Import risk analysis: Sheep and Goat Genetic Material

Review of Submissions

Biosecurity New Zealand
Ministry of Agriculture and Forestry
Wellington
New Zealand

May 2006

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Pre-Clearance
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Approved for general release

Debbie Pearson
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EXECUTIVE SUMMARY

Four submissions on the MAF risk analysis for the importation of sheep and goat semen and embryos into New Zealand were received from interested parties.

The questions, comments and recommendations of submitters are summarised in this review and the full submissions are included as appendices. The MAF response to submissions is given.

Based on reviewers' suggestions, MAF proposes that at the following recommendations be included in the import health standard (IHS) that will be produced based on the risk analysis:

1 The donors' quarantine period for lumpy skin disease should be increased as new information suggests that animals may excrete the virus in semen for longer than the 21 days cited in the risk analysis.

2 The requirement to test sheep for Borna disease should be dropped in view of the fact that such testing is not required for horses.

3 Donor animals should be derived from flocks where Borna disease has not occurred for the last 5 years.

In addition, the IHS should note that MAF reserves the right to audit germplasm collection centres and laboratories in exporting countries

Suggestions that were not accepted include:

1. That importations should be allowed from countries that vaccinate against foot and mouth disease. This suggestion may be technically sound but is rejected as foot and mouth disease would cause extreme economic damage to New Zealand. Therefore, a very conservative stance is justified. It is believed that stakeholders will support such a conservative stance.

2. That scrapie should be included in the present risk analysis. This is not accepted as MAF intends to assess this separately.

3. That it will be difficult to find flocks with a reliable history of freedom from jaagsiekte (ovine pulmonary adenomatosis). Although this is accepted as correct, a difficulty in finding suitable animals to import cannot justify a relaxation of measures to exclude the introduction of diseases.

The reasons for not accepting other suggestions from submitters are given in this review. Some of the points raised in submissions were beyond the scope of the risk analysis and, generally, no comments have been made about these.

It is concluded that the recommendations of the risk analysis are valid and should be incorporated into an IHS for the importation of sheep and goat germplasm.

INTRODUCTION

The MAF risk analysis on sheep and goat germplasm was released for public consultation on 26 October 2005 and submissions closed on 15 December 2005, but extensions for late submissions were granted to 15 January 2006. The following submissions were received:

	Date	Name	Organisation represented/location
1	20/6/05	G. L. Nortje	
2	11/1/06	A. J. Allison	Agricultural and Management Consultant
3	5/12/05	S. Newland	Meat & Wool New Zealand
4	10/1/06	J Thompson	Animal health consultant.

This document reviews each submission in turn, focussing on technical issues of contention. One of the submissions referred to a preliminary version of the document that was sent to an interested potential exporter in June 2005 and this reviewer's comments are included in this review of submission received (G. L. Nortje). However, several of the comments were not relevant to the current version of the risk analysis and are not included in the discussion.

Risk analyses are carried out by MAF in the context of Section 22 of the Biosecurity Act 1993 Section 22 (5) lays out what MAF is required to do in regard to issuing Import Health Standards (IHSs) to effectively manage the risks associated with the importation of risk goods. Risk analyses are conducted in accordance with MAF's policy statement on "Conducting Import Risk Analyses and Applying them in the Development of Import Health Standards", which can be found on the MAF website:

http://www.biosecurity.govt.nz/pests-diseases/risk-policy.htm

As explained in that policy risk analysis provides the best means of ensuring that Chief Technical Officers (CTOs), or those acting under their delegated authority, fulfil their legal obligations under Section 22 of the Biosecurity Act when developing Import Health Standards (IHSs). The policy also states that risk analysis is a management tool that incorporates scientific methods to enable regulators to gather and assess information and data in a thorough, consistent, logical and transparent way, to ensure that:

a) organisms that may cause unwanted harm are identified;
b) the likelihood of these organisms being introduced into New Zealand and the nature and possible effect on people, the environment and the economy is assessed;
c) appropriate biosecurity measures to effectively manage the risks posed by these organisms are developed;
d) the results, conclusions and recommendations arising from the analysis are effectively communicated amongst interested parties.

Section 22 (5) of the Biosecurity Act 1993 also requires CTOs to have regard to New Zealand's international obligations when carrying out risk analyses to support the issuing of IHSs. Of particular significance in this regard is the Agreement on the Application of Sanitary &

Phytosanitary Measures (the "SPS Agreement") of the World Trade Organization. MAF's Policy Statement on the SPS Agreement is also available on the MAF website:

http://www.biosecurity.govt.nz/sps/resources/policies/raspspol.htm

A key obligation under the SPS Agreement is that sanitary 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 must conform to an internationally recognised process that has been developed to ensure scientific objectivity and consistency. This methodology is outlined in Section 2.3 of the risk analysis. A comprehensive description is available in *Import Risk Analysis Animals and Animal Products* (Murray 2002)[1].

In applying this process every step has been taken to ensure transparency. The risk analysis provides a reasoned and logical discussion, supported by references to scientific literature. The risk analysis was peer reviewed, first internally and then externally by the experts listed on page iii of the risk analysis, who were chosen on the basis of their acknowledged expertise in their field. The process dictates that the critiques provided must be reviewed and, where appropriate, incorporated into the analysis.

The consultation on the risk analysis is for technical issues. For this reason, the review of submissions will address issues of science surrounding likelihood[2], not possibility[3], of events occurring. Speculative comments and economic factors other than the effects directly related to a potential hazard are beyond the scope of the document.

[1] Murray N (2002) *Import Risk Analysis Animals and Anima lProducts.* MAF, Wellington, New Zealand.
[2] Likelihood**:** The quality or fact of being likely or probable; probability; an instance of this.
[3] Possible: Logically conceivable; that which, whether or not it actually exists, is not excluded from existence by being logically contradictory or against reason.

REVIEW OF SUBMISSIONS

1. G. L. NORTJE

The submitter's questions and comments that are based on an earlier draft of the risk analysis which are not relevant to the final analysis are not discussed. Similarly, comments relating to format have not been considered since the analysis follows MAF's preferred format.

1.1 The submitter questions the fact that the number of 'yes' indicators in Table 1 which refer to diseases of concern for MAF does not correspond to the number of analyses carried out.

MAF response: Some organisms such as the *Mycoplasma* spp. and *Salmonella* spp. are listed as several species in Table 1 but the analyses of these organisms cover a group of organisms in the genus. For this reason there are 41 'yes' entries in Table 1 but only 34 analyses were carried out.

