	Copies of Submissions DAVID BURT, FEDERATED FARMERS ROBERT COURTNEY, AMBREED KEN COTTIER, LIVESTOCK IMPROVEMENT (LIC) NEIL & ROSE SANDERSON, ADVANCED GENETICS LTD ALLEN DONALD, GENETIC ENTERPRISES LTD LINDSAY BURTON, FONTERRA JOHN R CLIFFORD, USDA TRACY GALLAND, MEAT & WOOL NZ, THE MEAT INDUSTRY ASSOCIATION AND DEER INDUSTRY NEW ZEALAND	26 26 32 34 37 39 41 42 43

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Executive Summary

MAF Biosecurity New Zealand released the draft documents *Import Risk Analysis: Cattle germplasm from all countries* and *Import Risk Analysis: Live cattle from Australia, Canada, the European Union, and the United States of America* for public consultation on 18 July 2008. The closing date for public submissions on these documents was 12 September 2008.

This draft risk analysis for cattle germplasm covered the import of frozen bovine semen and *in vivo* derived bovine embryos from all countries. An initial list of 86 disease agents was compiled. Further consideration of these resulted in a preliminary hazard list of 37 disease agents or groups of disease agents, which were subjected to risk analysis. 28 of these preliminary hazards were considered to be potential hazards and were subjected to a risk assessment. A non-negligible risk was identified with the following hazards and options for risk management measures in order to effectively manage the risk associated with each of these hazards were presented:

Borna disease virus Bovine viral diarrhoea virus type 2 Crimean Congo haemorrhagic fever virus Foot and mouth disease virus Exotic bovine herpes viruses Lumpy skin disease virus Rift Valley fever virus Vesicular stomatitis virus Exotic Brucella spp. *Mycobacterium bovis* Mycoplasma mycoides subsp. mycoides SC Other exotic Mycoplasma spp. Exotic Salmonella spp. Exotic Leptospira spp. Chlamydophila abortus Coxiella burnetii

The draft risk analysis for live cattle examined the risks associated with the importation of cattle from Australia, Canada, the European Union (27 countries), and the United States of America. Of an initial list of 93 micro organisms or groups of organisms, 43 disease agents or groups of disease agents/diseases that are exotic to New Zealand or are the subject of a national eradication campaign in New Zealand, were included in a preliminary hazard list. Thirty four of these were considered to be potential hazards and were subjected to a risk assessment. A non-negligible risk was identified with the following hazards and options for risk management measures in order to effectively manage the risk associated with each of these hazards were presented:

Borna disease virus Exotic bovine herpes viruses Bovine viral diarrhoea virus type 2 Crimean Congo haemorrhagic fever virus Bovine ephemeral fever virus Foot and mouth disease virus Rabies virus Tick borne encephalitis viruses Vesicular stomatitis virus Bovine spongiform encephalopathy agent Bacillus anthracis Exotic Brucella spp. Mycobacterium bovis Exotic *Mycoplasma* spp. Pasteurella multocida types B and E Exotic Salmonella spp. Exotic *Leptospira* spp. Anaplasma spp. Chlamydophila abortus *Coxiella burnetii* Babesia spp. Theileria annulata Exotic lice, mites, and ticks *Hypoderma* spp. Exotic internal parasites Exotic weed seeds

Eight submissions were received, from Federated Farmers of New Zealand, AmBreed, Livestock Improvement (LIC), Advanced Genetics Ltd, Genetic Enterprises Ltd, United States Department of Agriculture, Fonterra, and the Meat Industry Association of New Zealand, Meat and Wool New Zealand, and Deer Industry of New Zealand.

Based on comments made by stakeholders in response to the published draft import risk analyses, this review of submissions document makes recommendations for changes required to amend the draft documents to final risk analyses. The next step in this process will be for the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ to draft an import health standard alongside a document that outlines the rationale for the preferred risk management measures. These documents will then be published for a six-week period of public consultation.

As a result of comments made in these submissions, it is recommended that the following changes should be made in the final risk analyses:

- The addition of tetracycline or macrolide antibiotics to imported germplasm will be added to the list of risk management options for *Chlamydophila abortus* in Section 38.3.1 of the bovine germplasm import risk analysis.
- Section 8.1.4 of the live cattle risk analysis and 7.1.4 of the bovine germplasm risk analysis will be amended to reflect the current OIE *Code* comments concerning the distribution of bluetongue virus.

• Table 1 (Hazard List) of the live cattle import risk analysis will be amended with respect to the notifiable status of Aujeszky's disease virus.

Comments made by Federated Farmers of New Zealand, Fonterra, and the Meat Industry Association of New Zealand, Meat and Wool New Zealand, and Deer Industry of New Zealand indicate a preference for the importation of germplasm in order to benefit from improved genetic material. These comments will be taken into account when prioritising the development of import health standards for bovine germplasm and live cattle.

1. Introduction

Risk analyses are carried out by MAF Biosecurity New Zealand under section 22 of the Biosecurity Act 1993, which lays out the requirements in regard to issuing Import Health Standards (IHSs) to effectively manage the risks associated with the importation of risk goods.

Draft risk analyses are written by the Risk Analysis Group and submitted to internal, interdepartmental, and external technical review before the draft risk analysis document is released for public consultation. The Risk Analysis Group of MAF Biosecurity New Zealand then reviews the submissions made by interested parties and produces a review of submissions document. The review of submissions identifies any matters in the draft risk analysis that need amending in the final risk analysis although the decision to implement these changes lies with an internal committee of MAF Biosecurity New Zealand. These documents inform the development of any resulting IHS by the Border Standards Group of MAF Biosecurity New Zealand for issuing under section 22 of the Biosecurity Act by the Director General of MAF on the recommendation of the relevant Chief Technical Officer (CTO).

Section 22(5) of the Biosecurity Act 1993 requires CTOs to have regard to the likelihood that organisms might be in the goods and the effects that these organisms are likely to have in New Zealand. Another requirement under section 22 is New Zealand's international obligations and of particular significance in this regard is the *Agreement on Sanitary & Phytosanitary Measures* (the "SPS Agreement") of the World Trade Organisation.

A key obligation under the SPS Agreement is that sanitary and phytosanitary measures must be based on scientific principles and maintained only while there is sufficient scientific evidence for their application. In practice, this means that unless MAF is using internationally agreed standards, all sanitary measures must be justified by a scientific analysis of the risks posed by the imported commodity. Therefore, risk analyses are by nature scientific documents, and they conform to an internationally recognised process that has been developed to ensure scientific objectivity and consistency.

MAF Biosecurity New Zealand released the draft documents *Import Risk Analysis: Cattle germplasm from all countries* and *Import Risk Analysis: Live cattle from Australia, Canada, the European Union, and the United States of America* for public consultation on 18 July 2008. Every step was taken to ensure that the risk analyses provided a reasoned and logical discussion, supported by references to scientific literature. The draft risk analyses were peer reviewed internally and externally and then sent for interdepartmental consultation to the Ministry of Health, the Department of Conservation and the New Zealand Food Safety Authority. Relevant comments were incorporated at each stage of this review process. The closing date for public submissions on the risk analyses was 12 September 2008.

Eight submissions were received. Table 1 lists the submitters and the organisations they represent.

This document is MAF Biosecurity New Zealand's review of the submissions that were made by interested parties following the release of the draft risk analyses for public consultation. Public consultation on risk analyses is primarily on matters of scientific fact that affect the assessment of risk or the likely efficacy of any risk management options presented. For this reason, the review of submissions will answer issues of science surrounding likelihood¹, not possibility², of events occurring. Speculative comments and economic factors other than the effects directly related to a potential hazard are beyond the scope of the risk analysis and these will not be addressed in this review of submissions.

Table 1. Submitters and Organisations Represented	ed
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Submitter	Organisation Represented/Location
David Burt	Federated Farmers of New Zealand
Robert Courtney	AmBreed
Ken Cottier	Livestock Improvement (LIC)
Neil & Rose	Advanced Genetics Ltd
Sanderson	
Allen Donald	Genetic Enterprises Ltd
John R Clifford	United States Department of Agriculture
Lindsay Burton	Fonterra
Tracy Galland	Meat Industry Association of New Zealand, Meat and Wool New Zealand, and
	Deer Industry of New Zealand

¹ Likelihood: The quality or fact of being likely or probable; probability; an instance of this.

² Possible: Logically conceivable; that which, whether or not it actually exists, is not excluded from existence by being logically contradictory or against reason.

2. Review of Submissions

2.1. DAVID BURT, FEDERATED FARMERS OF NEW ZEALAND

2.1.1. Federated Farmers recommends ... that the importation of live cattle from Australia, Canada, the European Union and the United States of America only be permitted from countries that are categorised by the OIE as posing a negligible BSE risk and where there is freedom from Foot and Mouth disease and where vaccination of cattle against Foot and Mouth Disease is not practised.

MAFBNZ response: Comments on the suitability of the options presented for risk management will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any IHS developed from these risk analyses.

As obliged under Article 3.1 of the WTO Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) the measures adopted in IHSs will be based on international standards, guidelines and recommendations where they exist, except as otherwise provided for under Article 3.3 (where measures providing a higher level of protection than international standards can be applied if there is scientific justification, or if there is a level of protection that the member country considers is more appropriate following a risk assessment).

2.1.2. Federated Farmers recommends ... that the importation of cattle germplasm only be permitted from countries where there is freedom from Foot and Mouth disease.

MAFBNZ response: Please see the response to 2.1.1 above.

2.1.3. Federated Farmers recommends ... that the literature concerning the possibility of TSE transmission by routes other than prions is considered and the implications for the importation of germplasm into New Zealand be evaluated.

