Import risk analysis: Deer germplasm

REVIEW OF SUBMISSIONS

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Import risk analysis: Deer germplasm

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Approved for general release

Christine Reed
Manager, Risk Analysis
MAF New Zealand

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Contents

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Executive Summary

MAF released the draft document *Import risk analysis*: Deer germplasm for public consultation on 21 March 2011. The closing date for public submissions was extended from 29 April until 13 May 2011 to accommodate an extension request from Deer Industry New Zealand.

Based on comments made by stakeholders in response to the published draft import risk analysis, this review of submissions document makes recommendations for changes required to amend the draft document to a final risk analysis.

The next step in this process will be for the Animal Imports and Exports Section of the Border Standards Directorate of MAF to draft an Import Health Standard along with a guidance document and a Risk Management Proposal 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 submissions received and in view of the progress being made in the *Mycobacterium bovis* eradication campaign, it is recommended that the fourth paragraph in Section 25.1.4. of the draft risk analysis is amended to the following to make it final.

"There has been considerable progress in reducing the number of infected herds in New Zealand. In mid 2010 there were only 98 infected cattle and deer herds, compared with 129 herds a year earlier. This is 26% less herds infected than a year earlier. The infected herd period prevalence at June30, 2010 was 0.26% (Animal Health Board 2010). Wild life reservoirs (mainly possum and ferrets) pose a continuing risk of reintroducing infection into free herds".

Animal Health Board (2010). *Annual Report for the year ending 30 June*. [Online] Available from: http://ahb.org.nz/Default.aspx?tabid=100 [Accessed 30/05/11].

1. Introduction

Risk analyses are carried out by MAF under Section 22 of the Biosecurity Act 1993, which lays out the requirements with 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 and external technical review before the draft risk analysis document is released for public consultation. The Risk Analysis Group of MAF 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. The decision to implement these changes lies with an internal committee of MAF. These documents inform the development of any resulting IHS by the Border Standards Group of MAF 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 released the draft document *Import risk analysis*: Deer germplasm for public consultation on 21 March 2011. Every step was taken to ensure that the risk analysis provided a reasoned and logical discussion, supported by references to scientific literature. The draft risk analysis was peer reviewed internally and externally before public release. Relevant comments were incorporated at each stage of this review process. After extension, the closing date for public submissions on the risk analysis was 13 May 2011.

MAF received two formal submissions to the draft risk analysis during the consultation period. Table 1. lists the submitters and the organisations they represent.

Table 1. Submitters and Organisations Represented

Submitter	Organisation Represented
Mark O'Connor	Deer Industry New Zealand
David Burt	Federated Farmers of New Zealand

This document is MAF's review of the submissions that were made by interested parties following the release of the draft risk analysis 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 likelihood, not possibility, 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.

The two submissions are copied into Section 3. The review of submissions Section 2, examines the submissions received from Federated Farmers New Zealand and Deer Industry New Zealand.

2. Review of Submissions

2.1. Mark O'Connor, Deer Industry New Zealand

2.1.1. Deer Industry New Zealand: The certainty/uncertainty with which the health status of a particular country can be determined will dictate whether importation can be made safely and what risk management procedures will be chosen. For example, Korean authorities' inability to find 43 imported Canadian deer (30.1.4) undermines confidence in South Korea's health status. Further, the health status of animal populations in China appears particularly opaque.

MAF response

Noted. The Imports Section of MAF considers the appropriate combination of sanitary measures to ensure the effective management of identified risks in the commodities.

An evaluation of an exporting country's standards and performance is not made in the risk analysis. The risk analysis supports the development of an IHS that will describe the requirements that achieve effective biosecurity risk management. MAF will consult Deer Industry New Zealand during the process of IHS development. Implementing arrangements for trade under the requirements established in the IHS are then negotiated with prospective exporting countries, during which MAF evaluates the systems the exporting country proposes to verify the IHS requirements.

The Veterinary Service of the exporting country is expected to demonstrate robust verification systems delivering a high level of confidence. MAF may require documentation of risk management and verification systems within an Official Assurance Programme in support of agreed Zoosanitary Certification requirements, and may undertake in-country assessments at the importer's expense. This would particularly apply for high risk commodities and trade from countries where no established bilateral relationship between MAF and the exporting Veterinary Service exists. During these negotiations MAF may draw on relevent expertise in the New Zealand industry to ensure the principles of equivalence, consistency with national treatment and avoiding arbitrary discrimination are adhered to.