1.2 The reviewer suggests that the risk analysis should include an OIE definition of each disease and give the OIE *Terrestrial Animal Health Code* chapter number for each disease.

MAF response: The OIE *Terrestrial Animal Health Code* does not number diseases. The *Code* is accessable on the OIE website, and since it is revised annually and new editions may contain alterations, including revised chapter numbers, citing disease definitions is not considered to be necessary or desirable.

2. J. ALLISON

2.1 The submitter suggests that a strategy could be implemented to allow safe importation from a country where vaccination against foot and mouth disease is practised, including testing of donor ewes and/or recipient ewes implanted with embryos.

MAF response: The International Embryo Transfer Society classifies foot and mouth disease as a Category 3 disease in sheep and goats, that is, one "for which preliminary evidence indicates that the risk of transmission is negligible provided that the embryos are properly handled between collection and transfer according to the IETS manual, but for which additional *in vitro* and *in vivo* experimental data are required to substantiate the preliminary findings". MAF does not believe that this IETS statement is sufficiently robust to consider importation of embryos a safe procedure. The *OIE Terrestrial Animal Health Code* does not provide any guidelines for the importation of small ruminant embryos from any country category (free, infected, vaccine practised or not practised). While MAF considers it highly unlikely that the submitter's suggestion would provide a safe method of importing embryos,since foot and mouth disease is a particularly infectious and economically devastating disease MAF considers that a precautionary position is appropriate.

2.2 The submitter suggests that scrapie should be included in the present review.

MAF response: Because of the complexity of issues surrounding the family of diseases known as transmissible spongiform encephalopathies (TSEs), of which scrapie is a member, MAF plans to conduct a separate risk analysis on scrapie. Until this can be conducted, the scrapie freedom assurance programmes based on earlier risk analyses will continue to be applied. At the present time there is some uncertainty about the differentiation of classical scrapie, atypical forms of scrapie that can infect resistant genotypes of sheep, and the possible occurrence of BSE in sheep. While a number of new diagnostic tests for scrapie have been developed in recent years (third eyelid biopsy, tonsil biopsy, rectal mucosa biopsy), none have been thoroughly validated and all pose technical problems with respect to incorporation into quarantine programmes.

2.3 The submitter suggests that MAF should reserve the right to audit collection centres and laboratories in exporting countries even if they have been approved by the veterinary authorities of the exporting countries.

MAF Response: MAF always reserves the right to audit collection centres and laboratories in exporting countries, especially where the exporting country is not one with which New Zealand has an established importing relationship.

2.4 The submitter is concerned that the requirement for embryos for export to be collected in approved embryo collection centres is too restrictive and that embryos can be safely and hygienically collected in other facilities such as suitable on farm facilities.

MAF response: The statement is not intended to be restrictive, and other facilities that are suitable and meet all the requirements specified in the IHS will be able to be approved by the veterinary authority of the exporting country.

2.5 The submitter suggests that in the processing of the embryos, referral to OIE and IETS recommendations is inadequate because in these documents trypsin treatment of the embryos is optional. The recommendations of the risk analysis should be more specific.

MAF response; Although trypsin treatment is known to assist in the removal of some pathogens (e.g. herpes viruses) its efficiacy has not been demonstrated for many organisms. In some animals trypsin may be harmful to the embryos. MAF considers that the use of trypsin, except where its use is specifically required (e.g. IBR in cattle embryos), is a quality issue for the importer to consider. For these reasons the risk analysis recommends that treatment with trypsin be optional unless specifically required in a particular application. The position is similar in the IETS *Manual* and the OIE *Code*.

2.6 The submitter is concerned that there is no consideration of the recovery of either follicular ova and or epidermal sperm. Applications suggested for such methods include the importation of rare species such as Argali from embryos derived from slaughtered animals from the wild and from very young animals.

MAF response: MAF considers that insufficient information demonstrating the safety of *in vitro* derived, cultured or multiplied embryos has been published in peer reviewed literature. Some pathogens are less easily removed from *in vitro* derived bovine embryos than from *in vivo* derived embryos (BVD and IBD). There is little information on small ruminant embryos. General use of *in vitro* derived embryos could open the way to the use of ova derived from unsafe sources such as animals killed at slaughterhouses or slaughtered wild animals, where the disease status of the donors can not be well defined. With the exception of embryos derived embryos from follicular ova, the health status of the donors can not, by definition, be checked while the *in vitro* derived embryos are stored pending results. For these reasons the risk analysis is restricted to the use of *in vivo* derived embryos. However, in situations where there may be particular advantages to be gained from *in vitro* derived or cultured embryos MAF is prepared to work with prospective importers to carry out appropriate risk analyses from which equivalent import conditions may be developed.

2.7 The submitter is concerned that there is no mention of testing recipient ewes in the risk analysis and states that it has been used successfully in the past.

MAF response: MAF's policy is, wherever possible, to manage risks offshore. In the risk analysis pre-entry testing and/or quarantine and selection of animals from disease-free countries or flocks is considered to provide sufficient safeguard to prevent the importation of all the organisms considered, with the exception of jaagsiekte and foot and mouth disease. Generally post-entry quarantine is considered necessary only for diseases with long incubation periods during which the presence of the pathogen cannot be detected. For this reason it is recommended as a measure against jaagsiekte. Prolonged quarantine is also used in scrapie freedom assurance programmes based on an earlier risk analysis for that disease.

2.8 The submitter raises questions about what the requirements will be in relation to animals imported from scrapie-infected countries and the use of germplasm collected from slaughtered animals.

MAF response: Neither scrapie nor germplasm collected from donors and fertilised *in vitro* were considered in the risk analysis.

2.9 The submitter states that there is no course of action prescribed in case a positive result to the bluetongue test is found in a donor. In particular would the whole importation be prohibited or only the importation of the germplasm from a single donor that is in breach of the requirement?

MAF response: Since bluetongue is transmitted only by insect vectors there would be no reason to reject the entire consignment unless all donors in the group have been exposed to *Culicoides*. Therefore, in the event of a donor testing positive to bluetongue, only the importation of germplasm from donors that are in breach of the requirements would be prohibited. For this disease there is no reason to prevent the importation of germplasm from donors that comply, even if they have been in contact with non-compliant animals. Banning importation of a whole consignment applies only for diseases that are transmitted directly between animals and when the animals have been housed together while in quarantine.

2.10 The submitter does not consider that *Recommendation ii, Section 5.3.2.3* is appropriate and wishes to know how it would be applied. The recommendation is that donor animals should be maintained free from contact with *Culicoides* spp. for at least 100 days immediately before germplasm collection. This should be achieved by keeping them in a *Culicoides*-free area, or in a seasonally free area in which *Culicoides* are inactive, or in an insect free isolation facility.