MAFBNZ response: Although it could be argued that there remains some uncertainty regarding the aetiology of bovine spongiform encephalopathy, the study of Wrathall et al (2002) showed that embryos were unlikely to carry BSE infectivity even if they are collected at the end-stage of the disease, when the risk of maternal transmission is believed to be highest. As described in the import risk analysis, this position has been endorsed by IETS who have classified the BSE agent in Category 1 indicating that there is sufficient evidence to show that the risk of transmission is negligible.

Article 11.6.1 of the Terrestrial Animal Health Code 2008 further supports this position by stating that 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, for semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society. These international standards have been vigorously debated by the 172 Member Countries and Territories of the OIE and New Zealand has taken a lead role in their development.

Furthermore, as a signatory of the WTO SPS Agreement, New Zealand is required to base sanitary measures on international standards, where they exist. If measures more stringent than international standards are adopted, they must be based on a scientific risk assessment. The risk analysis explored the available science and there does not appear to be any evidence to challenge the international standards in this instance.

2.1.4. Federated Farmers recommends ... where the above conditions relating to BSE and Foot and Mouth Disease have been met, that the risks associated with the other diseases under consideration be managed using a combination of options (in decreasing order of effectiveness):

Importation of animals/germplasm from countries or zones that are free from the disease.

Testing of animals/germplasm and treatment for disease status.

Quarantine prior to shipment with or without testing and clinical examination

MAFBNZ response: Noted

2.1.5. Federated Farmers recommends ... that the present risk assessment status of "negligible" for diseases in which *Culicoides* spp are implicated as vectors - Akabane Disease, Bluetongue and Palyam Virus infections – be reviewed in the light of information to be presented by the Meat Industry Association of New Zealand and Meat and Wool New Zealand in their Submission.

MAFBNZ response: The submission from the Meat Industry Association, Meat and Wool New Zealand and the Deer Industry Association of New Zealand is addressed later in this document. Please see Section 2.8.

2.1.6. Federated Farmers recommends ... that consideration is given to the provision of some background material to help place the subject matter in context.

MAFBNZ response: Some background information is provided in the "special considerations" section of both the cattle germplasm risk analysis (Section 4.5) and the live cattle risk analysis (Section 5.5). Although further information could be provided in these documents this would have no impact on the findings of both risk analyses.

2.1.7. The information on which the Australian status is based is, however, over ten years old. If there is any reason to believe this status may have since changed, particularly with regard to zoonotic hazards, then such organisms should be classified as "of concern".

MAFBNZ response: MAFBNZ has the flexibility to modify any IHS based on these risk analyses if an exporting country is subject to an exotic disease incursion.

Veterinary certificates will be required from exporting countries to certify country freedom from diseases and certification issues such as these will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ responsible for drafting any IHS based on the findings of these risk analyses.

2.1.8. The absence of definitions for the critical terms "negligible" and "non-negligible" is puzzling.

MAFBNZ response: Section 3.5.3 of MAFBNZ's risk analysis procedures defines "negligible" as "*not worth considering; insignificant*" and "non-negligible" is defined as "*worth considering; significant*."

2.1.9. When considering risk management, the document uses the term "could" as in "could be (an) effective ..." [eg Section7.3.1 (Anthrax), 10.3.1 (Salmonellosis)]. The use of the word in respect of risk management is ambiguous ... This ambiguity should be removed and replaced with the word "would" where its application would prove efficacious but the choice around the use of this measure is simply being presented as an option.

MAFBNZ response: The use of the word "could" when discussing risk management options reflects the fact that no decisions regarding sanitary measures have been made at this stage of the IHS development process.

2.1.10. The detail around this mechanism, where human intervention is required (such as management by means of quarantine measures) is inadequate. While some information about possible risk management frameworks for specific diseases is provided, effective risk management requires that a number of processes are involved, including monitoring and verification. The document provides no information on these and other key areas. It also gives no guidance around responsibility and accountability for risk management measures. In the absence of such critical information, it is not possible to support any risk management processes that rely on quarantine measures.

MAFBNZ response: Further detail surrounding such procedures will be provided when draft IHSs are written based on these risk analyses. These documents will be

subject to public consultation for a period of six weeks when stakeholders will have an opportunity to comment on these issues. Stakeholder submissions will be reviewed before a final IHS is issued.

2.1.11. "In line with the MAF Biosecurity New Zealand ...risk assessment methodologies ...the following analysis is carried out". Exposure assessment (b) is defined as "the likelihood of animals or humans in New Zealand being exposed to the potential hazard." This may (depending on what "animals" are defined here as) be better reworded as "the likelihood of animals or vectors (my emphasis) or humans in New Zealand being exposed ..." as non-animal vectors are also capable of harbouring and transmitting biological hazards.

MAFBNZ response: The wording used in the draft risk analysis is consistent with Article 2.2.4 of the current (2008) OIE *Code*, which states:

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of animals and humans in the importing country to the hazards (in this case the pathogenic agents) released from a given risk source, and estimating the probability of the exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

2.1.12. ...there is a substantial body of information in the scientific literature that suggests that changes in ambient temperature are likely to occur over New Zealand over the coming decades. This information could be used to assess the impact of any projected changes in vector and disease viability within New Zealand over an appropriate period – to coincide with the period between scheduled IHS reviews - and the risk analysis, and consequent IHS's could take this into account when they are developed.

MAFBNZ response: MAFBNZ risk analyses do not consider speculative events that could occur in the future, such as the possible establishment of disease vectors such as *Culicoides* spp. due to climate change. MAFBNZ has the flexibility to modify any IHS based on risk analyses when appropriate.

Please also see the response to 2.2.2 below.

2.1.13. The provision of some background material - either in the Draft Risk Analysis document or in the covering letter – to help place the issue in context, would be welcome.

MAFBNZ response: Please see the response to 2.1.6 above.

2.1.14. The absence of the importation of (tested) germplasm (except for BSE, Mollicutes Infections and Leptospirosis) rather than live animals as a risk management option in this document is puzzling.

MAFBNZ response: Section 5.4 of the import risk analysis for live cattle states "In addition to the options presented, unrestricted entry or prohibition may also be considered for all hazards".

Furthermore, MAFBNZ is able to consider information on benefits for New Zealand when determining the priority on the work programme for the subsequent development of import health standards for live cattle and bovine germplasm. The views expressed in submissions that germplasm import health standards provide the desired benefit of access to genetics will be taken into account during this prioritisation process.

2.1.15. The assumption about the viability of *Culicoides* spp in New Zealand is disputed by the Meat Industry Association of New Zealand and Meat and Wool New Zealand. In the light of the information that they will be including in their Submission, we strongly urge that the implications of their information be assessed and that the risk status of all diseases associated with *Culicoides* spp. be re-evaluated.

MAFBNZ response: The submission from the Meat Industry Association of New Zealand, Meat and Wool New Zealand, and Deer Industry of New Zealand is evaluated in Section 2.8 below.

2.1.16. Diseases present in germplasm but not cattle [Lumpy skin disease (GP Section 18); Rift Valley fever (GP, Section 24); Contagious bovine pleuropneumonia "CBPP" (GP, Section 32)] ...The consequences of any of these three diseases getting established in New Zealand would be very high, either from direct economic costs to affected farmers (CBPP, Rift Valley fever), trade impacts (CBPP, lumpy skin disease) or human health impacts (Rift Valley fever) ... For these reasons, we believe that strong measures are justified.

MAFBNZ response: Please see the response to 2.1.1 above.

2.1.17. Importation without restriction, or sanitary measures being applied, is not favoured as the sole risk management mechanism because there is still a risk that unwanted hitchhiker organisms, such as weed seeds, could be unknowingly imported. The country of origin of the source animals, will however play a major role in the in determining the 'package' of risk management measures that is required in any particular instance of animal importation, with testing and quarantine the other legs of the 'triage' process.

MAFBNZ response: Please see the response to 2.1.1 above.

2.1.18. Testing (of body fluids and other materials) and treatment (whether by vaccination or by the administration of particular drugs) could be used to manage many, but not all, of the diseases considered here, but its use without other measures would again pose

risks, both with respect to the importation of weed seeds and (eg) Mollicutes Infections.

MAFBNZ response: Please see the response to 2.1.1 above.

2.1.19. The use of this mechanism (*quarantine*) is presented as an option for the risk management of almost all the above diseases. Many of the diseases considered would also require the use of additional measures in conjunction with the quarantine process, such as testing of blood (eg Mycoplasmas, Q Fever) or other samples (eg faecal samples for Salmonellosis, Internal Parasites) samples to a more intensive management regime involving bedding (Ticks and Weed Seeds) ... In conjunction with the country of origin and appropriate testing – and with the proviso that the importation of germplasm as an alternative to the importation of live animals is not presented - the use of quarantine is a very important tool in the risk management of most of the exotic diseases assessed as presenting non-negligible risks.

MAFBNZ response: Please see the response to 2.1.1 above.

2.1.20. The risk estimation for this disease (*BSE*) in germplasm is given as 'negligible' on the basis that the prion is not transmitted in either semen or embryos. This may well be the case, but any evidence that the prion route is not the (only) mechanism of TSE infections should be very carefully evaluated given the potential animal and public health implications ... Given the long incubation period of the disease and the disastrous consequences on our international trade should BSE be imported into New Zealand very stringent risk management practice is required for this disease ... In view of these consequences, the importation of cattle should be prohibited from countries that have not been categorised by the OIE as posing a negligible BSE risk.

MAFBNZ response: Please see the response to 2.1.3 above. Comments on the suitability of the options presented for risk management will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any IHS developed from these import risk analyses.

2.1.21. In the case of foot and mouth disease however, the horrendous economic consequences should the disease enters the country mean that additional measures are justified and therefore ... The importation of germplasm should be prohibited from countries that are infected with foot and mouth disease and the importation of cattle from countries that are infected with foot and mouth disease or vaccinate against foot and mouth disease should also be prohibited.

MAFBNZ response: Please see the response to 2.1.1 above.

2.2. ROBERT COURTNEY, AMBREED

2.2.1. Any suggestion of a positive (bluetongue) test in this country would have very deleterious effect on our ability to export. I do not agree that a single test will not mean loss of country freedom status.

