Import risk analysis: The Scrapie Risk from Sheep and Goat Germplasm

REVIEW OF SUBMISSIONS

ISBN 978-0-478-37524-4 (print)

ISBN 978-0-478-37525-1 (online)

April 2011

This page is intentionally blank

MAF Biosecurity New Zealand
Pastoral House
25 The Terrace
PO Box 2526
Wellington 6011
New Zealand
Tel: 64 4 894 0100
Fax: 64 4 894 0731

Science Information and Risk Directorate
MAF Biosecurity New Zealand

Import risk analysis: The Scrapie Risk from Sheep and Goat Germplasm

REVIEW OF SUBMISSIONS

April 2011

Approved for general release

Christine Reed
Manager, Risk Analysis
MAF Biosecurity New Zealand

This page is intentionally blank

Contents

This page is intentionally blank

Executive Summary

MAF Biosecurity New Zealand (MAFBNZ) released the draft document *Import risk analysis*: The Scrapie Risk from Sheep and Goat Germplasm for public consultation on 20 January 2011. The closing date for public submissions was extended from 03 March until 24 March 2011 to accommodate an extension request from Biosecurity Australia.

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 MAFBNZ 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 comments made in submissions received, it is recommended that no changes be made to the draft risk analysis to make it final.

1. Introduction

Risk analyses are carried out by MAFBNZ 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 MAFBNZ 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 MAFBNZ. These documents inform the development of any resulting IHS by the Border Standards Group of MAFBNZ 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.

MAFBNZ released the draft document *Import risk analysis*: The Scrapie Risk from Sheep and Goat Germplasm for public consultation on 20 January 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 24 March 2011.

MAF received four 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
Peter Hewitt	Biosecurity Australia, Department of Agriculture, Fisheries and Forestry
Chris Houston	Beef and Lamb New Zealand Ltd
David Burt	Federated Farmers of New Zealand
Jock Allison	Agricultural and Management Consultant

This document is MAFBNZ'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 four submissions are copied into Section 3. The review of submissions Section 2, examines the submissions received from Biosecurity Australia, Beef and Lamb New Zealand Ltd, Federated Farmers of New Zealand and Jock Allison (consultant).

2. Review of Submissions

2.1. Peter Hewitt, Biosecurity Australia, Department of Agriculture, Fisheries and Forestry

2.1.1. Biosecurity Australia: We agree that restricting import to PrP genotypes that are highly susceptible to scrapie is at odds with selection programs in scrapie affected countries which favour scrapie PrP resistant genotypes.

MAFBNZ response

The risk analysis provides an option whereby donors could be restricted to particular genotypes. Scrapie resistant donors might provide additional security but could limit access to certain breeds in which these genotypes are uncommon.

2.1.2. Biosecurity Australia: We are also very aware that developments in knowledge on scrapie have occurred, some of this work being reported relatively recently. However, we note that some of this research has varying value or relevance to scrapie free countries, such as Australia and New Zealand, which maintain freedom through an appropriate suite of risk management measures, whilst facilitating imports to the extent possible.

MAFBNZ response

Biosecurity Australia's comment on the value and relevance of the recent developments in knowledge of scrapie and its applicability to free countries is noted.

MAFBNZ considers that the developments in knowledge are very significant advances made in understanding scrapie and that these are relevant to scrapie free countries. These have been assessed and evaluated for their applicability in managing the risk of scrapie transmission via germplasm.

2.1.3. Biosecurity Australia: We also agree that, while the available scientific literature points to low risk of transmission from sheep and goat semen and embryos from scrapie affected countries, a position we also supported in 2000, transmission cannot be entirely ruled out. We would generally support the premise that the more trials that are completed without the event occurring, the more confident one can be that it will not occur. However, the final basis for decision-making is that import conditions must meet an importing country's appropriate level of protection for the disease and commodity.

MAFBNZ response

It is noted that although Biosecurity Australia agree that there is a low risk of transmission from sheep and goat semen and embryos from scrapie affected countries, transmission cannot be entirely ruled out.