MAF response: *Culicoides*-free zones and seasonally *Culicoides*-free areas are defined in the OIE *Terrestrial Animal Health Code*. Seasonally free zones are those that become free from *Culicoides* with the advent of winter frosts or other climatic conditions unfavourable to *Culicoides*. No area will be recognised as free or seasonally free in countries that do not have good data to support the claim. Isolation in an insect-free isolation station will only apply where custom-built, insect-free isolation facilities are available for quarantine. Such facilities may be available in Australia, USA, and South Africa and, possibly, in other bluetongue-infected countries and can be certified insect-free by the veterinary authorities of those countries.

The 100 day recommendation was based on the edition of the *Terrestrial Animal Health Code* which was current at the time the risk analysis was conducted. The current edition of the *Code* recommends 60 days and this will be reflected in the IHS developed from the risk analysis.

2.11 The submitter suggests that *Recommendation iic in Section 7.3.2.3,* which indicates that quarantine station should be in a sheep pox free zone, is unnecessary.

MAF response: This recommendation is specified in the *Terrestrial Animal Health Code and* MAF will retain it, the justification being that presented in the release assessment of the risk analysis.

2.12 The submitter is of the opinion that in *Section 8.3.2.3 Recommendation ii,* the sentence "*Germplasm from animals that seroconvert or have a rising titre between the two tests should be disqualified from being exported to New Zealand"* is unnecessary. The submitter then queries whether a positive test in a single donor animal in a group of

donor animals will disqualify the export of semen from the whole group in the case of bluetongue as it does in the case of Crimean Congo haemorrhagic fever.

MAF response: MAF believes this recommendation should be retained. Since the test criteria that allow animals to be used as donors are defined, test results that define unsuitable donors should also be given.

In this case, quarantine will be in an area where ticks are present and if one animal in a group for export has sero-converted it means that the animal may have been exposed to ticks while in quarantine. Therefore, other animals in the group could also have been similarly exposed. Because of increasing resistance of ticks to acaricides and the fact that sheep may carry immature ticks that are hard to detect into quarantine stations, MAF is less confident that a quarantine station can be maintained free from ticks than it is that a quarantine station can be maintained free from *Culicoides*. Banning the importation of all animals in a group if one of the group is found to be positive to a critical test applies to Crimean Congo disease but not to bluetongue (see Section 2.9).

2.13 The submitter suggests that few countries keep reliable records of the occurrence of jaagsiekte, and quotes Sweden as an example of a country where records were inadequate when that country was visited.

MAF response: While accepting that it may be difficult to find suitable flocks from which to import sheep it remains MAF's view that imports should not be allowed from flocks where the records are inadequate.

2.14 The submitter suggests that the stipulation (relating to jaagsiekte) that only second generation progeny should be able to be released into New Zealand is draconian and that no indication is given of how old the first generation of imported animals (offspring of recipients of germplasm) must be before they are assessed for whether they have the disease.

MAF response: The risk analysis recommends that "at the end of three and a half years recipients of germplasm and the first generation progeny should be slaughtered and examined for the presence of lesions of jaagsiekte". As there is uncertainty about the incubation period and no diagnostic test is available for use in live animals, such a risk-averse position is warranted. This could change if acceptable evidence becomes available showing that the incubation period is indeed shorter than three and a half years. It could also change if a suitable diagnostic test becomes available. However at the present time MAF believes that the recommendations are scientifically justified.

2.15 The submitter suggests that requirements to import sheep only from closed flocks that are free from maedi-visna will make future imports of sheep very doubtful. He suggests that reliance could be placed on testing only.

The closed flock option is only one of three options for risk management. Flock testing as an alternative to flock accreditation has also been proposed in the risk analysis.

MAF response: Reliance solely on serological testing would require a test of very high sensitivity. The following statement is taken from the OIE *Manual of Diagnostic Tests and Vaccines* "…. However the sensitivity and specificity of the ELISA depends on the quality of the antigen. In the case of MV/OPP and CAE viruses, the production of satisfactory antigen has limited its routine application". It is also stated that "The AGID test is specific, reproducible and easy to perform but that experience is required in reading the results". It is MAF's view that because of the perceived difficulties with the ELISA and MAF's own experience that the AGID for CAE is less sensitive than the ELISA, reliance solely on serological testing of individual animals is unwise.

2.16 The submitter suggests that for salmonellosis and other diseases, importers should have the opportunity to test animals at an early stage so that they do not run the risk of having animals condemned because of testing requirements at the end of an expensive programme of preparing donors and collecting germplasm.

MAF response: MAF agrees with the submitter. However, MAF is concerned only in the results of tests specified in the risk analysis. MAF considers it logical for importers to conduct their own testing programmes to ensure that the donors and/or germplasm to be imported have been tested before official testing or quarantine begins. Contracts to purchase can be made conditional on the donors or germplasm having passed tests required by the purchaser. This would minimise the likelihood of animals being condemned through the official testing. Such preliminary testing would be the responsibility of the importer.

2.17 The submitter points out that for the importation of semen and embryos from many countries, antibiotic treatment of the animals for leptospirosis is permitted prior to embryo collection. The current risk analysis does not require treatment against leptospirosis but does include a requirement for the addition of antibiotics to the germplasm. The submitter asks whether there is a good reason for this.

MAF response: The efficacy of parentally administered antibiotics for the elimination of *Leptospira* from germplasm depends on the antibiotic reaching the semen or ovary in sufficient concentrations to eliminate the organism. This process is variable and cannot be depended on. It is therefore considered more reliable to add the antibiotics to the germplasm in appropriate doses. This is done routinely to virtually all semen diluents and can also be done while washing embryos. The efficacy of antibiotics is discussed in Sections 28.2.1.1 and 28.2.1.2 of the risk analysis. Treatment of germplasm with antibiotics is suggested as a possible option in Section 28.3.2.1 and finally as a recommendation in Section 28.3.2.3. The *OIE Terrestrial Animal Health Code* recommends treatment of embryos and addition of antibiotics to semen.

2.18 The submitter indicates that germplasm collection centres that are free from enzootic abortion will be difficult to find in most countries.

MAF response: It is MAF's view that enzootic abortion is an economically significant disease that should be excluded from New Zealand. Infected animals may remain asymptomatic and chronically infected. Therefore the requirement is that donors should be from flocks or germplasm collection centres that are free from this disease. Flock freedom is defined in the *Terrestrial Animal Health Code*. If flocks or germplasm collection centres free from enzootic abortion cannot be found, the alternative of flock testing has been proposed in the risk analysis.