MAFBNZ response: Both the live cattle and bovine germplasm risk analyses reflect the wording of the OIE *Code* (2006) in this regard. This is repeated in the current version of the *Code* (2008):

A BTV free country or zone in which surveillance has found no evidence that Culicoides likely to be competent BTV vectors are present will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or infected zones. (Article 8.3.2)

2.2.2. Also if you are so sure Culicoides will not reach this shore why have a Culicoides surveillance program?

MAFBNZ response: Since 1991 New Zealand has operated an arbovirus and *Culicoides* spp. surveillance programme to provide evidence of New Zealand's disease freedom from bluetongue virus, epizootic haemorrhagic disease virus (serotype 2), Palyam (D'Aguilar) virus, and Simbu viruses. The programme consists of three components: serological survey in cattle, light trapping for *Culicoides* spp, and passive surveillance. This ongoing surveillance programme provides evidence for New Zealand's continued freedom from arboviruses and *Culicoides* spp. However, if events such as climate change result in the establishment of *Culicoides* spp. in New Zealand at some point in the future, MAFBNZ has the flexibility to then modify any IHS if appropriate.

2.2.3. ...Culicoides may not be the only carrier. Please note the following press release 27/08/2008.

In 2006, Bluetongue virus – which infects livestock – reached Northern Europe for the first time. Some people thought that the outbreak would be limited to that particular year, as winter was expected to kill off the midges that host and spread the disease, bringing the threat of infection to an end. In actuality, the disease escalated in the following year, spreading to the UK. So, how did the virus survive the winter?

Drs Anthony Wilson, Karin Darpel and Philip Mellor of the Institute for Animal Health have discussed this puzzling question in an Unsolved Mystery article, published in the open access journal PLoS Biology, freely available to read from publication on the 26th of August.

The answer to this question is of great practical importance, as it will affect both national and international trade of Ruminants, the livestock susceptible to infection, and will dictate trade rules for a long time even after the infection has passed. The answer is also relevant to how we can deal with bluetongue and other unpleasant midge-transmitted diseases in the future.

Dr Mellor said: "Although the major mechanism of bluetongue virus spread is undoubtedly that of

Culicoides midges feeding on infected ruminants, growing the virus and then transmitting it to further susceptible animals, other mechanisms may also be at work. These may assume greater importance during the midge-free season (winter), such as we in northern latitudes experience."

Wilson and colleagues point out that evidence to date does not support the winter survival of bluetongue virus in the eggs of Culicoides midges. An alternative hypothesis is that, in mild winters such as that of 2006-07 in northern Europe, sufficient infected midges might survive until they become active again in spring. The midges may enter livestock barns to overwinter. Two other possibilities for disease endurance during winter are that bluetongue is spread by some susceptible species of longlived ticks and/or by simple mechanical transmission by Melophagus ovinus, a wingless parasite that lives in the fleece of sheep.

Additionally, there is evidence from Australia that bluetongue virus can survive in midges and in a small proportion of infected cattle for three to four months, which would be long enough for winter to come and go without killing the virus.

Closer to home, the recent outbreaks of bluetongue in northern Europe have provided evidence for a different overwinter route—transplacental infections; the virus spreading from an infected pregnant animal to its fetus, a phenomenon also demonstrated by experiment. This phenomenon might be particularly important in cattle, where the long gestation period of nine months (four for sheep) means that the virus can grow and survive within a fetus, at just the right temperature, throughout the coldest of winters. There is also circumstantial evidence that cattle could become infected orally if they eat the afterbirth of an infected offspring from another cow.

As Dr. Mellor summarizes, "Experiments have revealed a toolbox of possible mechanisms, with the potential to interact with and complement one another."

MAFBNZ response: As the above press release states, the major mechanism of bluetongue virus spread is undoubtedly that of *Culicoides* midges feeding on infected ruminants, growing the virus and then transmitting it to further susceptible animals. New Zealand undertakes ongoing surveillance to demonstrate freedom from *Culicoides* spp. As indicated in the *Code*, a bluetongue-free country in which surveillance has found no evidence that *Culicoides* likely to be competent bluetongue vectors are present will not lose its free status through the importation of vaccinated, seropositive or infective animals, or semen or embryos/ova from infected countries or infected zones.

2.3. KEN COTTIER, LIVESTOCK IMPROVEMENT (LIC)

2.3.1. The fact that the (Akabane) virus has been isolated from mosquitoes, but there has been no work carried out to investigate whether NZ mosquitoes are competent vectors, seems to weaken the conclusion that risk management measures are not justified. The virus is also present in one of our closest trading partners, and it seems that until the work is done, caution should prevail. Simple measures such as insect proof semen collections or out of season collections could be put in place.

MAFBNZ response: *Culicoides* spp. are considered to be the principal vector for Akabane virus. Ongoing surveillance since 1991 has consistently demonstrated that New Zealand is free of *Culicoides* spp. Provided that ongoing surveillance continues to demonstrate New Zealand's freedom from arbovirus vectors, risk management measures for Akabane virus are not justified.

2.3.2. What we are saying if we allow importation of bovine semen without any bluetongue risk management, is that the presence of viraemic cattle in NZ is inconsequential. Just a few years ago there was much to do regarding a serological positive cattle beast that was in quarantine here in NZ. If a diagnosis of bluetongue was made in NZ, (for example in a foetus from a cow inseminated with semen containing BTV), the political ramifications may be significant, despite assurances from the OIE. My personal opinion is that risk management procedures for bluetongue should still continue for the importation of bovine semen. Some of the measures may also reduce risk of other arboviruses.

MAFBNZ response: Please see the response to 2.2.1 above.

2.3.3. Borna disease ... has been identified as a risk and that management measures are justified. However aside from a semen import prohibition from all countries that have Borna disease, it would seem that risk management options are unsatisfactory. Cattle are subclinically infected, so selection from herds that have no recent infection history is probably meaningless. Serology is unreliable and I assume PCR tests are not validated. Intracerebral inoculation for virus isolation sounds impractical for a routine diagnostic test for semen imports.

MAFBNZ response: Comments on the suitability of the options presented for risk management will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any IHS developed from these risk analyses.

2.3.4. The consequences of F& M in NZ are so serious that importation of bovine germplasm from infected countries should be prohibited. Countries that do not vaccinate and employ stamp out policies should be acceptable to import from within times frames related to the last outbreak.

MAFBNZ response: Please see the response to 2.3.3 above.

2.3.5. Ibaraki disease ... is in the same category as Bluetongue, Akabane and Palyam and similar arguments apply. Although risks are low, I believe we should have some risk management procedures in place.

MAFBNZ response: Because ongoing surveillance demonstrates New Zealand's freedom from *Culicoides* spp., risk management measures for Ibaraki disease are not justified. Please see the response to 2.3.1 above.

2.3.6. The hazard identification conclusion for (Jembrana) disease seems to be written for live cattle imports, rather than semen/embryo imports

MAFBNZ response: Section 17.1.5 (Hazard identification conclusion) states, "The virus could not be introduced by importation of **germplasm** from other cattle (*Bos indicus* or *Bos taurus*). Therefore the agent is not considered to be a potential hazard in the commodity."

2.3.7. Epizootic haemorrhagic disease and Palyam ...the diseases are similar to bluetongue and the same arguments apply

MAFBNZ response: Please see the response to 2.3.5 above.

2.3.8. Rabies...I agree with the conclusion that semen and embryos are commodities that are safe and require no risk management. However, there are reports of non-bite rabies transmission, so in the interests of safety, I would include simple safeguards such as vaccination and/or no rabies in the collection centre for the 6 months prior to collection.

MAFBNZ response: The entry assessment for rabies was considered to be negligible for both semen and embryos. Therefore risk management measures are not justified for this organism.

2.3.9. As a general comment on antibiotics in semen, it is recognised here at LIC that antibiotics are toxic to sperm, some antibiotics more than others. However enrofloxacin, which possibly is one of the better antibiotics against mollicutes, has been used in liquid (fresh) semen production with some success ... I do not understand the last option suggested in the risk management section. The culture of

mollicutes is notoriously difficult. The absence of culture positives may not mean a great deal.

MAFBNZ response: Comments on the suitability of the options presented for risk management will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any IHS developed from these risk analyses.

2.3.10. Anaplasmosis ... is one of those diseases that in theory should be transmitted by infected semen, but studies to date have not supported this. Anaplasma is found in blood cells, semen often will contain blood cells. The absence of clinical signs in donor bulls at the time of collection could be supported by the use of acaricides and/or tetracycline treatments

MAFBNZ response: There is no evidence that *Anaplasma* spp. can be transmitted in semen. Furthermore, given the requirement that semen will only be collected from clinically healthy donors (Section 3 of the import risk analysis; commodity definition), the entry assessment for this organism is considered to be negligible and risk management measures are not justified.

2.3.11. Has there been any consideration of antibiotics in semen and the survivability of Chlamydophila?

MAFBNZ response: There are no studies which have examined the susceptibility of bovine *Chlamydophila* isolates to commonly used antimicrobial agents.

Jones et al (1990)³ did demonstrate heterotypic resistance to tetracycline, erythromycin, and clindamycin in clinical isolates of *Chlamydia trichomatis*. Similarly, Lefevre and Lepargneur (1998)⁴ described heterotypic resistance to tetracycline in *Chlamydia trachomatis* in France. In both these cases it was noted that the resistant isolates did not grow well, suggesting that a resistant phenotype was associated with a cost to organism viability.

In contrast, a study of antimicrobial susceptibility on 50 clinical isolates of *Chlamydia trachomatis* recovered from patients in Israel concluded that all isolates tested were susceptible to the tested antimicrobials (macrolides and tetracyclines)⁵.