A key obligation under the SPS Agreement is that sanitary and phytosanitary measures must be based on scientific principals and maintained only while there is sufficient scientific evidence for their application. In the case of *in vivo* derived sheep embryos there is clear evidence presented in the risk analysis showing that this commodity is safe and that embryos are not a vehicle for scrapie. In February 2010 the International Embryo Transfer Society (IETS) informed the OIE's Terrestrial Animal Health Standards Commission that its Research

Subcommittee of the Health and Safety Advisory Committee had, on the basis of a careful review of all peer-reviewed scientific studies, classified scrapie as a Category 1 disease; a disease "…for which sufficient evidence has accrued to show that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS Manual." This IETS recommendation was adopted by the World Assembly of Delegates at the May 2010 General Session of the OIE and is now incorporated into the *Terrestrial Animal Health Code*. Further, there is strong scientific evidence presented in the risk analysis that supports the conclusion that semen is not a vehicle for scrapie, even with no safeguards in place.

2.1.4. Biosecurity Australia: We endorse BNZ's assessment that the consequences of introducing scrapie would be high. While BNZ expresses uncertainty about estimating the consequences of introduction, in Australia's case, it is notable that we have many export conditions for a variety of sheep/goat related materials that currently require certification of country freedom from scrapie.

MAFBNZ response

It is noted that Australia's acceptable level of protection is to trade only with countries free from scrapie for a variety of sheep/goat related materials.

2.1.5. Biosecurity Australia: I note reliance in the draft IRA on current OIE Code recommendations for semen and embryos. There is, for example, a clear expression of support for the safety of embryos with intact zona pellucida washed according to the procedures of the International Embryo Transfer Society, and indications that BNZ might consider this sufficient risk management. However, the IRA is unclear about what other options, if any, might be considered necessary to meet New Zealand's appropriate level of protection.

MAFBNZ response

In the case of *in vivo* derived sheep embryos there is clear evidence presented in the risk analysis showing that this commodity is safe and that embryos are not a vehicle for scrapie. The safety of *in vivo* derived embryos is also recognised in the *Terrestrial Animal Health Code* of the OIE.

The Imports and Exports Section of MAFBNZ decides on the appropriate combination of sanitary measures to ensure the effective management of scrapie in the commodities.

2.1.6. Biosecurity Australia: There is also ambiguity concerning other options, for example, the value of the scrapie free status of the flock of origin, how this would be assessed, and how it could be incorporated in a scientifically sound and practical way into proposed risk management. It would appear that donor age restrictions are not likely to feature in New Zealand's proposal. Overall, the IRA suggests that scrapie restrictions on imported genetic material may be reduced substantially compared to previous requirements.

MAFBNZ response

An importing country is entitled to expect validity in the veterinary certification of export. 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.

The Imports and Exports Section of MAFBNZ decides on the appropriate combination of sanitary measures to ensure the effective management of scrapie in the commodities.

2.1.7. Biosecurity Australia: At this time, Australia requires additional risk management, beyond the Code recommendations, for scrapie. Please note that Australia's comments to the OIE Code Commission have reflected this position.

MAFBNZ response

It is noted that Australia requires additional measures beyond the internationally agreed standard.

2.1.8. Biosecurity Australia: We would be able to provide more specific and detailed comment on recommendations contained in the draft IHS and look forward to reviewing your compilation of the relevant facts and comments into an IHS that reflects acceptable risk management for this disease. On this point, it seems worthwhile to reiterate our support for harmonisation of Australian-New Zealand import conditions where possible so that Trans-Tasman trade can continue to be facilitated.

MAFBNZ response

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

MAFBNZ will consult Biosecurity Australia throughout the process of IHS development and notes Biosecurity Australia's support for harmonisation where possible.

2.2. Chris Houston, Beef and Lamb New Zealand Ltd

2.2.1. B+LNZ: Introduction of scrapie into New Zealand sheep flock would potentially have very serious consequences for our industry. Accordingly, and recognising MAF's mandate in this area, we place a large amount of trust in the expertise of MAFBNZ to prevent this from occurring.

MAFBNZ response

Noted.

2.2.2. B+LNZ: Accuracy and completeness of the risk assessment- The document appears to be comprehensive and well referenced. We have no reason to question the validity of the evidence presented and are not aware of any significant omissions. The technical expertise of the author, Prof MacDiarmid, is well known and respected within the industry.

MAFBNZ response

Noted.