2.19 The submitter seeks clarification about whether a positive test for Q fever will disqualify importation of a whole shipment or just the animal that tests positive.

MAF response: It is recommended that only the germplasm from animals that test positive should be disqualified in the case of Q fever.

2.20 The submitter raises several questions about MAF's policy regarding the production of import health standards. He makes a case for more flexibility and suggests that in some cases where the disease status of a country is difficult to assess, MAF should send a veterinarian to investigate the situation. He alludes to the expense and human resources committed to the production of an IHS for ovine embryos from Israel with no recognisable gain.

MAF response: MAF endeavours to be flexible and to negotiate with would-be importers in special cases where development of a one-off IHS is required. Visits to other countries to assess the veterinary services will also be considered. However, MAF's resources are limited such a visit is perceived to benefit a single or a few individuals, the expense, and business risk, may have to be borne by the beneficiaries of the work. MAF's responsibility is to preserve New Zealand's disease free status, even if means that an IHS cannot be developed or maintained despite a potential importer having made considerable investment in the project.

3 MEAT & WOOL NEW ZEALAND

3.1 The submitter suggests that the assumption in the risk analysis that germplasm should be collected from healthy animals should be a requirement rather than an assumption.

MAF response: When MAF produces an IHS based on this risk analysis recommendations and assumptions become requirements prefaced by must or shall. When produced the IHS will be available for public consultation.

3.2 The submitter suggests that the assumption that male donors will be of equal health status to the female donor at the time of semen donation or natural mating should be explicitly stated in the requirements.

MAF response: When MAF produces an IHS based on this risk analysis recommendations and assumptions become requirements prefaced by must or shall. When produced the IHS will be available for public consultation.

3.3 The submitter suggests that the statement "When Import Health Standards are written for particular cases these recommended periods may be modified." in Section 2.3 of the risk analysis needs to be clarified, indicating whether changes to the recommendations of the risk analysis in the IHS would be provided and consulted upon.

MAF response: Because precise information is not always available, the quarantine periods recommended in the risk analysis are to some extent based on the judgment of the risk analyst. Such recommendations can be modified when drafting the IHS should there be practical reasons for minor changes that can be justified on a scientific basis.

3.4 The submitter sought clarification of Section 6.3.2.3, i, ii, iii of the risk analysis (recommendations regarding Borna disease). He enquired whether the recommendations mean i (alone) or ii and iii.

MAF Response: It is confirmed that it means either i (alone) or ii and iii.

3.5 With regard to Section 6.3.2.3, ii, (relating to Borna disease) the submitter suggested that "The minimum period of flock freedom, and the conditions under which it would be accepted, should be indicated. If this measure is being left flexible to allow the actual period of flock freedom to be determined on a case by case basis this should be explicitly stated. As currently stated it is unclear whether the veterinary officials of the exporting country dealing with the specific consignment makes the decision as to what is acceptable or whether this is the role of New Zealand officials. Given that only New Zealand officials will be aware of New Zealand's acceptable level of risk this is a decision that should be made by them and this should also be explicitly stated."

MAF response: As a result of this review of submitter comments and further consultation in MAF it is recommended that the IHS should stipulate the period of flock freedom from the disease as 5 years.

3.6 With regard to the recommendations regarding Rift Valley fever the submitter commented that "Further clarification is required regarding the reasoning behind the OIE recommended measures for the trade of live animals from infected, disease free countries (i.e. "resided for 6 months….in which climatic changes predisposing to **outbreaks** of Rift Valley fever have not occurred").

Given that Rift Valley fever has the potential to impact on both animal and human health, and "little is known as to how the virus is maintained through inter epidemic periods" Meat & Wool New Zealand considers that accepting genetic material from donors under this condition (ii) poses an unacceptably high level of risk. The measure is difficult to quantify (i.e. what exactly are the climatic changes other than "high" summer rain levels, does this mean the whole country has had these conditions or those regions where the animals have lived?), does not take into account the lack of knowledge about how the virus is maintained (and therefore whether a non-negligible risk exists of donor animals becoming infected even under these climatic conditions), and is a lesser standard for "country freedom" than would normally be accepted for other diseases posing a similar level of risk.

Given that an alternative measure (iii) is provided as an option which would provide a greater level of risk mitigation with minimal negative impacts on the ability to trade Meat & Wool New Zealand recommend that the option of this measure (ii) be removed."

MAF response: For many years at a time, Rift Valley fever does not appear in those African countries which do experience outbreaks. Then, in an abnormally wet summer when masses of mosquitoes emerge, such as in the South African highveld, outbreaks are experienced. Rift Valley fever occurs only in Africa and the Arabian peninsular. It is dependent on mosquito activity in the wet season. Such activity ceases completely after the first frost in winter. Winters are also dry and offer no breeding places suitable for the particular types of mosquitoes. Given an infective period of 30 days in animals, the OIE has accepted the principle that for long periods most countries in Africa will be free from Rift Valley fever.

Provided that the animals have resided in a country in which the disease has not occurred and in which the conditions for it to occur have not been present, there is no possibility of importing the virus. This applies to live animals and germplasm.

3.7 With regard to testing for enzootic abortion, Section 33.3.1.3 the submitter enquired whether embryos unsuitable for export (for commercial reasons) are able to be used for testing purposes.

MAF response: The intention is that if there are embryos unsuitable for commercial purposes (zona pellucida not intact etc) they should be used for testing. If there are no embryos that are unsuitable for implantation, an aliquot of high grade embryos should be sacrificed for testing. Therefore it is recommended that in the IHS "Wash fluid and an aliquot of embryos should be tested" or similar wording should be used.

4 JOANNE THOMPSON

4.1 The submitter enquired whether the safeguards for simbu-group viruses could be aligned with the safeguards for bluetongue virus with respect to the management of the testing.

MAF response: The recommendations for simbu-group viruses are already similar to those for bluetongue with the exception that the time period for residence or quarantine is different. This is necessitated by the different incubation and viraemic periods for the two diseases.

4.2 The submitter suggests that with regard to Borna disease recommendation iii with respect to testing is excessive and greater than is presently required for horses.

MAF response: MAF aggress with the submitter and it is now recommended to drop this requirement.

4.3 As a result of new information that has been published it is suggested that lumpy skin disease virus can be excreted in the semen of infected animals for 42 days, rather than the 21 cited in the risk analysis. Therefore it is recommended that quarantine should altered appropriately in the risk analysis.