McOrist (2000)⁶ reviewed antibiotic resistance in obligate intracellular bacteria and commented that acquired resistance amongst these bacteria is rarely reported and

16 • ROS Import Risk Analysis: Cattle germplasm & Live cattle

³ Jones RB, Van der Pol B, Martin DH and Shepard MK (1990) Partial characterisation of *Chlamydia trachomatis* isolates resistant to multiple antibiotics. *The Journal of Infectious Diseases* 162, 1309-1315.

⁴ Lefevre JC and Lapargneur JP (1998) Comparative in vitro susceptibility of a tetracycline-resistant *Chlamydia trachomatis* strain isolated in Toulouse (France). *Sexually Transmitted Diseases* 25, 350-352.

⁵ Samra Z, Rosenberg S, Soffer Y and Dan M (2001) In vitro susceptibility of recent clinical isolates of *Chlamydia trachomatis* to macrolides and tetracyclines. *Diagnostic Microbiology and Infectious Disease* 39, 177-179.

⁶ McOrist S (2000) Obligate intracellular bacteria and antibiotic resistance. *Trends in Microbiology* 8, 483-486.

that tetracyclines and erythromycin have remained the first-choice drug for the major diseases caused by these bacteria since their launch. McOrist went on to comment that Gram-negative obligate intracellular bacteria have failed as a group to exhibit acquired resistance to antibiotics, for which numerous resistance pathways are common in other bacteria.

Reflecting the above, the addition of tetracycline or macrolide antibiotics to imported germplasm could be considered in order to effectively manage the risk due to *Chlamydophila abortus* in addition to the measures described in Section 38.3.1 of the draft import risk analysis for cattle germplasm from all countries.

2.4. NEIL & ROSE SANDERSON, ADVANCED GENETICS LTD

2.4.1. There is a new version of the IETS manual currently in the final stages of preparation due for printing very soon ... I am aware that this document is heavily revised on the previous versions and should be considered before finalising the Risk Analysis document as there are many references throughout the body of the document referring to historical documentation and data quoted by the IETS.

MAFBNZ response: MAFBNZ has the flexibility to amend risk analyses or IHSs if future publications question previously published scientific findings.

2.4.2. With respect to the risks associated with disease transmission in embryo washing, flushing, holding fluids. There are a number of preparations now available which are bovine serum free ... However most of the serum containing solutions undergo rigorous quality control as is stated in the document.

MAFBNZ response: Noted

2.4.3. Currently the existing protocols for importation of Bovine embryos all request Donor isolation or Quarantine either before and /or after flushing ... This is an expensive and at times unnecessary imposition given the low risks associated with embryo transmission of disease, and the questionable surety given by isolation ... It is almost prohibitive to obtain in milk dairy cows to collect because of this restriction and is seriously impacting on the genepool available to import from ... Owners do not want to send valuable cows off their farms, there are animal welfare issues associated with moving in milk cows and there are very few collection centres available to milk cows

...So I would request that all protocols are revisited and reassessed with these issues in mind and if any associated risk factors can be mitigated by either more tests on the donors especially post collection ,but on farm of origin, or embryo washing analysis e.g. by PCR, then this would enable more genetics to become available

MAFBNZ response: The commodity assessed in the import risk analysis for cattle germplasm was semen and embryos collected from places that meet the standards as specified in Sections 3.2.1 and 3.3.1 of the 2006 OIE *Code* (Chapter 4.5 and 4.7 of the 2008 *Code*).

These standards do not prohibit the use of on-farm collection. Further details of the requirements to be met will be clarified in draft IHSs developed from the published risk analysis, which will be released for a six-week period of public consultation.

2.4.4. New Zealand has been putting pressure on some of our trading partners to allow on farm collections to occur from NZ for export of Bovine Embryos so under the SPS agreement we must be consistent.

MAFBNZ response: Please see the response to 2.4.3 above.

2.5. ALLEN DONALD, GENETIC ENTERPRISES LTD

2.5.1. To our knowledge the only two countries that require this test on semen and embryo imports are Argentina & New Zealand. The testing for "Q Fever" is not a routine test in Al Collection Centres around the world. We would have to specifically request that it is done for NZ shipments. This results in delays and extra costs for us ... In summary I would request that as the risk is negligible that it is no longer a requirement.

MAFBNZ response: As indicated in the risk analysis, Q fever is recognised worldwide with the exception of New Zealand and possibly Norway. Although this disease is generally associated with few clinical effects in cattle and sheep, it is a significant cause of caprine abortion and is a serious disease of people. The risk estimate for *Coxiella burnetti* is non-negligible and risk management measures to prevent the entry of this organism are justified.

2.5.2. Please note that most of the dairy bulls we are collecting semen from are permanently on a Quarantine Collection Centre which routinely tests bulls at 6 monthly intervals. Sometimes it is not possible that semen collected in the 30-60 days period is available. This means that extra testing has to be done and/or bulls re-collected for NZ. This puts extra costs on the semen as NZ is not a large importer of semen, overseas companies are reluctant to work outside the normal. Beef bulls usually are on centre for specific local and export collections. Generally there is no problem in NZ collections as the semen is collected to meet NZ protocol. However in some cases the bull has to be held back on centre for the post collection tests. In some cases with the bull owners reluctant to hold the bull on centre for 30 days (at very high cost per day) it would help if in these cases the tests were done on farm.

MAFBNZ response: The details of testing requirements for imported germplasm will be described in the draft IHSs developed from the published risk analysis. Please also see the response to 2.4.3 above.

2.5.3. The requirement that all the lab tests for semen of bulls and/or embryos be attached with the Import Helath Certs... is an area that needs serious thought as to how better it can be done. ...At present it is a shambles. The lab reports are in the language of the exporting company and Port Entry Officials have trouble with interpretation. Each lab has their own way of identifying bulls eg Short Name, Stud Code, Registration No or other. Also as bulls are routinely tested on a bulk sample of several bulls being pooled. Only if there is a positive there will be a re-test to find which bull it is. In one case it is only when a positive test is found the Centre is notified. ...We are now getting the extra time involved being costed to us plus the increase in our Port Entry charges adding to our costs. ...A simple form attached to our Import Health Certs for confirmation could be completed with them. If this is acceptable it would help speed up clearance at Port Entry.

MAFBNZ response: These comments will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any IHS developed from these import risk analyses.

2.6. LINDSAY BURTON, FONTERRA

2.6.1. Fonterra's position on the RA's is one of very strong support for confining the trade to that of semen and embryos. We are unable to find justification for the importation of live animal imports given that the requirements for bringing new genetic into NZ can be met by importation of germplasm without experiencing the same level of risk as that posed by live animals.

MAFBNZ response: This will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any IHS developed from the published risk analyses.

As obliged under Article 3.1 of the WTO Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) the measures adopted in IHSs will be based on international standards, guidelines and recommendations where they exist, except as otherwise provided for under Article 3.3 (where measures providing a higher level of protection than international standards can be applied if there is scientific justification, or if there is a level of protection that the member country considers is more appropriate following a risk assessment).

Furthermore, MAFBNZ is able to consider information on benefits for New Zealand when determining the priority on the work programme for the subsequent development of import health standards for live cattle and bovine germplasm. The views expressed in submissions that germplasm import health standards provide the desired benefit of access to genetics will be taken into account during this prioritisation process.

2.7. JOHN R CLIFFORD, USDA

2.7.1. The documents are well organised and comprehensive. In general, we found the risk assessments to be accurate and appropriately referenced. The risk management options are adequately described and consistent with the standards set forth by the World Organisation for Animal Health (OIE) when standards exist.

MAFBNZ response: Noted

2.8. TRACY GALLAND, MEAT & WOOL NEW ZEALAND, THE MEAT INDUSTRY ASSOCIATION, AND DEER INDUSTRY NEW ZEALAND

2.8.1. M&WNZ, MIA and DINZ question whether the importation of live animals into New Zealand is a sensible approach given the economics of live animal shipments, particularly with regard to the importation of animals for slaughter, and the relative ease around importation of semen and embryos ...The parties would consider a broad approach which allows the importation of semen and embryos with relative ease except in exceptional circumstances and making this the preferred method of importing novel genetic material. ...The parties believe that such an approach allows for a more efficient means of administering import health standards and regulating the import of live animals while reducing the risks associated with such imports and at the same time allowing an import trade to proceed.

MAFBNZ response: This will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any IHS developed from the published risk analyses.

As obliged under Article 3.1 of the WTO Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement) the measures adopted in IHSs will be based on international standards, guidelines and recommendations where they exist, except as otherwise provided for under Article 3.3 (where measures providing a higher level of protection than international standards can be applied if there is scientific justification, or if there is a level of protection that the member country considers is more appropriate following a risk assessment).

Furthermore, MAFBNZ is able to consider information on benefits for New Zealand when determining the priority on the work programme for the subsequent development of import health standards for live cattle and bovine germplasm. The views expressed in submissions that germplasm import health standards provide the desired benefit of access to genetics will be taken into account during this prioritisation process.

2.8.2. The risk analysis "import of live cattle from Australia, Canada, the European Union and the Unites States of America" states that the vector for bluetongue is *Culicoides* spp. (midges), and that "*[bluetongue]* is absent in southern hemisphere countries south of 34° south, including New Zealand, and northern hemisphere countries north of 50° north (OIE 2006)." ...However, the current OIE Terrestrial Animal Health code makes no such statement. Rather it says: "The global BTV distribution is currently between latitudes of approximately 53 °N and 34 °S but is known to be expanding in the northern hemisphere." It is not possible to check the wording of the 2006 version of the Code Chapter as this is no longer available online. The risk analysis should be changed to reflect this.

MAFBNZ response: The wording in the draft risk analysis reflects the OIE *Code* when this chapter of the document was first drafted. It should be noted that earlier

editions of the OIE *Code* described 40°N as the northern boundary for bluetongue. Furthermore, it is likely that future editions of the OIE *Code* will describe a northern boundary greater than 53°N. The comment reflects a common difficulty encountered when citing a "living" document such as the OIE *Code*.