2.2.3. B+LNZ: Adequacy of description of risk management measures- We feel that applicable risk management measures are adequately described. It would be informative for any risk management regimes that have been put in place, for these commodities, in other scrapie free countries to also be described.

MAFBNZ response

Appendix 3 of the risk analysis outlines the international standard when importing sheep and goat germplasm. However, this standard has recently changed in regards *in vivo* derived sheep embryos. The *Code* now recommends that no scrapie-related conditions, regardless of the scrapie risk status of the sheep and goat population of the exporting country should be applied to *in vivo* derived sheep embryos so long as they have been handled in accordance with Chapter 4.7.

2.2.4. B+LNZ : Preferred risk management options- We are unclear about what combination of risk management options would represent the optimum regime for managing the risk in the commodities, as many of the options presented appear to have significant associated constraints. Our initial view is that the development of any risk management regime should fully explore the benefits and constraints of requiring that germplasm is sourced only from scrapie-free flocks.

MAFBNZ response

MAF acknowledges the submitters initial view of sourcing germplasm from scrapie-free flocks. However, in the case of *in vivo* derived sheep embryos there is clear evidence presented in the risk analysis showing that this commodity is safe conditional on the embryos being collected and processed according to the *Code's* recommendations. Further, there is strong scientific evidence presented in the risk analysis that supports the conclusion that semen is not a vehicle for scrapie, even with no safeguards in place.

It is noted that the submitter is unclear what combination of risk management options would represent the optimum risk management regime. The Imports and Exports Section of MAF decides on the appropriate combination of sanitary measures to ensure the effective management of scrapie.

This comment will be considered when decisions are made regarding risk management measures in the draft IHS. Stakeholder submissions in relation to the draft IHS are reviewed before a final IHS is issued.

MAF will consult stakeholders throughout the process of IHS development.

2.2.5. B+LNZ: Alternative measures- We are not aware of any alternative measures to those presented.

MAFBNZ response

Noted.

2.3. David Burt, Federated Farmers of New Zealand

2.3.1. FFNZ: Federated Farmers is supportive of a review of the risks around the importation of sheep and goat germplasm in regard to scrapie. The Federation notes that the measures currently in place in this area are considered to provide "firm guarantees against the introduction of ... scrapie..." and believe that the sum of any new measures introduced must provide the same level of assurance.

MAFBNZ response

Noted. This comment will be considered when decisions are made regarding risk management measures in the draft IHS.

2.3.2. FFNZ: In respect of embryos, it appears, on the basis of the IRA document, that it is highly unlikely that scrapie can be transmitted by transfer of embryos collected and processed according to the recommendations of the International Embryo Transfer Society (or the relevant OIE standard). The risk may be further reduced if insemination is only carried out by rams of the (scrapie resistant) ARR/ARR genotype, but it is noted that the usefulness of this secondary measure for goats is unproven. A further requirement for donor flocks to meet the OIE criteria for flock freedom, while unlikely to materially affect the risk, may transfer some of the risk management burden off-shore.

MAFBNZ response

Noted. However, importing embryos that are from ewes inseminated with ARR/ARR scrapie resistant rams is unwarranted, as the safety of embryos has been clearly demonstrated This comment will be considered when decisions are made regarding risk management measures in the draft IHS.

2.3.3. FFNZ: Options for embryos [Section 3.3.8 (pp 38 – 41)] Based on the information provided, appropriate management measures may be: A requirement that donor flocks meet the OIE criteria for flock freedom (the IRA notes that this would shift risk management off-shore) and that Insemination is only carried out by rams of the (scrapie resistant) ARR/ARR genotype – it is noted that the usefulness of this measure for goats is unproven - and The (other) conditions of the OIE code are met, including the need to collect and process embryos according to the recommendations of the International Embryo Transfer Society/OIE.

MAFBNZ response

The proposed combination of risk management measures for embryos will be considered by the Imports Team when drafting the IHS. However, importing embryos that are from ewes inseminated with ARR/ARR scrapie resistant rams is unwarranted, as the safety of embryos has been clearly demonstrated.