MAF response: MAF recognizes that the new information is available and agrees that the IHS should reflect this.

4.4 The submitter suggests that in Section 8.3.2.3 iii of the risk analysis serological testing for Crimean Congo haemorrhagic fever could be done within 21 days prior to the start of germplasm collection instead of the suggested 1 week.

MAF response: An animal tested 3 weeks before germplasm collection could be negative but, because of recent infection, be positive a few days later. Such an animal would be a suitable donor because it would be immune at the time of germplasm collection. However, when negative at the initial test but positive at the second test after germplasm collection, the animal would be to have a rising titre and its germplasm would be disqualified from importation. For this reason the initial test should be conducted as close to the start of germplasm collection as possible.

4.5 Regarding Sections 12.3.2.3 iia and iiia of the risk analysis the reviewer suggest that the sentence “animals that are serologically positive should be disqualified” should be altered to read “animals that are serologically positive and their flockmates should be disqualified”

MAF response: In both these instances the requirement is that all imported animals should come from flocks that have been accredited or tested to to demonstrate freedom from Maedi-visna virus. The detection of any seropositive animal would disqualify the flock of origin. This will be specified in the IHS.

4.6 In relation to PPR in Section 15.3.2.3 iib of the risk analysis the reviewer states that vaccination is not equivalent to testing *and* therefore suggests that vaccination and testing should be specified instead of testing *or* vaccination. Semen should also be tested.

MAF response: The clause in question is taken from the *Terrestrial Animal Health Code*. The proposed additional requirements are considered to be excessive.

4.7 Regarding the recommendations relating to Rift Valley fever, the submitter questions whether MAF could be confident that quarantine premises said to be insect-free were genuinely free from mosquitoes. For this reason, the submitter proposes testing in addition to a quarantine requirement of 30 days.

MAF response: The recommendations are consistent with those in the *Terrestrial Animal Health Code.*. MAF is confident that it is, indeed, possible to maintain quarantine premises, free from insects in general and in particular from the clouds of mosquitoes associated with Rift Valley fever outbreaks. This issue is discussed further in section 3.6.

4.8 The submitter suggests that the seasonal nature of sheep breeding means that it is impractical for them to be held in a mosquito free area during germplasm collection. The submitter considers it unlikely that the mosquito-free period in winter would coincide the season suitable for germplasm collection.

MAF response: MAF will note this point in drafting an IHS.

4.9 With respect to *Mycoplasma* infections the submitter proposes deletion of clause 23.3.2.3 ib recommending that germplasm be cultured and a decision made on importation after isolates have been identified. It should be replaced with the requirement that farms, donors and germplasm collection centres be certified free from clinical and diagnostic signs of infection for the previous 5 years.

MAF response: A requirement for freedom from clinical and diagnostic evidence of infection does not provide sufficient protection. Such a statement could mean only that no serious attempt has been made to diagnose mycoplasmal infections or that appropriate records have not been kept. Properties that have never been tested would be favoured above those that have.

4.10 The submitter suggests that in the case of salmonellosis flock freedom, centre freedom and animal history should replace the requirement for testing germplasm in Section 25.3.2.3 of the risk analysis.

MAF response: Statements on flock freedom without any formal testing programme cannot be relied upon to provide adequate assurances.The most appropriate means of providing assurance that germplasm is *Salmonella* free is to test each batch.

APPENDIX 1: COPIES OF SUBMISSIONS

1. G. L Nortje

Submissions on the draft risk analysis:
Importation of Ovine and Caprine Embryos and semen.
(Received for consultation on 20 June 2005)

GL Nortje (D.Sc. Agric.)

Document review:

Legend: P = page; L = line; § = paragraph. (Pages might be different due to repagination when printing)

P3, Executive summary	Table 2 is mentioned and the breakdown of what is recorded and eventually included in the analyses very helpful – It is expected that the number of analyses, i.e. 34 (§5, L6) would correspond with the number "Yes" indicators in the "Concern" column, (Table 2, P7). The numbers of "Yes-es" are 31, and the difference in totals is not apparent.
Suggestion:	It would be helpful to also list the number of diseases agents according to the respective microorganism groups, they are actually listed in Table 2.
P4, §2 & 3.	These are actually footnotes to Table 1 – the way it is currently formatted is confusing.
P4, §5, L3	Reference for the MAF document on scrapie is omitted from the text and needs to be included.
P7, Table 2	It would be useful, and it is recommended that the table be extended to include not only the causative organisms, but also name of the disease as listed in the OIE list, and the OIE number for the disease. This extension would assist comparative analysis and use of the document.
P10, §2	Omit – repetitive with P7, §4.
P14	Change the numbering of the individual diseases to follow a more logical order. Sections 1 through 4 make sense – they are headings for definitive sections of the document and then individual diseases are given the same status. If individual diseases were treated as sub sections of a section called "Individual disease risk analyses", it would facilitate the reading of the document. It would further also

	be helpful to number the individual diseases according to the order it appears in Table 2 for easy reference.
P14, §5, L2	Change "……St George and Kirkland, 2004)]and the….." to " St George and Kirkland, 2004) and the…."
P14, §5.1.2	According to the "Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, 2004", SECTION 2.10. DISEASES NOT COVERED BY LIST A AND B, Chapter 2.10.2. Bunyaviral diseases of animals (excluding Rift Valley fever), includes Akabane disease. Therefore depicting it as part of the OIE List seems incorrect.
§8.3.4, References	The following is a useful reference to add to the list: Carolyn G. Hatalski, Ann J. Lewis, and W. Ian Lipkin, Borna Disease. University of California, Irvine, California, USA. http://www.cdc.gov/ncidod/EID/vol3no2/hatalski.htm
General recommendation 1	It would add to the document's readability and value to add the OIE Disease definition to each disease. For example: **A100 Sheep pox and goat pox** Serious, often fatal, diseases characterized by widespread skin eruption. Both diseases are confined to parts of southeastern Europe, Africa, and Asia. The poxviruses of sheep and goats (capripoxviruses) are closely related, both antigenically and physicochemically. They are also related to the virus of lumpy skin disease (see above). Reports on the natural susceptibility of sheep to goat poxvirus and vice versa are conflicting; at least some strains seem capable of infecting both species. For easy reference to a similar usage see the SA Department of Agriculture web page at http://www.nda.agric.za/vetweb/Animal%20Disease/AD_Introduction_Main.htm. The use of the OIE disease number again is very useful.
General recommendation 2:	Wherever it is stated that a particular disease is part of the OIE list, the reference, i.e. the Chapter and sub paragraph should be listed for easy reference.
§11.1.5	Formatting: Change "*Conclusio n*" to "*Conclusion*"
§14.1.5	Formatting: Change "*Conclusio n*" to "*Conclusion*"
§16.1.4, Last line	Amend: "…….No seroconversion has been detected n sentinel cattle and no *Culicoides* have been trapped……."
§27.1.1	When referring to nomenclature method, it is useful to refer to the source to enable anybody who wants to do further reading to have easy access. The preferred source is LPSN (List of Prokaryotic names with Standing in Nomenclature, formerly known as "List of