2.8.3. We would also recommend that the above statement from the risk analysis be reworded so as to more accurately reflect the statement in the OIE code, which simply states the known distribution of BTV, rather than categorically stating BTV to be absent in certain parts of the world. ...This issue has been addressed in the second import risk analysis "import of live sheep and goats from Australia", which more accurately states: "It is absent in southern hemisphere countries south of 34° south, including New Zealand, and northern hemisphere countries north of 53° north".

MAFBNZ response: In response to the concern raised regarding this issue, the wording in the final import risk analyses will be amended to reflect to wording of the current (2008) OIE *Code*.

2.8.4. The risk analyses also make numerous notes of cattle remaining viraemic for "up to 50 days". The OIE code states that the infective period for BTV "shall be 60 days".

MAFBNZ response: The risk analysis statement that infected cattle remain viraemic for about 50 days reflects the 2004 comments from DW Verwoerd and BJ Erasmus on page 1206 of Infectious *Diseases of Livestock* (Oxford University Press) as cited in the references to the risk analysis chapter on bluetongue.

2.8.5. *Culicoides* midges can be carried very long distances under the right meteorological conditions, with evidence of movement of diseases over several hundred kilometres being recorded on multiple occasions in scientific literature. As Australia is currently home to known BTV vectors, there is the possibility that those vectors could travel to NZ, given the right atmospheric conditions. We would like to see both risk analyses changed to reflect this possibility.

MAFBNZ response: As indicated in the risk analyses, a *Culicoides* surveillance programme has been operating in New Zealand since 1991, under which around 15,000 insects collected from light traps are examined annually and sentinel cattle are monitored for seroconversion to viruses transmitted by *Culicoides* spp. (bluetongue, epizootic haemorrhagic disease, Akabane and Palyam viruses). To date, seroconversion to arboviruses has not been detected in sentinel cattle and no *Culicoides* have been trapped. Furthermore, should disease vectors such as *Culicoides* spp. become established in New Zealand, MAFBNZ has the flexibility to modify Import Health Standards as appropriate.

2.8.6. In section 14.1.4, on the epidemiology of Bovine Viral Diarrhoea virus, it is stated that "BVDV2 has not been described in Australia". Section 14.3.1 Risk management options then goes on to say that "Animals could be imported from countries in which BVDV2 does not occur (Australia) without testing or quarantine". The first statement does not justify the second, in that there is no scientific evidence given to prove that BVDV2 does not occur in Australia. It is known that mucosal disease does exist in Australia, which may suggest that BVDV2 is present. The IRA should give more scientifically accurate consideration of BVDV2 in relation to importation from Australia.

MAFBNZ response: The requirements for Australian certification of freedom from BVDV2 will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any IHS developed from the published risk analyses

- 2.8.7. in Table 1, the following diseases are listed as not notifiable to the OIE:
 - Aujesky's disease virus
 - Bovine virus diarrhoea virus
 - Crimean Congo haemorrhagic virus
 - West Nile disease virus

When in fact all four are notifiable to the OIE.

MAFBNZ response: As stated in Section 5.1 of the import risk analysis, the hazard list reflects organisms as listed in the 2005 *Code*. Bovine virus diarrhoea virus, Crimean Congo haemorrhagic virus, and West Nile virus were not listed by the OIE at that time. MAFBNZ acknowledges that Aujeszky's disease should be listed as a notifiable disease in the hazard list and this error will be corrected in the risk analysis.

3. Copies of Submissions

3.1. DAVID BURT, FEDERATED FARMERS

SUBMISSION TO BIOSECURITY NEW ZEALAND ON TWO DRAFT IMPORT RISK ANALYSES "CATTLE GERMPLASM FROM ALL COUNTRIES" AND "CATTLE FROM AUSTRALIA, CANADA, THE EUROPEAN UNION AND THE UNITED STATES OF AMERICA"

1. Introduction

1.1 Federated Farmers welcomes the opportunity to comment on the above documents published in June 2008.

1.2 Federated Farmers is an industry organisation that has a long history of representing the interests of rural farming communities throughout New Zealand.

1.3 The Federation aims to add value to its members' farming business. Our key strategic outcomes include the need for New Zealand to provide an economic and social environment within which:

- Our members may operate their business in a fair and flexible commercial environment;
- Our members' families and their staff have access to services essential to the needs of the rural community; and
- Our members adopt responsible management and environmental practices.

2. These two Draft Import Risk Analyses consider the risks posed by frozen semen and *in vivo* derived frozen embryos [Cattle Germplasm ... ("GP")] and the risks due to disease-causing organisms associated with the importation of cattle from the designated countries [Cattle from Australia ... ("CA")].

3. Federated Farmers recommends:

I. That the importation of live cattle from Australia, Canada, the European Union and the United States of America only be permitted from countries that are categorised by the OIE as posing a negligible BSE risk and where there is freedom from Foot and Mouth disease and where vaccination of cattle against Foot and Mouth Disease is not practised.

II. That the importation of cattle germplasm only be permitted from countries where there is freedom from Foot and Mouth disease.

III. That the literature concerning the possibility of TSE transmission by routes other than prions is considered and the implications for the importation of germplasm into New Zealand be evaluated.

IV. Where the above conditions relating to BSE and Foot and Mouth Disease have been met, that the risks associated with the other diseases under consideration be managed using a combination of options (in decreasing order of effectiveness): - Importation of animals/germplasm from countries or zones that are free from the

- Importation of animals/germplasm from countries or zones that are free from the disease.

- Testing of animals/germplasm and treatment for disease status.

- Quarantine prior to shipment with or without testing and clinical examination V. That the present risk assessment status of "negligible" for diseases in which *Culicoides* spp are implicated as vectors - Akabane Diseases, Bluetongue and Plyam Virus Infections – be reviewed in the light of information to be presented by the Meat Industry Association of New Zealand and Meat and Wool New Zealand in their Submission.

VI. That consideration is given to the provision of some background material to help place the subject matter in context.

4. General comments:

4.1 Comments in a related Submission applicable

A number of general comments were made in a related Submission, by Federated Farmers, in respect of the Biosecurity New Zealand "Draft Import Risk Analysis: Live sheep and goats from Australia" document. These points apply equally to this Submission.

(NB these general comments are reproduced here for completeness):

4.1 Preliminary Hazard List

It is important that this step is based on current information. Some diseases (eg Borma disease, Louping ill and related viruses) are not "of concern" on the basis that they are classified as exotic in both New Zealand and Australia. The information on which the Australian status is based is, however, over ten years old. If there is any reason to believe this status may have since changed, particularly with regard to zoonotic hazards, then such organisms should be classified as "of concern".

4.2 Terminology

The absence of definitions for the critical terms "negligible" and "nonnegligible" is puzzling. The apportioning of hazards according to this classification during the risk assessment process determines whether or not they are further considered. In the absence of any definitions, it is difficult to avoid the inference that the risk management process as currently performed is ad hoc and therefore potentially flawed. [If this were not the case, then there must be some agreement within Biosecurity New Zealand at least, as to what these terms mean and if this is the case, then it follows that the terms are capable of being defined.]

4.3 A comment on the language used in the "Risk Management Options" sections of the document

When considering risk management, the document uses the term "could" as in "could be (an) effective …" [eg Section7.3.1 (Anthrax), 10.3.1 (Salmonellosis)]. The use of the word in respect of risk management is ambiguous. In this context it can mean either:

- Its application in a risk management context is optional or
- Its use may or may not be effective in managing the hazard when it is applied.

This ambiguity should be removed and replaced with the word "would" where its application would prove efficacious but the choice around the use of this measure is simply being presented as an option.

4.4 Risk management mechanism(s)

The detail around this mechanism, where human intervention is required (such as management by means of quarantine measures) is inadequate. While some information about possible risk management frameworks for specific diseases is provided, effective risk management requires that a number of processes are involved, including monitoring and verification. The document provides no information on these and other key areas. It also gives no guidance around responsibility and accountability for risk management measures.

In the absence of such critical information, it is not possible to support any risk management processes that rely on quarantine measures.

4.5 Risk Analysis [Section 2.3.2]

"In line with the MAF Biosecurity New Zealand ... risk assessment methodologies ... the following analysis is carried out". Exposure assessment (b) is defined as "the likelihood of animals or humans in New Zealand being exposed to the potential hazard."

This may (depending on what "animals "are defined here as) be better reworded as "the likelihood of animals or vectors (my emphasis) or humans in New Zealand being exposed ..." as non-animal vectors are also capable of harbouring and transmitting biological hazards.

4.6 A general point about ,, future-proofing "the risk analysis process

This risk analysis information will be used to inform and develop Import Health Standards (IHS). In the interests of avoiding the waste of publicly funded resources in unnecessarily amending these Standards, it is suggested that consideration is given to "future-proofing" the risk analysis process.

As an example, there is a substantial body of information in the scientific literature that suggests that changes in ambient temperature are likely to occur over New Zealand over the coming decades. This information could be used to assess the impact of any projected changes in vector and disease viability within New Zealand over an appropriate period – to coincide with the period between scheduled IHS reviews - and the risk analysis, and consequent IHS's could take this into account when they are developed.

4.2 Provision of contextual information

The provision of some background material - either in the Draft Risk Analysis document or in the covering letter – to help place the issue in context, would be welcome. For example, what is the reason for the draft being developed and what is the current commercial value of trade in the area that is being discussed.

<u>4.3 Provenance of the Draft Import Risk Analysis for Cattle from Australia ...document</u> The absence of the importation of (tested) germplasm (except for BSE, Mollicutes Infections and Leptospirosis) rather than live animals as a risk management option in this document is puzzling. This together with the inclusion of the "compartment(alisation)" term for BSE and Bovine Tb risk management but not for the other diseases examined, raises questions about the 'age' of the draft risk analysis document. This would, however, not be of concern if the entire document was current in terms of good risk analysis and risk management practice.