2.3.4. FFNZ: In respect of semen, the same broad conditions would apply (ie donor rams to meet the OIE criteria for flock freedom; restricting semen donors to the ARR/ARR genotype – though as above the usefulness of this measure for goats is unproven; semen to be collected and processed according to the recommendations of the OIE.) The Federation notes that the research in respect of semen does not appear to be as voluminous as that available for embryos and therefore considers that whether or not this materially increases the risk to New Zealand in respect of this disease is a matter that should be considered – as should the necessity (or otherwise) of addressing the issue of ATS [atypical scrapie] in the Import Health Standard that will be the ultimate output of this process.

MAFBNZ response

Noted. Although the cumulative scientific evidence for semen is not as voluminous as for embryos, there is strong evidence presented in the risk analysis that shows semen not to be a vehicle for scrapie. Restricting semen donors to the scrapie resistant genotype could provide additional assurance for any who don't accept the evidence that semen is not a vehicle for scrapie transmission.

This comment will be considered when decisions are made regarding risk management measures in the draft IHS.

So-called atypical scrapie is generally recognised as "… clinically, pathologically, biochemically and epidemiologically unrelated to 'classical' scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep" (*Code* Article 14.9.1). Atypical scrapie has been detected in New Zealand and no practical measures are available to mitigate any risk posed by a spontaneously-occurring degenerative condition.

2.3.5. FFNZ: Options for semen Based on the information provided, appropriate management measures may be: A requirement that donor flocks meet the OIE criteria for flock freedom (the IRA notes that this would shift risk management off-shore) and that Restricting semen donors to rams of the (scrapie resistant) ARR/ARR genotype – it is noted that the usefulness of this measure for goats is unproven - and The conditions of the OIE code are met, including the need to collect and process semen according to the recommendations of the OIE. Note: As noted above, the Federation remains concerned at the relative lack of research available – as discussed in the IRA – compared to that published on embryos and consider that this matter should be considered further.

MAFBNZ response

There are good grounds for considering that semen is not a vehicle for scrapie (see Section 3.1.4.5. of the risk analysis). Imports of semen, with no additional safeguards, would be unlikely to introduce scrapie. Restricting semen donors to the scrapie resistant ARR/ARR genotype could provide additional confidence that scrapie would not be associated with the commodity.

The proposed combination of risk management measures for semen will be considered by the Imports Team when drafting the IHS.

2.3.6. FFNZ: Comment on the risk management options provided. Ante-mortem tests for scrapie – Bioassays [Section 3.3.3.1 (pp 29 – 36)] [From the statements made in the IRA, this] leads Federated Farmers to believe that the bioassays currently available are not, of themselves, an effective means of ensuring the absence of scrapie from sheep or goats.

MAFBNZ response

Agreed. This comment will be considered when decisions are made regarding risk management measures in the draft IHS.

2.3.7. Selection of donors on the basis of age [Section 3.3.6 (page 37) The use of older animals, with or without additional restrictions on genotypes is likely to provide some risk mitigation but age based control measures should be used in conjunction with other measures.

MAFBNZ response

Noted. This comment will be considered when decisions are made regarding risk management measures in the draft IHS.

2.3.8. Quarantine of offspring [Section 3.3.7 (pp 37 – 38) Used as part of New Zealand's current SFAP, it is noted that, of itself, quarantine is insufficient to ensure the continued absence of scrapie from sheep and goat flocks.

MAFBNZ response

Noted. This comment will be considered when decisions are made regarding risk management measures in the draft IHS.

2.3.9. Atypical scrapie (ATS) The comment of the 2007 OIE ad hoc group reported in the IRA (page 44) that "There is currently no epidemiological evidence of an association between classical and atypical scrapie" is noted. Whether or not the presence or absence of ATS is a matter of concern for overseas countries is an issue that may need to be considered in relation to the development of the consequential IHS.

MAFBNZ response

Atypical scrapie is not an OIE listed disease and measures for atypical scrapie are not proposed in the risk analysis. The *Code* chapter on scrapie specifically excludes atypical scrapie which is clinically, pathologically, biochemically and epidemiologically unrelated to classical scrapie. The *Code* states that atypical scrapie may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.

2.4. Jock Allison, Agricultural and Management Consultant

2.4.1. Jock Allison: The completion of the above analysis [scrapie in sheep and goat germplasm] 5+ years after the MAF 2005 IRA on small ruminant germplasm and 2006 Review of Submissions is welcome. It is a comprehensive and impressive document. I have no substantive comments to make.