	Bacterial names with Standing in Nomenclature (LBSN)" and available at http://www.bacterio.cict.fr/.
General recommendation 3	A number of organisms not listed in the OIE lists are included in the Risk analysis. The reason for consideration should be explained. The OIE, respected, as the authoritative body regarding Animal Health must have reasons why certain diseases are not considered as potential risk organisms, or at least are not currently included in the OIE Lists. I am convinced that there are very good reasons for considering organisms beyond the OIE lists in a risk analysis like this, but it will add to the status of the document when these inclusions are motivated in the preamble to the document.
Table 2, P10, Spirochaetes:	Amend . "……*Theilera* spp. (sheep species)" to "*Theileria* spp."

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Import Risk Analysis : Sheep & Goat Genetic Material

Comments on the 10th October 2005, Discussion Document

Dr A J Allison, January 2006

The document contains a very comprehensive consideration of almost all of the major diseases which might be considered as of concern when importing sheep and goat genetic material from any country in the world. The opportunity to comment is appreciated, as often there are a number of different risk avoidance scenarios which would allow an importation to be considered when particular criteria identified (ie. as in this report for a particular disease, and or a developed IHS) would rule out further consideration. The criterion for Foot & Mouth Disease is a good example, where the recommended sanitary measure is .....

> *"importation of semen and embryos should be restricted to importation from countries that are free from foot and mouth disease and in which vaccination is not practised".*

I suggest that it is possible to consider a strategy to safely import from a country which vaccinates for F & M disease, through testing of donor ewes, and or the recipient ewes implanted with embryos.

The integration of all of the recommendations for each disease in the development of an IHS (including scrapie) will mean that some modifications may have to be made to achieve a workable programme. Clearly what must precede this will be a detailed country analysis to eliminate as many diseases from consideration as possible.

Comments on particular issues in the report are as follows .....

1. Scrapie : This disease is not included in the analysis as it has previously been undertaken, and MacDiarmid 1996 is given as the reference. Scrapie is one of the most difficult diseases to avoid, and which has necessitated long periods of quarantine to be implemented.

   The reference is based on a conference presentation in 1995, and it is likely that there has been progress made in the last decade with our capability to assess and or reduce and eliminate risk of introduction of scrapie. Tests for the disease (has there

been any progress on the eyelid and or the tonsil test, for example) and or research on the transmission of the disease on washed or unwashed embryos?, have been undertaken in the ensuing period, and may add to our armoury in the quest to reduce risk. There has been a considerable amount of research undertaken in the UK since 1995 (and probably also elsewhere), and this should have been considered in a comprehensive analysis.

What would be the proposed strategy for selection of donor animals according to their PRP status, in an importation programme to minimise the probability that the disease be introduced into NZ? This should be part of the present review. In addition there should be consideration of the age of the donor animals, such as a stipulation that the animals should be at least 5 years of age (or full mouth) to minimise the opportunity for scrapie, if it is present in the country of origin, to have manifest. MacDiarmid (1996) illustrates a risk analysis undertaken using embryo transfer, a quarantine period of 5 years, and intracerebral inoculation of kid goats as three safeguards which could be undertaken

Clearly Scrapie is one of the most difficult diseases for which to eliminate or minimise risk of introduction, and any treatise concerning risks for importation of sheep and goat genetic material should have the most up to date information.

2. Page 3. *"The commodities will : be collected and processed at suitable collection centres and laboratories that have been approved for the purpose by the veterinary authority of the exporting country"*

Firstly, with the adoption of the criterion above, MAF have also implicitly accepted that the veterinary authorities in any country should specify exactly what facilities are acceptable for the collection of embryos and or semen. Would MAF be happy to accept the specifications of veterinary authorities in countries where there is not particularly good organisation and or training and experience evident in the administration. I suggest that MAF should maintain the right to specify and audit facilities in the event that importation is considered from countries where the animal health administration is not of a standard to engender MAF's confidence. A good example might be Saudi Arabia, a country from which we are interested in sourcing Najdi sheep (the "Royal Sheep") embryos. I personally would not consider the Saudi veterinary authorities as being of a particularly high standard.

Secondly the requirement to collect embryos for export in "approved embryo collection centres" is a policy which has been adopted by MAF (and by a number of other countries within the OIE ??). This is the polict presently operating within NZ. This is I suggest a restrictive policy which makes the organisation of exporting more difficult logistically and administratively than it needs to be without necessarily adding anything to ensure that embryos and or semen are collected and frozen according to the highest sanitary standards. For example there is no reason to suggest that the recovery of embryos from donor ewes in a woolshed thoroughly cleaned and set up with a separate small room for microscopes and the washing and freezing of embryos, is likely to be any less sanitary (for the embryos) that a purpose built veterinary surgery or other facility which has the particular criteria to be "approved" by MAF.

Further for export consignments the requirement to transport donor ewes and or goats to an "approved" collection centre will not always be very convenient, and the change of environment for the donor animals will often militate against the best results from the super-ovulation hormonal regimes required for such programmes. Best results will most often be achieved on a farm of origin, and the programming of the donor ewes, the insemination of the donor ewes, and the embryo recovery surgery can often be very conveniently undertaken on property. This can be done without any potential detriment to the implementation of sanitary or phytosanitary procedures which are required as part of particular IHSs.

Transporting donor animals to approved collection centresinvariably adds to the difficulty and expense of exporting without I suggest adding anything to the sanitary treatment of the embryos for export.

3. Page 3, *The commodities will : Be processed and packaged according standards laid down in the OIE …… etc etc, and IETS etc etc"*

The experience we have had over the years is that the washing criteria laid down in the above documents specifies the number of washes, and the volume of fluid required in each consecutive wash. Trypsin washing (in two of the intermediate washes, with the embryos in the trypsin solution for a prescribed time) is also an option. However a number of IHSs (certainly for export) specify in wording something like ……..