2.1.2. Deer Industry New Zealand: How effectively the competent authority in the exporting country adheres to the Code requirements (germplasm collected and prepared in accordance with the Code chapters 4.5, 4.6 and 4.7) will have a strong bearing on the confidence that can be placed in the management of the risks.

MAF response

Noted. An evaluation of an exporting country's standards and performance is not made in the risk analysis. MAF may conduct an evaluation of veterinary services when drafting IHSs developed from the risk analysis, particularly when there is no existing trade. Please refer to MAFs response to submission 2.1.1. above.

2.1.3. Deer Industry New Zealand: The submitter notes that there are likely to be differences in the confidence that can be placed on the health status of animals that are long term residents in collection centres as compared to those that are drawn from the general deer population specifically for a collection event.....the clinical history of the latter is less certain

and entry into the collection centre is much more dependent on the efficacy of the risk management procedures used to qualify them.

MAF response

Noted. Facilities that are suitable and where the animals are resident or are joining from the general deer population will be required to meet all the requirements specified in the IHS and be able to be approved by the veterinary authority of the exporting country.

2.1.4. Deer Industry New Zealand: We agree that the likelihood of transmission of this organism [*Mycobacterium avium* subsp. *paratuberculosis*] via germplasm is low but we consider some effort should be made to ensure donor animals are not clinically affected by Johne's disease. The donors should be negative to an internationally acceptable antibody test, e.g. Paralisa or a commercial test optimised for red deer, and/or faecal culture.

MAF response

Johnes disease is not subject to control measures in New Zealand and is widespread and established in livestock (cattle, deer, goats and possibly more rarely camelids and sheep). Therefore, it is not classified as a potential hazard in the risk analysis.

Since deer germplasm is not subjected to any domestic control measures for Johnes disease, any measures imposed on imported deer germplasm only would violate Article 2.3 of the SPS Agreement.

The measures recommended in the *Code* chapters 4.5., 4.6. and 4.7. would ensure donor animals are not clinically affected. There are no internationally prescribed tests for Johnes disease. However, an importer could negotiate for donor animals to be screened with a test of their choosing should they wish.

2.1.5. Deer Industry New Zealand: Bluetongue- We are surprised at the risk estimate (5.2.6) which proposes that a New Zealand recipient animal could be infected by exposure to infected semen but this is of no consequence for New Zealand because of the absence of the vector. Infection may well have consequences for the recipient(s) even though the national disease-free status is not affected. The risk estimate also assumes that the risk of introduction of the vector is minimal which may not be the case. We consider some effort should be made to ensure viraemic donor animals are not sampled by requiring serological or agent identification testing in accordance with the Terrestrial Manual.

MAF response

Bluetongue is a disease primarily of sheep and occasionally goats. The epidemiology Section 5.1.4. notes that cases of bluetongue may be subclinical and serologically positive healthy animals are frequently identified.

As outlined in Section 5.2.5., a *Culicoides* surveillance programme has been operating in New Zealand since 1991. Sentinel cattle are monitored for seroconversion to bluetongue virus transmitted by *Culicoides* spp. To date, seroconversion to bluetongue has not been detected in sentinel cattle and no *Culicoides* have been trapped.

Requiring serological or agent identification testing is not considered justifiable since the risk estimate is negligible. This is consistent with the position taken for bluetongue in other animal import risk analyses.

2.1.6. Deer Industry New Zealand: Mycobacterium bovis- The description of the epidemiology of the disease in New Zealand (25.1.4, forth paragraph) damns the New Zealand eradication programme with faint praise. While this is of no consequence to the risk estimation, we believe the progress of the programme in New Zealand should be cast in a more positive light.

MAF response

The fourth paragraph will be amended to read: "There has been considerable progress in reducing the number of infected herds in New Zealand. In mid 2010 there were only 98 infected cattle and deer herds, compared with 129 herds a year earlier. This is 26% less herds infected than a year earlier. The infected herd period prevalence at June 30, 2010 was 0.26% (Animal Health Board 2010). Wild life reservoirs (mainly possum and ferrets) pose a continuing risk of reintroducing infection into free herds.

Animal Health Board (2010). *Annual Report for the year ending 30 June*. [Online] Available from: http://ahb.org.nz/Default.aspx?tabid=100 [Accessed 30/05/11].

2.1.7. Deer Industry New Zealand: Coxiella burnetii-28.2.3 Consequence assessment appears to understate the risk to human health. Q fever is a significant occupational hazard in some countries e.g. Australia. For this reason we believe it important to reduce the risk of importation of the organism using all the methods set out in the Risk Management options (28.3.1).

MAF response

The risk to human health is also discussed in Section 28.1.4.