4.4 Risk considerations around specific diseases

5.1 Diseases considered as presenting a 'negligible risk'

5.1.1 Diseases in which Culicoides spp are implicated as vectors: Akabane Diseases [GP (Section 5), CA (Section 6)], Bluetongue [GP (Section 7), CA (Section 8)], Palyam Group Viruses [GP (Section 21), CA (Section 19)]

These diseases are not classified as hazards because *Culicoides* spp are thought not to be present in New Zealand (eg CA page 66) so the viruses could not become established here. The assumption about the viability of *Culicoides* spp in New Zealand is disputed by the Meat Industry Association of New Zealand and Meat and Wool New Zealand. In the light of the information that they will be including in their Submission, we strongly urge that the implications of their information be assessed and that the risk status of all diseases associated with *Culicoides* spp. be re-evaluated.

5.2 Diseases considered to present 'non-negligible' risks

5.2.1 Diseases present in germplasm but not cattle [Lumpy skin disease (GP Section 18); Rift Valley fever (GP, Section 24); Contagious bovine pleuropneumonia "CBPP" (GP, Section 32)]

The consequences of any of these three diseases getting established in New Zealand would be very high, either from direct economic costs to affected farmers (CBPP, Rift Valley fever), trade impacts (CBPP, lumpy skin disease) or human health impacts (Rift Valley fever).

For these reasons, we believe that strong measures are justified, namely:

Germplasm donors should ideally come from a country or zone that is free from these diseases or, be resident in such an area (prior to germplasm collection) for the period of time necessary to ensure that there is no risk of infection posed by the use of the germplasm.

5.2.2 Diseases present in Cattle but not Germplasm [Bovine Ephemeral fever (CA Section 16), Rabies (Section 20), Tick Borne Encephalitis (Section 22), Anthrax (Section 26), Haemorrhagic Septicaemia (Section 31), Anaplasmosis (Section 36), Family Anaplasmataceae Infection (Section 37), Babesiosis (Section 41), Theileriosis (Section 43), Lice (Section 44), Mange Mites (Section 45), Ticks (Section 46), Warble Fly (Section 47), Internal Parasites (Section 48) and Weed Seeds (Section 49) – excluding BSE

Risk management options for these diseases are given, variously, as:

- Importation of animals without restriction from countries or zones that are free from the disease according to the OIE definitions of country and zone freedom.
- Importation form zones that have been free of the disease for an appropriate period of time.
- Quarantine prior to shipment, with or without testing for disease states and checking for evidence of disease.
- Disease treatment by (eg) vaccination or with prophylactic antibiotics.

Considering these options:

1. Importation of live animals

Importation without restriction, or sanitary measures being applied, is not favoured as the sole risk management mechanism because there is still a risk that unwanted hitchhiker organisms, such as weed seeds, could be unknowingly imported.

The country of origin of the source animals, will however play a major role in the in determining the 'package' of risk management measures that is required in any particular instance of animal importation, with testing and quarantine the other legs of the 'triage' process.

2. Testing for, and treatment of, disease states

Testing (of body fluids and other materials) and treatment (whether by vaccination or by the administration of particular drugs) could be used to manage many, but not all, of the diseases considered here, but its use without other measures would again pose risks, both with respect to the importation of weed seeds and (eg) Mollicutes Infections.

3. Quarantine

The use of this mechanism is presented as an option for the risk management of almost all the above diseases. Many of the diseases considered would also require the use of additional measures in conjunction with the quarantine process, such as testing of blood (eg Mycoplasmas, Q Fever) or other samples (eg faecal samples for Salmonellosis, Internal Parasites) samples to a more intensive management regime involving bedding (Ticks and Weed Seeds).

In conjunction with the country of origin and appropriate testing – and with the proviso that the importation of germplasm as an alternative to the importation of live animals is not presented - the use of quarantine is a very important tool in the risk management of most of the exotic diseases assessed as presenting non-negligible risks.

5.2.3 Bovine Spongiform Encephalopathy ["CA" Section 25; "GP" Section 41]

The risk estimation for this disease in germplasm is given as 'negligible' on the basis that the prion is not transmitted in either semen or embryos. This may well be the case, but any evidence that the prion route is not the (only) mechanism of TSE infections should be very carefully evaluated given the potential animal and public health implications [See, for example, "Studies on the alimentary pathogenesis of BSE agent and natural scrapie in sheep in mice. Implications for diagnosis and control" pp 22 – 23 in Comments on Transmissible Spongiform Encephalopathies: The European Union's Research Response to a Major Public and Animal Health Challenge, European Commission, Directorate General for Research Biotechnologies, Agriculture and Food (2007)]

Given the long incubation period of the disease and the disastrous consequences on our international trade should BSE be imported into New Zealand very stringent risk management practice is required for this disease.

In view of these consequences, the importation of cattle should be prohibited from countries that have not been categorised by the OIE as posing a negligible BSE risk.

5.2.4 Diseases present in both Cattle and Germplasm [Borna Disease (GP Section 8, CA Section 9)], Bovine Viral Diarrhoea Virus (GP Section 12, CA Section 14), Crimean Congo Haemorrhagic Fever (GP Section 13, CA Section 15), Foot and Mouth Disease (GP Section 14, CA Section 17), Bovine Herpes Virus (GP Section 15, CA Section 11), Vesicular Stomatitus (GP Section 26, CA Section 23), Brucellosis (GP Section 29, CA Section 27), Bovine Tuberculosis (GP Section 31, CA Section 28), Salmonellosis (GP Section 35, CA Section 32), Mollicutes Infections (GP Section 33, CA Section 30), Leptospirosis (GP Section 36, CA Section 33), Chlamydiosis (GP Section 38, CA Section 38), Q fever (GP Section 39, CA Section 39).

As before, a range of risk management options is provided;

- Importation of animals/germplasm with or without some controls pertaining to (lack of) exposure to disease organisms.
- Quarantine prior to shipment, with or without testing for disease states checking for evidence of disease.
- Disease treatment by (eg) vaccination or with prophylactic antibiotics.
- Prohibiting the importation of live animals with only germplasm (screened for disease or otherwise) permitted to be imported.

As above, many of these diseases can be managed using a combination of options (in decreasing order of effectiveness):

- Importation and testing of germplasm only
- Importation of animals from countries from countries or zones that are free from the disease.
- Testing of animals and treatment for, disease states.
- Quarantine prior to shipment with or without testing and clinical examination.

While the lowest risk option would be the importation of germplasm, it appears that such action would contravene SPS requirements in some instances (eg for Bovine Tuberculosis)

In the case of foot and mouth disease however, the horrendous economic consequences should the disease enters the country mean that additional measures are justified and therefore:

The importation of germplasm should be prohibited from countries that are infected with foot and mouth disease.

end

the importation of cattle from countries that are infected with foot and mouth disease or vaccinate against foot and mouth disease should also be prohibited.

3.2. ROBERT COURTNEY, AMBREED

I am very concern that in both Risk analysis documents bluetongue is not classified as a hazard.

This may be true at the present time but with the predict global warming the ability of Culicoides spp to survive may change in this country and they could become established. Parts of Europe was of the opinion that they where free from bluetongue and look now how far this disease has spread.

Also to the germplasm industry exports are very dependent on having country freedom from this disease. Importing countries tend to take a very dim view and the statement of negligible consequent is totally wrong. Any suggestion of a positive test in this country would have very deleterious effect on our ability to export. I do not agree that a single test will not mean loss of country freedom status. What about more than one positive test? Surely it is conceivable that more than one possible test may be produced.

Also if you are so sure Culicoides will not reach this shore why have a Culicoides surveillance program? It is my opinion that Culicoides must be determined a risk.else there would be no need for such a program. Also following the experience in Northern Europe the epidemiology may be unknown or very confused. From this press release Culicoides may not be the only carrier. Please note the following press release 27/08/2008.

In 2006, Bluetongue virus – which infects livestock – reached Northern Europe for the first time. Some people thought that the outbreak would be limited to that particular year, as winter was expected to kill off the midges that host and spread the disease, bringing the threat of infection to an end. In actuality, the disease escalated in the following year, spreading to the UK. So, how did the virus survive the winter?

Drs Anthony Wilson, Karin Darpel and Philip Mellor of the Institute for Animal Health have discussed this puzzling question in an Unsolved Mystery article, published in the open access journal PLoS Biology, freely available to read from publication on the 26th of August.

The answer to this question is of great practical importance, as it will affect both national and international trade of Ruminants, the livestock susceptible to infection, and will dictate trade rules for a long time even after the infection has passed. The answer is also relevant to how we can deal with bluetongue and other unpleasant midge-transmitted diseases in the future.

Dr Mellor said: "Although the major mechanism of bluetongue virus spread is undoubtedly that of Culicoides midges feeding on infected ruminants, growing the virus and then transmitting it to further susceptible animals, other mechanisms may also be at work. These may assume greater importance during the midge-free season (winter), such as we in northern latitudes experience."

Wilson and colleagues point out that evidence to date does not support the winter survival of bluetongue virus in the eggs of Culicoides midges. An alternative hypothesis is that, in mild winters such as that of 2006-07 in northern Europe, sufficient infected midges might survive until they become active again in spring. The midges may enter livestock barns to overwinter. Two other possibilities for disease endurance during winter are that bluetongue is

spread by some susceptible species of long-lived ticks and/or by simple mechanical transmission by Melophagus ovinus, a wingless parasite that lives in the fleece of sheep.

Additionally, there is evidence from Australia that bluetongue virus can survive in midges and in a small proportion of infected cattle for three to four months, which would be long enough for winter to come and go without killing the virus. Closer to home, the recent outbreaks of bluetongue in northern Europe have provided evidence for a different overwinter route—transplacental infections; the virus spreading from an infected pregnant animal to its fetus, a phenomenon also demonstrated by experiment. This phenomenon might be particularly important in cattle, where the long gestation period of nine months (four for sheep) means that the virus can grow and survive within a fetus, at just the right temperature, throughout the coldest of winters. There is also circumstantial evidence that cattle could become infected orally if they eat the afterbirth of an infected offspring from another cow.