"embryos will be washed according to OIE standards as specified by the Research Subcommittee of the IETS"

but the requirement or otherwise for trypsin washing is not defined. The specification within a particular IHS can be interpreted either way and exports and imports have been undertaken I suggest using either specification in the past. Thus the requirement or not for the trypsin wash gets down to a negotiation between the MAF veterinarian and the exporter (or importer). The scientific data on whether or not a trypsin wash affords greater security for internationally traded embryos through a reduction in the risk of disease transmission in comparison with washing without trypsin is not comprehensive which does not assist in decision making as to whether it is required or not.

4. In the risk analysis there is no consideration of the recovery of either follicular ova, and or epidymal sperm. The former is probably the most likely scenario for the consideration of an import. It is clear that the technology for the recovery of follicular ova is now becoming well developed and is used commercially in multiplication programmes (ie. The Waite Research Institute in Australia, Dr Simon Walker).

The use of such technology (plus the collection of epidymal sperm) perhaps provides technology to facilitate the importation of ova from the likes of the Agali sheep where ova and sperm could be derived from slaughtered animals from the wild, matured and fertilised in vitro, and then recipient ewes in maximum security quarantine could be tested for the main diseases in question. This technology also allows the recovery of ova from very young lambs (ie. 6 to 8 weeks old or

younger), and as such may allow a scenario where pathogen free lambs are reared for female donors as a strategy for the embryo recovery and import from difficult animal health environments.

In other programmes where donor ewes had to be slaughtered at the end of an "in vivo" embryo recovery programme there is the potential to recover follicular ova and to fertilise them "in vitro" thus increasing the harvest of embryos within a programme.

5. In all of the recommended sanitary measures there is no definition of the testing of recipient ewes for any disease. This criterion has been a feature of IHSs implemented in successful importation programmes into New Zealand in the past, and why this has now been eliminated as a possibility for inclusion in IHSs is not clear? Is this because ……

   a) the testing programmes suggested give a greater degree of risk avoidance than is afforded by the testing of recipient (of frozen embryos) ewes, ??or

   b) with the now non availability of the Somes Island quarantine facility, MAF do not have available a suitable facility in which to confine recipient ewes prior to testing??

   In the development of acceptable minimal risk IHSs will the inclusion of the testing of the recipient ewes simplify the requirement for the testing within the embryo collection quarantine??

6. For many of the diseases specified there is the requirement to test donor ewes a specific period of time after collection, ie. from 14 to 60 days after collection. This of course eliminates the possibility of collecting embryos at slaughter of the donor ewes at the end of a programme. Clearly in most embryo collection programmes the monetary value of the donors is diminished somewhat due to the surgical intervention (usually two recoveries attempted). Also most often older ewes are purchased and the vendor will not want the ewes back again after a programme. Consequently the animals (from a far off country) are of little value and will most likely be slaughtered.

   In the past, (ie. importation of Ovine embryos from Israel), I have had a long and involved discussion with MAF re the collection of embryos at slaughter, with the rationale that the embryos (to be washed in trypsin) derived at that time constituted a lower risk that the animal tissue which was to be imported and used directly for the inoculation into kid goats as part of a scrapie bioassay. This rationale was finally accepted, although too late for implementation.

   Clearly in the development of any IHS sheep or goats, the requirement for a scrapie bioassay programme will be necessary. Thus it will be a requirement to import tissue from lymph nodes, spinal cord, brain, spleen etc to allow the preparation of a homogenate for the intracerebral inoculation of kid goats. In the original Israeli IHS we were then required to send samples of the tissue to Pirbright for testing for F & M disease prior to the material being allowed entry into NZ. The fact that consideration of scrapie will be a requirement for integration into any IHS will

mean that there will opportunities to modify strategies for other disease requirements within that IHS.

7. Bluetongue, page 27. There is no definition of the course of action in the situation where a positive test is evident after testing. Is it one positive test ……

   a) removal of the embryos from that animal only, or
   b) the total importation is aborted?

   Further, I do not believe that MAF would allow the specification of ii) on page 27 to be an option? How would the criterion be assessed? It is most likely that testing requirements would be implemented because the degree of certainty in effectively achieving the 100 days freedom from contact might not be acceptable.

8. Sheep & Goat Pox, page 38. The specification of a Sheep & Goat Pox free zone might not be a practical possibility in some countries??, and the criteria in a) and b) on page 38 should be sufficient.

9. Crimean Congo Haemorrhagic Fever, page 43. The two sentences ……..

   "Germplasm from animals that sero-convert or have rising titres between the two tests should be disqualified from being exported to New Zealand" and

   "If any animal from a group of donors is disqualified due to testing procedures, germplasm from all animals in the group should be disqualified"

   are not required. The second sentence says it all, with the first being unnecessary. Perhaps some definition of the word "group" is required. Is it meant that in the event of any positive test for Bluetongue, that the proposed import to NZ is denied?

10. Jaagsiekte, page 53. It is stated that *"Importation of embryos from countries where reliable records are not available should not be allowed"*

    I suggest that reliable records for this disease are not available in many countries around the world. Even in Sweden (from where we imported the East Friesian), records re this disease were sparse indeed, in fact there was little experience with the disease?

    The stipulation that only second generation progeny should be able to be released from quarantine, after the first generation progeny have been shown to be free from the disease is draconian. In any importation programme where the numbers of animals available at the end of a successful quarantine period is a critical economic indicator, the removal of all of the first generation is a very heavy stipulation. Such a stipulation is likely to make many decide that an importation can simply not be economic. In the review of the disease there is conflicting information as to the incubation period for the disease, and there is no indication of how old the first generation progeny (presumably those born from the imported embryos?) have to be before the assessment of whether the animals have the disease or not?

In previous IHSs there has been pathological and histological examination of older animals (donors) to look for evidence that there may be Jaagsiekte present? This is not included in the recommendations here. Surely the donor animals should be examined in detail?

11. Maedi Visna, page 64. Recommendation iii) states *" flocks that are not officially accredited should have been maintained as a closed flock and remained free from clinical disease for 3 years.*

    Such a stipulation would rule out most countries in the world. If in fact complement fixing antibodies can be detected 3-4 weeks after infection (reference given), then what is the problem with testing donor ewes before and after embryo collection (3 to 4 weeks, or longer?). This seems to be a simple an effective alternative if the research data are correct.

    If the stipulation re "closed flocks" is retained as gospel, then any consideration of more imports of sheep and goats ever to NZ, must be considered as very doubtful indeed.

12. Salmonellosis, page 130/131. It is suggested that donor animals (both male and female) are tested for salmonella prior to starting on an embryo recovery programme. Waiting until the end of an expensive embryo recovery programme to potentially identify Salmonella species exotic or unwanted in NZ, may be too much of a risk to take, and not a commercially prudent course of action.