The Imports Section of MAF decides on the appropriate combination of sanitary measures to ensure the effective management of Q fever. These decisions are presented in a draft IHS and a Risk Management Proposal document.

MAF will consult Deer Industry New Zealand throughout the process of IHS development.

2.1.8. Deer Industry New Zealand: Chronic Wasting Disease-…..We note that horizontal transmission appears more frequent in CWD than in scrapie.

MAF response

Noted.

2.1.9. Deer Industry New Zealand: Chronic Wasting Disease- Finding herds with a well-understood history of freedom from CWD is a critical step in selecting donors. MAF will know from past experience how difficult it is to get reliable herd/flock histories for CWD and scrapie particularly in countries where the diseases are endemic. For example, the analysis in 30.1.4 Epidemiology does not give us confidence that the Korean situation is at all well understood.

MAF response

The risk analysis highlights that the current disease status for Korea is uncertain. An evaluation of an exporting country's standards and performance is not made in the risk analysis. The risk analysis supports the development of an IHS that will describe the requirements that achieve effective biosecurity risk management. MAF will consult Deer Industry New Zealand during the process of IHS development. Implementing arrangements for trade under the requirements established in the IHS are then negotiated with prospective

exporting countries, during which MAF evaluates the systems the exporting country proposes to verify the IHS requirements.

The Veterinary Service of the exporting country is expected to demonstrate robust verification systems delivering a high level of confidence. MAF may require documentation of risk management and verification systems within an Official Assurance Programme in support of agreed Zoosanitary Certification requirements, and may undertake in-country assessments at the importer's expense. This would particularly apply for high risk commodities and trade from countries where no established bilateral relationship between MAF and the exporting Veterinary Service exists. During these negotiations MAF may draw on relevent expertise in the New Zealand industry to ensure the principles of equivalence, consistency with national treatment and avoiding arbitrary discrimination are adhered to.

2.1.10. Deer Industry New Zealand: The epidemiological analysis (30.1.4) notes the Biorad ELISA test has a high sensitivity when compared to the immunohistochemical tests on lymphoid tissue in the live animal. The question is how good is the immunohistochemical test? We would want to have better evidence on the sensitivity/specificity of the immunohistochemical test before we could accept it as a qualifying test.

MAF response

Agreed. Section 30.3 notes that diagnostic tests are not validated for deer. Thus, tests currently available are not, of themselves, an effective means of ensuring the absence of chronic wasting disease in deer. This comment will be considered when decisions are made regarding risk management measures in the draft IHS.

2.1.11. Deer Industry New Zealand: In our view, the consequence of introducing CWD demands a significantly more conservative approach than most of the other diseases being considered. This would certainly not include points 3 or 4 in section 30.3.

MAF response

It is noted that prohibiting importation from areas where CWD occurs is the submitter’s preference. This comment will be considered by the Imports Section of MAF when decisions are made regarding risk management measures in the draft IHS.

MAF will consult Deer Industry New Zealand throughout the process of IHS development.

2.1. DAVID BURT, FEDERATED FARMERS OF NEW ZEALAND

2.1.1. Chronic Wasting Disease (CWD). This is discussed in Section 30 (pages 129-134) of the IRA. The document notes (Section 30.2.1 Entry Assessment) that "The transmission of CWD in semen has not been studied" and concluded that "... the risk of CWD entry in semen is non-negligible.

New Zealand has been fortunate that prion based animal diseases are not present in the country as the effect on the economy would be catastrophic if any such agent (eg BSE, Scrapie or Chronic Wasting Disease) became established here.

To minimise this risk, the Federation believes that the importation of deer germplasm from areas where CWD is known to occur (Korea, North America) should be prohibited.

MAF response

It is noted that the option of prohibiting importation from areas where CWD occurs is the submitter's preference. The options given cover a range of possible risk mitigation measures that could be used to mitigate the identified risk. This comment will be incorporated into the 'Risk Management Proposal' document to help decide what constitutes an acceptable risk and what measure to apply to reduce the risk to an acceptable level.

This comment will be considered by the Imports Section of MAF when decisions are made regarding risk management measures in the draft IHS.