As Dr. Mellor summarizes, "Experiments have revealed a toolbox of possible mechanisms, with the potential to interact with and complement one another."

3.3. KEN COTTIER, LIVESTOCK IMPROVEMENT (LIC)

Submissions on Import Risk Analysis: Cattle germplasm from all countries

29/8/2008

General Comments

The document is well written and easy to follow, and in particular the section entitled Special Considerations is very good in that it clarifies some factors that remain problem areas in germplasm imports. However, while it is recognised that this is the first stage in the development of import controls, there are some conclusions within the risk analysis based on probability that may not hold up to political scrutiny and this in the end, may dictate the level of risk management. This may be particularly relevant with the conclusions on bluetongue.

Another factor to consider is the level of confidence in some veterinary administrations in some countries. Our traditional trading partners offer a good level of confidence, whereas others may not, and this should have a direct bearing on risk management. One of the conclusions in the section on rinderpest is that it does not occur in any of our "likely trading partners" which implies that this risk analysis will not be applied across all countries, as the title suggests.

There are some new hazards identified that have been ignored in previous import standards. Mycoplasma and Chlamydia have been difficult to deal with because of the difficulties presented at diagnostic level. Nevertheless they can be quite pathogenic and the possibility of arriving in cattle germplasm needs addressing.

Proving their presence or absence in NZ may be a hurdle to imposing meaningful risk management.

The compilation of the hazard list is full and well explained, and the list of diseases excluded because they are transmitted by insects only, or because of life-cycles, seems to be logical.

Comments on specific diseases

Comments will be made on specific diseases only where there is some disagreement, or some other factor that should be considered.

Because my area of expertise is confined to semen, the following comments will apply only to semen imports.

Akabane

The fact that the virus has been isolated from mosquitoes, but there has been no work carried out to investigate whether NZ mosquitoes are competent vectors, seems to weaken the conclusion that risk management measures are not justified. The virus is also present in one of our closest trading partners, and it seems that until the work is done, caution should prevail. Simple measures such as insect proof semen collections or out of season collections could be put in place.

Bluetongue

The risk analysis presents arguments that conclude that risk is negligible on the basis that Culicoides has not been found in NZ. This is an enormous step away from previous bluetongue risk management and depends on the following:

- that Culicoides will be identified by our present surveillance if it were to be present.
- that mechanical transmission of bluetongue does not occur.

• that other arthropod vectors are not in any way implicated in bluetongue transmission Bluetongue is complicated, and much of the epidemiology surrounding the disease is still poorly understood. I am not sure that all of the above is known with certainty. For example, it has recently been established that bluetongue can transmit vertically.

Serotype 8 currently circulating in Europe has been shown to cross the placenta and cause foetal abnormalities. This was previously thought not to occur, and may be relevant to the argument on over-wintering of BTV. The point is that there is much uncertainty about the disease.

Global warming may also complicate the scene with potential increased spread of Culicoides

The political aspects of bluetongue cannot be ignored. What we are saying if we allow importation of bovine semen without any bluetongue risk management, is that the presence of viraemic cattle in NZ is inconsequential. Just a few years ago there was much to do regarding a serological positive cattle beast that was in quarantine here in NZ. If a diagnosis of bluetongue was made in NZ, (for example in a foetus from a cow inseminated with semen containing BTV), the political ramifications may be significant, despite assurances from the OIE.

My personal opinion is that risk management procedures for bluetongue should still continue for the importation of bovine semen. Some of the measures may also reduce risk of other arboviruses.

Borna disease

This disease has been identified as a risk and that management measures are justified. However aside from a semen import prohibition from all countries that have Borna disease, it would seem that risk management options are unsatisfactory. Cattle are subclinically infected, so selection from herds that have no recent infection history is probably meaningless. Serology is unreliable and I assume PCR tests are not validated. Intracerebral inoculation for virus isolation sounds impractical for a routine diagnostic test for semen imports.

Foot and mouth disease

The consequences of F& M in NZ are so serious that importation of bovine germplasm from infected countries should be prohibited. Countries that do not vaccinate and employ stamp out policies should be acceptable to import from within times frames related to the last outbreak.

Ibaraki disease

This disease is in the same category as Bluetongue, Akabane and Palyam and similar arguments apply. Although risks are low, I believe we should have some risk management procedures in place.

Jembrana disease

The hazard identification conclusion for this disease seems to be written for live cattle imports, rather than semen/embryo imports

Epizootic haemorrhagic disease and Palyam

The diseases are similar to bluetongue and the same arguments apply

Rabies

I agree with the conclusion that semen and embryos are commodities that are safe and require no risk management. However, there are reports of non-bite rabies transmission, so in the interests of safety, I would include simple safeguards such as vaccination and/or no rabies in the collection centre for the 6 months prior to collection.

Mollicutes

I agree with the analysis put forward regarding these disease agents. Obviously some are more pathogenic than others, and the likelihood of those agents being present in NZ without clinical evidence is probably remote. However, the likely response from traditional trading partners when difficult risk management is required will be a request for proof that NZ is indeed free.

As a general comment on antibiotics in semen, it is recognised here at LIC that antibiotics are toxic to sperm, some antibiotics more than others. However enrofloxacin, which possibly is one of the better antibiotics against mollicutes, has been used in liquid (fresh) semen production with some success.

I do not understand the last option suggested in the risk management section. The culture of mollicutes is notoriously difficult. The absence of culture positives may not mean a great deal.

Anaplasmosis

This is one of those diseases that in theory should be transmitted by infected semen, but studies to date have not supported this. Anaplasma is found in blood cells, semen often will contain blood cells. The absence of clinical signs in donor bulls at the time of collection could be supported by the use of acaricides and/or tetracycline treatments

Chlamydiosis

Has there been any consideration of antibiotics in semen and the survivability of Chlamydophila?

Ken Cottier Semen Collection Centre Veterinarian LIC

3.4. NEIL & ROSE SANDERSON, ADVANCED GENETICS LTD

29 August 2008

I wish to make several comments on the risk analysis paper that is out for public consultation My feild of interest is Bovine Embryo Imports and associated risks I am dissapointed that I did not recieve a copy of this paper and had to find out of its existance by chance the day before submissions are due.

There are some questions that I would like to discuss with members of the IETS and it is not possible to do this until tomorrow so can i please ask for an extension until early next week to make some further informed comment

I make the following general comments

1) There is a new version of the IETS manual currently in the final stages of preparation due for printing very soon.

I am aware that this document is heavily revised on the previous versions and should be considered before finalising the Risk Analysis document as there are many references throughout the body of the document referring to historical documentation and data quoted by the IETS.

2) With respect to the risks associated with disease transmission in embryo washing, flushing, holding fluids. There are a number of preparations now available which are bovine serum free.

However most of the serum containing solutions undergo rigorous quality control as is stated in the document.

Thankyou Neil & Rose Sanderson MVSc

12 September 2008

I have a few further comments to add to my comments sent in an email to you on 29th August I am involved in importation of Bovine Embryos

Currently the existing protocols for importation of Bovine embryos all request Donor isolation or Quarantine either before and /or after flushing.

This is an expensive and at times unnecessary imposition given the low risks associated with embryo transmission of disease, and the questiuonable surity given by isolation.

It is almost prohibitive to obtain in milk dairy cows to collect because of this restriction and is seriously impacting on the genepool available to import from.

Owners do not want to send valuable cows off their farms, there are animal welfare issues associated with moving in milk cows and there are very few collection centres available to milk cows.

So I would request that all protocols are revisited and reassessed with these issues in mind and if any associated risk factors can be mitigated by either more tests on the donors especially post collection ,but on farm of origin, or embryo washing analysis eg by PCR, then this would enable more genetics to become available

For Example the current Protocol BOVEMBCAN is very restrictive as it is interpreted by the Canadain authorities as requiring up to 90 days donor quarantine.

I do not think the risk requires any quarantine and the risk could be mitigated by strategic testing regime for BVDV maybe with PCR.

Other countries face similar restrictions which should be examined.

New Zealand has been putting pressure on some of our trading partners to allow on farm collections to occur from NZ for export of Bovine Embryos so under the SPS agreement we must be consistent.

Thanks Neil & Rose Sanderson

3.5. ALLEN DONALD, GENETIC ENTERPRISES LTD

As major importers of semen and embryos for both our company and many private individuals we would like to make the following submissions.

1. No 39 – "Q fever"

To our knowledge the only two countries that require this test on semen and embryo imports are Argentina & New Zealand. The testing for "Q Fever" is not a routine test in AI Collection Centres around the world. We would have to specifically request that it is done for NZ shipments. This results in delays and extra costs for us.

We are very concerned with keeping NZ's high health status but on discussions with our suppliers most have not heard of "Q Fever" until we bring it to their attention and know of no cases in their country. IN over 20 years of importing semen I have only had three bulls rejected through positive test to "Q Fever".

In summary I would request that as the risk is negligible that it is no longer a requirement.

2. An area as importers that we continually have problems with is the requirement for semen testing to be done between 20 - 60 days. Many times the tests are outside this period eg 67 days.

Please note that most of the dairy bulls we are collecting semen from are permanently on a Quarantine Collection Centre which routinely tests bulls at 6 monthly intervals. Sometimes it is not possible that semen collected in the 30-60 days period is available. This means that extra testing has to be done and/or bulls re-collected for NZ. This puts extra costs on the semen as NZ is not a large importer of semen, overseas companies are reluctant to work outside the normal. Beef bulls usually are on centre for specific local and export collections. Generally there is no problem in NZ collections as the semen is collected to meet NZ protocol. However in some cases the bull has to be held back on centre for 30 days (at very high cost per day) it would help if in these cases the tests were done on farm.