MAFBNZ response

Noted.

2.4.2. Jock Allison: It is important that the information contained therin is coordinated with the information in the 2005 review into draft import health standards to allow consideration of imports of small ruminants into New Zealand. Is this step only proceded with when requested by would be importers? Please advise.

MAFBNZ response

The review of submissions document identifies any matters in the draft risk analysis that need amending and makes recommendations for changes required to finalise the risk analysis. This comment is outside the scope of this document, and has been forwarded to the Imports Team of MAFBNZ who have provided the appropriate advice to the submitter.

3. Copies of Submissions

3.1. Peter Hewitt, Biosecurity Australia, Department of Agriculture, Fisheries and Forestry

Sent: Friday, 25 March 2011

Subject: NZ – scrapie

Dear Christine

Please find attached a response on BNZ's draft IRA on scrapie in sheep and goat germplasm.

Regards
Louise

Louise Kench
Principal Veterinary Officer
Animal Biosecurity, Biosecurity Services Group
Australian Government Department of Agriculture, Fisheries and Forestry
Ph: +61 2 6272 3681
Email: louise.kench@daff.gov.au

Australian Government
Department of Agriculture, Fisheries and Forestry

25 March 2011

Ms Christine Reed
Manager, Biosecurity Risk Analysis Group
Science, Information and Risk Directorate
Policy, Science and Economics Branch
Ministry of Agriculture and Forestry
Pastoral House 25 The Terrace
PO Box 2526, Wellington
NEW ZEALAND

Dear Christine

Thank you for the opportunity to comment on the Biosecurity New Zealand (BNZ) document *Import Risk Analysis: Scrapie in sheep and goat germplasm, Draft for public consultation 20 January 2011*. We appreciate your agreement to extend the consultation period and would like to offer the following comments.

Like BNZ, Animal Biosecurity understands that our producers wish to introduce highly desired ovine and/or caprine genetic material from scrapie affected countries to improve existing bloodlines or introduce new breeds. We understand the need to support the safe trade in genetic material while protecting the importing country's animal health status for scrapie. We agree that restricting import to PrP genotypes that are highly susceptible to scrapie is at odds with selection programs in scrapie affected countries which favour scrapie PrP resistant genotypes.

We are also very aware that developments in knowledge on scrapie have occurred, some of this work being reported relatively recently. However, we note that some of this research has varying value or relevance to scrapie free countries, such as Australia and New Zealand, which maintain freedom through an appropriate suite of risk management measures, whilst facilitating imports to the extent possible.

We also agree that, while the available scientific literature points to low risk of transmission from sheep and goat semen and embryos from scrapie affected countries, a position we also supported in 2000, transmission cannot be entirely ruled out. We would generally support the premise that the more trials that are completed without the event occurring, the more confident one can be that it will not occur. However, the final basis for decision-making is that import conditions must meet an importing country's appropriate level of protection for the disease and commodity.

18 Marcus Clarke Street Canberra City ACT GPO Box 858 Canberra ACT 2601 ph +61 2 6272 3933 fax +61 6272 3008 www.daff.gov.au ABN 24 113 085 695

DEPARTMENT OF AGRICULTURE, FISHERIES AND FORESTRY

We endorse BNZ's assessment that the consequences of introducing scrapie would be high. While BNZ expresses uncertainty about estimating the consequences of introduction, in Australia's case, it is notable that we have many export conditions for a variety of sheep/goat related materials that currently require certification of country freedom from scrapie.

I should also draw your attention to some particular points of difference.

I note reliance in the draft IRA on current OIE Code recommendations for semen and embryos. There is, for example, a clear expression of support for the safety of embryos with intact zona pellucida washed according to the procedures of the International Embryo Transfer Society, and indications that BNZ might consider this sufficient risk management. However, the IRA is unclear about what other options, if any, might be considered necessary to meet New Zealand's appropriate level of protection.

There is also ambiguity concerning other options, for example, the value of the scrapie free status of the flock of origin, how this would be assessed, and how it could be incorporated in a scientifically sound and practical way into proposed risk management. It would appear that donor age restrictions are not likely to feature in New Zealand's proposal.