3. Copies of Submissions

3.1. MARK O'CONNOR, DEER INDUSTRY NEW ZEALAND

Sent: Tuesday, 10 May 2011
Subject: Re: Deer Germplasm draft IRA

DEER INDUSTRY
NEW ZEALAND

10 May 2011

TO: MAF Biosecurity New Zealand,
Attn. Risk Analysis Team Support Officer
PO Box 2526
WELLINGTON 6140

FROM: Deer Industry New Zealand
PO Box 10 702,
WELLINGTON 6011

Mark O'Connor, Chief Executive
04 471 6113, mark.oconnor@deernz.org

By email: *risk.analysis@maf.govt.nz*

SUBMISSION ON "IMPORT RISK ANALYSIS ON DEER GERMPLASM"

Deer Industry New Zealand (DINZ) is satisfied that the import risk analysis on deer germplasm provides a comprehensive database on which future import health standards (IHS) can be based. We recognise that the development of an IHS for a particular country requires a detailed analysis of the health status of the animal populations in that country. The certainty/uncertainty with which that status can be determined will dictate whether importation can be made safely and what risk management procedures will be chosen. For example, Korean authorities' inability to find 43 imported Canadian deer (30.1.4) undermines confidence in South Korea's health status. Further, the health status of animal populations in China appears particularly opaque.

We note that only two forms of germplasm namely semen and in-vivo derived embryos are considered in the analysis. We assume that this is because these two forms are the only ones likely to be involved in trade in the foreseeable future.

We note the analysis is predicated on "the germplasm [being] imported [being] collected and prepared to standards at least equivalent to those recommended in the OIE Terrestrial Animal Health Code" (specifically chapters 4.5, 4.6 and 4.7). How effectively the competent authority in the exporting country adheres to the Code requirements will have a strong bearing on the confidence that can be placed in the management of the risks.

We also note that there are likely to be differences in the confidence that can be placed on the health status of animals that are long term residents in collection centres as compared to those that are drawn from the general deer population specifically for a collection event. Whereas the former are quarantined from the general population and likely to be under close individual supervision and observation, the clinical history of the latter is less certain and entry into the collection centre is much more dependent on the efficacy of the risk management procedures used to qualify them.

We agree with the approach taken in the analysis that in the absence of information specific to deer, extrapolation from what is known for other species, particularly ungulate species is a sensible one.

Section 3.8 Preliminary Hazard List

We note that *Mycobacterium avium* subsp *paratuberculosis* has been excluded from the preliminary hazard list on the grounds that it is endemic in New Zealand and is not known to be transmitted via germplasm. However, paragraph 25.2.1.2 states:

> "*Mycobacterium paratuberculosis* is known to adhere strongly to the *zona pellucida* of embryos and to be resistant to removal by washing (Rhode et al 1990). Therefore, infection of the genital tract could occur in deer and the organisms could adhere to the *zona pellucida*. However, infections of the genital tract are rare in cattle and no records were found of such cases in deer. The likelihood of entry of the organism in embryos is therefore assessed to be low."

We agree that that the likelihood of transmission of this organism via germplasm is low but we consider some effort should be made to ensure donor animals are not clinically affected by Johne's disease. The donors should be negative to an internationally acceptable antibody test, e.g. Paralisa or a commercial test optimised for red deer, and/or faecal culture.

5. Bluetongue Virus

We are surprised at the risk estimation (5.2.6) which proposes that a New Zealand recipient animal could be infected by exposure to infected semen but this is of no consequence for New Zealand because of the absence of the vector. Infection may well have consequences for the recipient(s) even though the national disease-free status is not affected. The risk assessment also assumes that the risk of introduction of the vector is minimal which may not be the case.

We consider some effort should be made to ensure viraemic donor animals are not sampled by requiring serological or agent identification testing in accordance with the *Terrestrial Manual*.

25. *Mycobacterium bovis*

The description of the epidemiology of the disease in New Zealand (25.1.4, fourth paragraph) damns the New Zealand eradication programme with faint praise. While this is of no consequence to the risk estimation, we believe the progress of the programme in New Zealand should be cast in a more positive light.

28. *Coxiella burnetii*

28.2.3 Consequence assessment appears to understate the risk to human health. Q fever is a significant occupational hazard in some countries e.g. Australia.

For this reason we believe it important to reduce the risk of importation of the organism using all the methods set out in the Risk Management options (28.3.1).

30. Chronic Wasting Disease

The degree of uncertainty about the transmissability of CWD through deer germplasm stemming from the lack of direct evidence and uncertainty over the validity of extrapolation from cattle (BSE) and sheep (scrapie) studies leads us to the view that a risk-averse approach is required. We note that horizontal transmission appears more frequent in CWD than in scrapie.

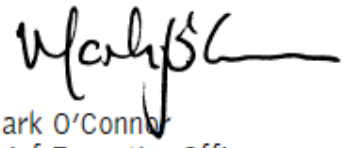
Finding herds with a well-understood history of freedom from CWD is a critical step in selecting donors. MAF will know from past experience how difficult it is to get reliable herd/flock histories for CWD and scrapie particularly in countries where the diseases are endemic. For example, the analysis in 30.1.4 Epidemiology does not give us confidence that the Korean situation is at all well understood.