3. The requirement that all the lab tests for semen of bulls and/or embryos be attached with the Import Helath Certs.

This is an area that needs serious thought as to how better it can be done.

At present it is a shambles. The lab reports are in the language of the exporting company and Port Entry Officials have trouble with interpretation. Each lab has their own way of identifying bulls eg Short Name, Stud Code, Registration No or other. Also as bulls are routinely tested on a bulk sample of several bulls being pooled. Only if there is a positive there will be a re-test to find which bull it is. In one case it is only when a positive test is found the Centre is notified.

We are now getting the extra time involved being costed to us plus the increase in our Port Entry charges adding to our costs.

A simple form attached to our Import Health Certs for confirmation could be completed with them. If this is acceptable it would help speed up clearance at Port Entry.

IN SUMMARY

We are very conscious of keeping NZ's excellent health status and have given serious thought to the areas we have requested that consideration for change be made

Allen Donald

3.6. LINDSAY BURTON, FONTERRA

Howard

Thanks for emails re below and apologies for delays in getting back to you. I have been party to the content of the of the MIA/M&W submission. Fonterra's position on the RA's is one of very strong support for confining the trade to that of semen and embryos. We are unable to find justification for the importation of live animal imports given that the requirements for bringing new genetic into NZ can be met by importation of germplasm without experiencing the same level of risk as that posed by live animals. Could you take this into consideration when considering the RAs please. Kind regards

Lindsay

3.7. JOHN R CLIFFORD, USDA

Thank you for the opportunity to review the draft import risk analyses on "Cattle from Australia, Canada, the European Union and the United States of America" and "Cattle Germplasm form all countries".

The documents are well organised and comprehensive. In general, we found the risk assessments to be accurate and appropriately referenced. The risk management options are adequately described and consistent with the standards set forth by the World Organisation for Animal Health (OIE) when standards exist.

We look forward to receiving the final import health standards when the documents are issued.

3.8. TRACY GALLAND, MEAT & WOOL NZ, THE MEAT INDUSTRY ASSOCIATION AND DEER INDUSTRY NEW ZEALAND

1. Introduction

- 1.1 Meat & Wool New Zealand (M&WNZ), the Meat Industry Association (MIA) and Deer Industry New Zealand (DINZ) welcome the opportunity to make a submission on the document: "Import risk analysis: live cattle from Australia, Canada, the European Union, the United States of America"
- 1.2 M&WNZ is an industry-good body funded under the Commodity Levies Act through a levy paid by producers on all beef, sheep and goats slaughtered in New Zealand, and on wool sold. M&WNZ's activities aim to increase preference for New Zealand beef, sheep, goat meat and wool internationally and domestically; to maintain and extend trade access for New Zealand red meat and wool; and to fund research and development to help improve the profitability of New Zealand farmers.
- 1.3 M&WNZ's contact for this submission is: Ben O'Brien Meat & Wool New Zealand P O Box 121 Wellington Phone: (04) 474 0839 Fax: (04) 474 0800 Email: Ben.O'Brien@meatandwoolnz.com
- 1.4 The Meat Industry Association of New Zealand Inc (MIA) is a voluntary trade association representing New Zealand meat processors, marketers and exporters. It is an incorporated society (owned by members) that represents companies' supplying the majority of New Zealand sheep meat exports and all beef exports.
- 1.5 MIA's contact for this submission is: Tracy Galland Meat Industry Association P.O Box 345 Wellington Phone: (04) Fax: (04) 473 1731 Email: <u>Tracy.Galland@mia.co.nz</u>
- 1.6 DINZ is the levy funded industry-good body established under the Deer Industry New Zealand Regulations (2004). One of its key functions is to promote and assist the development of the deer industry in New Zealand. Levies are collected on the products of velvet antler and venison. For venison, levies are paid on a share basis between deer farmers and venison processors and marketers. For velvet, levies are paid by velvet producers.
- 1.7 DINZ's contact for this submission is: Mark O'Connor

Deer Industry New Zealand P.O Box 10702 Wellington Phone: (04) 473 4500 Fax: (04) 472 5549 Email: Mark.OConnor@deernz.org

2.0 General comments

- 2.1 M&WNZ, MIA and DINZ question whether the importation of live animals into New Zealand is a sensible approach given the economics of live animal shipments, particularly with regard to the importation of animals for slaughter, and the relative ease around importation of semen and embryos.
- 2.2 The parties would consider a broad approach which allows the importation of semen and embryos with relative ease except in exceptional circumstances and making this the preferred method of importing novel genetic material.
- 2.3 The parties believe that such an approach allows for a more efficient means of administering import health standards and regulating the import of live animals while reducing the risks associated with such imports and at the same time allowing an import trade to proceed.
- 2.4 The parties would be happy to discuss such an approach at MAF's convenience.
- 2.5 There are several issues with information contained within the risk analysis: Import of live cattle from Australia, Canada, the European Union and the United Stated of America. These primarily are concerned with the Bluetongue disease virus (BTV); however there are other discrepancies also.
- 2.6 Much of the information given with relation to BTV, especially in relation to its known vector the midge *Culicoides* spp. is inaccurate and out of date.
- 2.7 These inaccuracies call into question the validity of the remaining risk analyses carried out in the document, and the validity of the document as a whole.
- 2.8 The risk analysis also contains statements about the importation of cattle from Australia in relation to Bovine Viral Diarrhoea virus (BVDV2) that are unjustified in their conclusions.
- 2.9 The issues relating to BTV seem to have been addressed in the risk analysis: import of live sheep and goats from Australia, which contains more accurate information on the latitudes in which BTV is known to occur.
- 2.10 However the issues raised in this submission relating to the likelihood of *Culidoides* spp. being found in NZ should be more accurately reflected in both risk analyses.

3. Specific comments

Bluetongue

The risk analysis "import of live cattle from Australia, Canada, the European Union and the Unites States of America" states that the vector for bluetongue is *Culicoides* spp. (midges), and that "*[bluetongue]* is absent in southern hemisphere countries south of 34° south, including New Zealand, and northern hemisphere countries north of 50° north (OIE 2006)."

However, the current OIE Terrestrial Animal Health code makes no such statement. Rather it says: "The global BTV distribution is currently between latitudes of approximately 53 °N and 34 °S but is known to be expanding in the northern hemisphere." It is not possible to check the wording of the 2006 version of the Code Chapter as this is no longer available online. The risk analysis should be changed to reflect this.

We would also recommend that the above statement from the risk analysis be reworded so as to more accurately reflect the statement in the OIE code, which simply states the known distribution of BTV, rather than categorically stating BTV to be absent in certain parts of the world.

This issue has been addressed in the second import risk analysis "import of live sheep and goats from Australia", which more accurately states: "It is absent in southern hemisphere countries south of 34° south, including New Zealand, and northern hemisphere countries north of 53° north".

Surveillance in New Zealand has not detected the presence of *Culicoides*. There is the possibility that incursions have been made from time to time but the midges have failed to over-winter and died out. However relatively small changes in winter temperatures due to global climate change could allow the midges to persist and establish long term. Allowance for this possibility should be made in both risk analyses.

The risk analyses also make numerous notes of cattle remaining viraemic for "up to 50 days". The OIE code states that the infective period for BTV "shall be 60 days".

It is noted that there are 24 serotypes of BTV. Serotype 8 is recognised as an important pathogen of cattle as well as sheep, and emerged unexpectedly in the Netherlands in 2006. The virus was of sub-Saharan origin, and the method by which it reached northern Europe is unclear. *Culicoides* midges can be carried very long distances under the right meteorological conditions, with evidence of movement of diseases over several hundred kilometres being recorded on multiple occasions in scientific literature. As Australia is currently home to known BTV vectors, there is the possibility that those vectors could travel to NZ, given the right atmospheric conditions. We would like to see both risk analyses changed to reflect this possibility.

The risk analysis "import of live cattle from Australia, Canada, the European Union and the Unites States of America" is out of date with respect to Bluetongue virus on many counts, and this throws in to doubt the validity of the rest of the document. We would like to see the document thoroughly revised so as to more accurately reflect the current situation regarding BTV, and indeed all other diseases mentioned.

The following sections refer exclusively to the risk analysis: "import of live cattle from Australia, Canada, the European Union and the United States of America"

Bovine Virus Diarrhoea

In section 14.1.4, on the epidemiology of Bovine Viral Diarrhoea virus, it is stated that "BVDV2 has not been described in Australia". Section 14.3.1 Risk management options then goes on to say that "Animals could be imported from countries in which BVDV2 does not occur (Australia) without testing or quarantine". The first statement does not justify the second, in that there is no scientific evidence given to prove that BVDV2 does not occur in Australia. It is known that mucosal disease does exist in Australia, which may suggest that BVDV2 is present. The IRA should give more scientifically accurate consideration of BVDV2 in relation to importation from Australia.

Other Issues

In addition to these specific issues relating to Bluetongue, there are also numerous discrepancies between introductory data and that contained in the body of the report. For example, in Table 1, the following diseases are listed as not notifiable to the OIE:

- Aujesky's disease virus
- Bovine virus diarrhoea virus
- Crimean Congo haemorrhagic virus
- West Nile disease virus

When in fact all four are notifiable to the OIE, and are listed as such in their respective risk analyses in the body of the document.

4. Conclusion

M&WNZ, MIA and DINZ all support a robust, scientific approach to risk analyses.

The points raised above call into question whether this has in fact been the case with these risk analyses, and as a result we must question the validity of these analyses.

Therefore M&WNZ, MIA and DINZ are not able to support the conclusions given in the current risk analysis and would wish to see further improvements to reflect more accurately the risks posed.

Both M&WNZ and the MIA would be prepared to participate in discussions around streamlining the HIS process along the lines proposed in paragraphs 2.1 to 2.4 in this submission.