Overall, the IRA suggests that scrapie restrictions on imported genetic material may be reduced substantially compared to previous requirements.

At this time, Australia requires additional risk management, beyond OIE recommendations, for scrapie. Please note that Australia's comments to the OIE Code Commission have reflected this position. I refer you to the following DAFF webpages for further details of our current import policy with regard to scrapie:

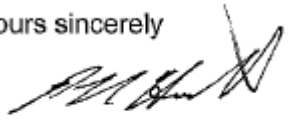
http://www.daff.gov.au/ba/ira/final-animal/ovine-caprine-canadausaeu

http://www.daff.gov.au/ba/ira/final-animal/scrapie.

From the recent, informative bilateral discussions in Wellington, I appreciate your new process for policy development and that the IRA presents the scientific basis which underpins development of an import health standard (IHS). We would be able to provide more specific and detailed comment on recommendations contained in the draft IHS and look forward to reviewing your compilation of the relevant facts and comments into an IHS that reflects acceptable risk management for this disease. On this point, it seems worthwhile to reiterate our support for harmonisation of Australian-New Zealand import conditions where possible so that Trans-Tasman trade can continue to be facilitated.

Thank you once again for the opportunity to comment.

Yours sincerely



Dr Peter Hewitt
Manager, Ruminant section
Animal Biosecurity

3.2. Chris Houston, Beef and Lamb New Zealand Ltd

Sent: Friday, 04 March 2011
Subject: Scrapie in sheep and goat germplasm - Import Risk Analysis

4 March 2011

Christine Reed
Manager – Risk Analysis Group
MAF Biosecurity New Zealand
by email

Dear Christine

"Scrapie in sheep and goat germplasm" – draft risk analysis for public consultation

Beef + Lamb New Zealand Limited, as representatives of sheep and beef farmers appreciate the opportunity to provide comment on this import risk analysis. As set out in the document, introduction of scrapie into the New Zealand sheep flock would potentially have very serious consequences for our industry. Accordingly, and recognizing MAF's mandate in this area, we place a large amount of trust in the expertise of MAFBNZ to prevent this from occurring.

In your letter dated 20th January, you indicated that you would value comment on four specific questions – I'm happy to address these below:

1. Accuracy and completeness of the risk assessment
The document appears to be comprehensive and well referenced. We have no reason to question the validity of the evidence presented and are not aware of any significant omissions. The technical expertise of the author, Prof MacDiarmid, is well known and respected within the industry.

2. Adequacy of description of risk management measures
We feel that applicable risk management measures are adequately described. It would be informative for any risk management regimes that have been put in place, for these commoditie in other scrapie free countries to also be described.

3. Preferred risk management options
We are unclear about what combination of risk management options would represent the optimum regime for managing the risk in the commodities, as many of the options presented appear to have significant associated constraints. Our initial view is that the development of any risk management regime should fully explore the benefits and constraints of requiring that germplasm is sourced only from scrapie-free flocks.

4. Alternative measures
We are not aware of any alternative measures to those presented.

Once again, B+LNZ appreciates the opportunity to comment on this risk analysis and we look forward to receiving any review of submissions and / or draft import health standard that follows.

Yours sincerely

Chris Houston
Senior Advisor – Technical policy

beef + lamb new zealand ltd
level 4, wellington chambers, 154 featherston street, wellington 6011, new zealand
po box 121, wellington 6140, new zealand
freephone 0800 beeflamb (0800 233 352) email enquiries@beeflambnz.com website www.beeflambnz.com

3.3. David Burt, Federated Farmers of New Zealand

Sent: Thursday, 3 March 2011
Subject: Submission on IRA: Scrapie in sheep and goat germplasm - Draft for public consultation

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: Scrapie in sheep and goat germplasm

Date: 3 March 2011

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

Federated Farmers of New Zealand
Box 715, Wellington 6140, New Zealand

P 04 494 9182
F 04 473 1081
dburt@fedfarm.org.nz

SUBMISSION TO BIOSECURITY NEW ZEALAND ON A DRAFT IMPORT RISK ANALYSIS "SCRAPIE IN SHEEP AND GOAT GERMPLASM"

1. FEDERATED FARMERS CONCERNS

Federated Farmers is supportive of a review of the risks around the importation of sheep and goat germplasm in regard to scrapie.