The epidemiological analysis (30.1.4) notes the Biorad ELISA test has a high sensitivity when compared to the immunohistochemical tests on lymphoid tissue in the live animal. The question is how good is the immunohistochemical test? We would want to have better evidence on the sensitivity/specificity of the immunohistochemical test before we could accept it as a qualifying test.

In our view, the consequence of introducing CWD demands a significantly more conservative approach than most of the other diseases being considered. This would certainly not include points 3 or 4 in section 30.3.

For further information, please contact the undersigned.

Yours sincerely



Mark O'Connor
Chief Executive Officer

3.2. DAVID BURT, FEDERATED FARMERS OF NEW ZEALAND

Sent: Thursday, 5 May 2011
Subject: Submission on Draft Import Risk Analysis: "Deer Germplasm"

SUBMISSION

TELEPHONE 0800 327 646 | WEBSITE WWW.FEDFARM.ORG.NZ

FEDERATED FARMERS OF NEW ZEALAND

To: Biosecurity New Zealand

On the: Draft Import Risk Analysis: Deer Germplasm

Date: 5 May 2011

Contact: **DAVID BURT**
POLICY ADVISOR, MEAT & FIBRE

Federated Farmers of New Zealand
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SUBMISSION TO BIOSECURITY NEW ZEALAND ON

"IMPORT RISK ANALYSIS: DEER GERMPLASM". DRAFT FOR PUBLIC CONSULTATION

1. FEDERATED FARMERS CONCERNS

Federated Farmers of New Zealand notes the publication of the draft Import Risk Analysis (IRA) for deer germplasm. The document examines technical issues that are, in general, outside the mandate of the Federation and its members.

The Federation believes that, in this instance and with two exceptions, comment on the issues is most appropriately left to other organisations who are more directly involved in this area.

The exceptions are:

1. The Federation is strongly supportive of a cost effective biosecurity system that supports our international reputation for producing very high quality and safe meat and dairy products. It would be of grave concern to the Federation if this reputation was placed at risk by an overly risk averse view by MAF in respect of potential trade impacts arising from this Import Risk Analysis.

2. To minimise the risk of Chronic Wasting Disease (CWD), the Federation believes that the importation of deer germplasm from areas where CWD is known to occur (Korea, North America) should be prohibited

These issues are discussed below.

We would be pleased to discuss these matters with you in more detail should you believe this is necessary. Please contact David Burt, Policy Advisor Meat & Fibre [dburt@fedfarm.org.nz; DDI 04 494 9182] in the first instance.

2. BACKGROUND

Our Submission is in accordance with the request for comment on the above draft document by the Manager Risk Analysis Group, Policy and Risk Directorate, MAF Biosecurity New Zealand in a letter dated 21 March 2011.

3. GENERAL COMMENTS

3.1 The importance of appropriately weighting valid, science based biosecurity measures against potential trade concerns.

The determination of risks posed by the importation of biological material into New Zealand is a science based one – such as is epitomised by the Import Risk Analysis document under discussion.

Moreover, New Zealand is entitled to take measures to protect life or health to the extent that such actions are consistent with international trade agreements that we are signatory to. Balancing such actions however are the potential impacts on trade if the measures taken are considered to unfairly advantage a nation.

Such decisions are, of necessity, judgemental. As a trading nation however, whose economy is largely dependent on our ability to stay free from animal diseases and zoonoses that affect many of our trading partners, it is essential that an effective biosecurity system remains of paramount importance in the decision-making process.

A stated above, the Federation would be extremely concerned if trade considerations were given undue weighting in this process.

3.2 Chronic Wasting Disease (CWD)

This is discussed in Section 30 (pages 129 – 134) of the IRA. The document notes (Section 30.2.1 Entry Assessment) that "The transmission of CWD in semen has not been studied" and concluded that "… the risk of CWD entry in semen is non-negligible".

New Zealand has been fortunate that prion based animal diseases are not present in the country as the effect on the economy would be catastrophic if any such agent (eg BSE, Scrapie or Chronic Wasting Disease) became established here.

To minimise this risk, the Federation believes that the importation of deer germplasm from areas where CWD is known to occur (Korea, North America) should be prohibited.

4. ABOUT FEDERATED FARMERS OF NEW ZEALAND

4.1 Federated Farmers of New Zealand is a member-based organisation representing farming and other rural businesses. Federated Farmers has a long and proud history of representing the needs and interests of New Zealand farmers.

4.2 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.