    In fact with the many diseases identified as "of concern" there should be an opportunity in the negotiation of an IHS to have preliminary health testing programmes, Such a strategy could eliminate some diseases of concern, particularly if the diseases were stipulated as those which would indicate the termination of a proposed importation programme. The removal of a risk of total failure as early as possible in an importation programme which involves ...

    a) **sparse and or " deemed unreliable" animal health information,**
    b) **the possible presence of a disease within the donors, and or flock of origin,**

    is an important commercial consideration. ie. No one likes to spend a great deal of money to later find out a terminating factor, when that could have been sorted out much earlier. Also a great deal of MAF time being wasted could also be avoided.

    We are all in this game for the elimination and or the minimisation of risk, and the earlier some of the candidates can be disposed of the better. Thus consideration of the recommended sanitary measures for each disease when an IHS is being put together must to some extent be flexible, as long as measures taken do not increase the risk.

13. Leptospirosis, page 145 : many IHSs for the importation of embryos and or semen to other countries from NZ, have a requirement for the donor animals to be treated with antibiotics at prescribed levels in the period prior to embryo collection. The

recommendation here does not include such a measure, but includes the addition of antibiotics to washing media and dilution media for semen. This is an option available which has not been considered in the report. Is there a good reason for this?

14. Enzootic Abortion (Chlamydiosis), page 164. It is recommended that donors should be selected from flocks or from animals kept on germplasm collection centres that are infection free. This situation in any country throughout the world, would I suggest be very rare indeed.

15. Q Fever : p 170 : Under recommendation i, a) it is stated that a positive test should result in the prohibition of importation of the germplasm. Is this intended to be from that animal only, or the whole potential shipment??

Finally in the development if IHSs there should always be the opportunity for a "would be importer" to negotiate with MAF on the approach to be taken. In many situations there are alternative courses of action (from a specified IHS) which achieve the same and or a better degree of protection against introduction of disease. Further alternative courses of action which achieve this end may result in a more practical and economic way of achieving the same result.

It is my belief that it is potentially possible to import germplasm from anywhere in the world, even countries where there is poor definition of disease status, and in fact where many of the diseases we want to avoid are present. This will not be possible if there are blanket exclusions, which eliminate the consideration of alternative courses of action.

When imports are being considered from countries where the animal health information is difficult to access, and or might be considered by MAF as unreliable, or not up to date, it may be necessary to send a MAF Vet (or another veterinarian on contract) on a mission to assess the country animal health status, as a preliminary approach to consideration of any development of an IHS. This was the strategy adopted in the 1980s when we funded a visit by a MAF vet to Israel as a prelude to the development of the HIS which we implemented. Finally MAF should allocate time to IHS development for animals and or genetic material which is likely to be imported, and which is of some economic moment to the country. I note here that the IHS for the importation of "ovine embryos from Israel" which was developed in the late 1980s and which was used for a successful importation, was subsequently reviewed and stipulations for testing for many more diseases were included. The IHS was subsequently withdrawn during 1985 I think. This work undertaken by the MAF veterinary service probably took a considerable amount of time, and then the IHS was cancelled, meaning that a considerable expense and human resources had been committed for no recognisable gain. Such a situation should be avoided in the future.

3 SEAN NEWLAND

Sheep and Goat Genetic Material Import Risk Analysis

2.3, para 2 Assumption that semen and embryos will be collected only from animals that have been examined and found to be healthy.

While this is a sensible assumption, if carrying out an examination of the donor animals (with suitable results) is part of the risk management process this should be stated as a requirement. It is entirely possible that pressure will be brought to bear in some instances for products from "less than healthy" animals to be collected due to the commercial interests of an exporter. If such a situation were to occur this should not be allowed to impact on the biosecurity of New Zealand.

Should be explicitly stated in the requirements.

2.3, para 6 Assumption that male donors will be of equal health status to the female donor at the time of semen donation or natural mating.

Should be explicitly stated in the requirements.

2.3, para 7 "When Import Health Standards are written for particular cases these recommended periods may be modified."

This statement needs to be clarified. Import Health Standards and the risk mitigation measures contained within them are either based on a risk analysis (such as this) or are consulted upon separately. Presumably this statement means that for particular IHSs further information would be provided and consulted upon if there was an intention of using quarantine periods less than those stated in this IRA? If this is not the case what is meant?

6.3.2.3, i,ii,iii

Presumably the measures required are either i (alone), or ii and iii? Is this the case?

6.3.2.3, ii. "…from flocks with a **long history** of freedom..."

The minimum period of flock freedom, and the conditions under which it would be accepted, should be indicated. If this measure is being left flexible to allow the actual period of flock freedom to be determined on a case by case basis this should be explicitly stated. As currently stated it is unclear whether the veterinary officials of the exporting country dealing with the specific consignment makes the decision as to what is acceptable or whether this is the role of New Zealand officials. Given that only New Zealand officials will be aware of New Zealand's acceptable level of risk this is a decision that should be made by them and this should also be explicitly stated.

17.3.2.3, para 1 "Immediately prior to collection of germplasm donors of ??? should have:…"

17.3.2.3, ii

Further clarification is required regarding the reasoning behind the OIE recommended measures for the trade of live animals from infected, disease free countries (i.e. "resided for 6 months….in which climatic changes predisposing to **outbreaks** of Rift Valley fever have not occurred").

Given that Rift Valley fever has the potential to impact on both animal and human health, and "little is known as to how the virus is maintained through inter epidemic periods" Meat & Wool New Zealand considers that accepting genetic material from donors under this condition (ii) poses an unacceptably high level of risk. The measure is difficult to quantify (i.e. what exactly are the climatic changes other than "high" summer rain levels, does this mean the whole country has had these conditions or those regions where the animals have lived?), does not take into account the lack of knowledge about how the virus is maintained (and therefore whether a non-negligible risk exists of donor animals becoming infected even under these climatic conditions), and is a lesser standard for "country freedom" than would normally be accepted for other diseases posing a similar level of risk.

Given that an alternative measure (iii) is provided as an option which would provide a greater level of risk mitigation with minimal negative impacts on the ability to trade Meat & Wool New Zealand recommend that the option of this measure (ii) be removed.

33.3.1.3, ii b "…embryos that are **substandard and not suitable for export**,…"

Does this simply means that those embryos harvested within the export programme but determined to be unsuitable for export (for commercial reasons) are able to be used for testing purposes?

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4 JOANNE THOMPSON

Hand written comments on a draft of the risk analysis were submitted.