The Federation notes that the measures currently in place in this area are considered to provide "firm guarantees against the introduction of … scrapie…" and believe that the sum of any new measures introduced must provide the same level of assurance.

In respect of embryos, it appears, on the basis of the IRA document, that it is highly unlikely that scrapie can be transmitted by transfer of embryos collected and processed according to the recommendations of the International Embryo Transfer Society (or the relevant OIE standard). The risk may be further reduced if insemination is only carried out by rams of the (scrapie resistant) ARR/ARR genotype, but it is noted that the usefulness of this secondary measure for goats is unproven. A further requirement for donor flocks to meet the OIE criteria for flock freedom, while unlikely to materially affect the risk, may transfer some of the risk management burden off-shore.

In respect of semen, the same broad conditions would apply (ie donor rams to meet the OIE criteria for flock freedom; restricting semen donors to the ARR/ARR genotype – though as above the usefulness of this measure for goats is unproven; semen to be collected and processed according to the recommendations of the OIE.)

The Federation notes that the research in respect of semen does not appear to be as voluminous as that available for embryos and therefore considers that whether or not this materially increases the risk to New Zealand in respect of this disease is a matter that should be considered – as should the necessity (or otherwise) of addressing the issue of ATS in the Import Health Standard that will be the ultimate output of this process.

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 stakeholder comment on the above draft document *["Import Risk Analysis*: Scrapie in sheep and goat germplasm DRAFT FOR PUBLIC CONSULTATION", 20 January 2011] by the Manager, Risk Analysis Group, Policy and Risk Directorate, in a covering letter dated 20 January 2011.

3. GENERAL COMMENTS

3.1 The need to maintain firm guarantees against the introduction of scrapie into New Zealand

The Risk Analysis notes [Section 3.3.8 "Options for embryos, (page 38)] that "*The benchmark against which … options must be assessed is the safety provided by the SFAP's under which … previous importations of sheep have been made*" and further (in 2008), "*MAF risk assessments … concluded that the SFAP's provide firm guarantees against the introduction of either scrapie or BSE*".

While it is important that scientific developments are taken into consideration when reviewing risk management options – and the subsequent publication of Import health Standards - Federated Farmers believes that the scrapie-free status currently enjoyed by New Zealand must not be placed at risk. As a consequence, any new control measure, or combination of measures that are introduced in respect of the importation of sheep or goat germplasm must provide the same level of guarantee that already exist around scrapie.

3.2 The need to balance critical, risk management outcomes with other issues, such as animal welfare.

The document notes [Section 3.3.1, "Bioassays" (page 30)], in respect of intracerebral inoculation that *"one could question whether the technique would still be acceptable, given the current greater awareness of animal welfare issue*". While noting also that *"… mishaps have occurred when the technique has been applied in New Zealand …*" it is unclear from the document whether this technique is still practised as part of New Zealand's Scrapie Freedom Assurance Programme (SFAP).

While the Federation is supportive of incorporating animal welfare advances into the risk management framework, consideration of such advances should not be looked at in isolation from the context in which they are to be applied. Changes to biosecurity risk management options should not be driven by - or be beholden to – the court of public opinion on animal welfare.

4. COMMENT ON THE RISK MANAGEMENT OPTIONS PROVIDED

4.1 Ante-mortem tests for scrapie – Bioassays [Section 3.3.3.1 (pp 29 – 36)]

The IRA document states, (page 35) when considering the "likelihood of identifying a flock as infected using biopsy of lymphoid tissue" that "*… the sensitivity of tests which examine lymphoid tissues for accumulations of PrP^{SC} is not sufficient to give good assurances on the scrapie-free status of an individual sheep or goat*"

Similarly, it notes (page 36) the use of whole-of-flock biopsy RAMALT testing would be conditional on the flock having a minimum number of infected animals to be effective, a condition that, (based upon the cited work of Ortiz-Pelaez and Del Rio Vilas) cannot be relied upon.

When, in addition it is realised that bioassays are only able to detect scrapie from about half-way through the incubation period (page 34), this leads Federated Farmers to believe that the bioassays currently available are not, of themselves, an effective means of ensuring the absence of scrapie from sheep or goats.

4.2 The risk of transmission of scrapie via semen or embryo transfer [Section 3.1.4.5 "Transmission", (pp 19 – 22)]

There is substantial documentation that supports the contention, as the IRA concludes (page 22) "*… it is highly unlikely that scrapie can be transmitted by transfer of embryos collected and processed according to the recommendations of the*

International Embryo Transfer Society" (though only one study is cited pertaining to goats).

The evidence around the risk of transmission from semen however, is less conclusive, with much less literature examined in this *area*. This is presumably why the scrapie risk from this tissue is stated differently *"… there are good grounds for considering that that semen is not a vehicle for scrapie*" [Section 3.3.4] viz "*There is very strong evidence that embryos, collected according to the recommendations of the OIE, are not a vehicle for scrapie*" [Section 3.3.5].

The phrasing of the above comment concerning semen is hardly a ringing endorsement in terms of the risk it presents around scrapie transmission and the Federation considers that risks in this (semen) area warrant further consideration.

4.3 **Selection of donors on the basis of age** [Section 3.3.6 (page 37)]
The use of older animals, with or without additional restrictions on genotypes is likely to provide some risk mitigation but age based control measures should be used in conjunction with other measures.

4.4 **Quarantine of offspring** [Section 3.3.7 (pp 37 – 38)]
Used as part of New Zealand's current SFAP, it is noted that, of itself, quarantine is insufficient to ensure the continued absence of scrapie from sheep and goat flocks.

4.5 **Options for embryos** [Section 3.3.8 (pp 38 – 41)]
Based on the information provided, appropriate management measures may be:

- A requirement that donor flocks meet the OIE criteria for flock freedom (the IRA notes that this would shift risk management off-shore) and that
- Insemination is only carried out by rams of the (scrapie resistant) ARR/ARR genotype – it is noted that the usefulness of this measure for goats is unproven - and
- The (other) conditions of the OIE code are met, including the need to collect and process embryos according to the recommendations of the International Embryo Transfer Society/OIE

4.6 **Options for semen**
Based on the information provided, appropriate management measures may be:

- A requirement that donor flocks meet the OIE criteria for flock freedom (the IRA notes that this would shift risk management off-shore) and that
- Restricting semen donors to rams of the (scrapie resistant) ARR/ARR genotype – it is noted that the usefulness of this measure for goats is unproven - and
- The conditions of the OIE code are met, including the need to collect and process semen according to the recommendations of the OIE.

Note: As noted above, the Federation remains concerned at the relative lack of research available – as discussed in the IRA – compared to that published on embryos and consider that this matter should be considered further.

4.7 **Atypical scrapie (ATS)**
The comment of the 2007 OIE *ad hoc* group reported in the IRA (page 44) that "*There is currently no epidemiological evidence of an association between classical and atypical scrapie"* is noted.

Whether or not the presence or absence of ATS is a matter of concern for overseas countries is an issue that may need to be considered in relation to the development of the consequential IHS.

5. ABOUT FEDERATED FARMERS OF NEW ZEALAND

5.1 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.

5.2 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.

3.4. Jock Allison, Agricultural and Management Consultant

Dated: Monday, 7 February 2011
Subject: Import risk analysis : Scrapie in sheep and goat germplasm:

Jock Allison
M.Agr.Sc. Ph.D ONZM
AGRICULTURAL AND
MANAGEMENT CONSULTANT

5 Arthur Street, Dunedin, **NEW ZEALAND**
Telephone: 64 3 477 2903
Fax: 64 3 477 2933
Mobile: 64 21 363 337
Email: jock.allison@xtra.co.nz

7th February 2011

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

Dear Sir / Madame,

Import Risk Analysis : Scrapie in Sheep & Goat Germplasm :

The completion of the above analysis 5+ years after the MAF 2005 IRA on small ruminant germplasm and 2006 Review of Submissions is welcome. It is a comprehensive and impressive document. I have no substantive comments to make.

It is important that the information contained therein is coordinated with the information in the 2005 review into draft import health standards to allow consideration of imports of small ruminants into New Zealand. Is this step only proceded with when requested by would be importers?

Please advise,

Thankyou,

Jock Allison