



Issues Register

Official Assurance Programme

Requirements for Export of Live Animals and Germplasm

Note that new material added since the last update, will be shown in italics.

19 August 2009

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Part 1 Preliminary provisions

Issue title	Process for amendments to notices
Date received	14 October 2008
OAP reference	All of OAP
Issue details	What would be the process for making amendments to the notices?
MAFBNZ Response	Regarding amendment of section 60 or section 167 notices, the power to issue such notices includes the power to amend them (Interpretation Act 1999). If these are minor amendments or those that are merely clarifying the original intent, there would be no need for consultation. We would only have to notify the amendments as we did for the issue of the original notices. If there are major amendments, these would have to be consulted on and then notified.

Issue title	Procedure for dispensations during implementation
Date received	24 September 2008
OAP reference	All of OAP
Issue details	What is the procedure for dispensations?
MAFBNZ Response	Dispensations have to be applied for and may be given by MAFBNZ with respect to timing of when an exporter/centre operates under the new standards. But an exporter cannot operate under parts of one standard and parts of another. Dispensations must be recorded on a register. No dispensations may be given after 1 May 2009.

Issue title	Implementation when audits are on or close to 1 February 2009
Date received	14 January 2009
OAP reference	Implementation
Issue details	Under what OAP are centres/teams audited whose expiry occurs on or very close to 1 February 2009?
MAFBNZ	An audit scheduled for 19 January 2009, will be done according to the current ('old') OAP. However, the semen centre/embryo team will need another audit prior to 1 May 2009.

Response	<p>This will need to be done to ensure that the semen centre/embryo team is operating according to the new OAP and their updated manual. Centres/teams may then chose either an audit date of 6 months from this new audit date, or follow their usual audit schedule i.e. for the 20 July 2009.</p> <p>Centres/Teams whose registration expires after 1 February 2009 will need to be audited against the revised ('new') OAP.</p> <p>From 1 May 2009, all semen centres and embryo teams will need to have been audited against the revised OAP. If the current approval of a centre(s) expires at the beginning of June, it will need to have a full audit done (as per revised OAP) prior to 1 May 2009.</p> <p>We highly recommend that the semen centre/embryo team sends its revised work manual to its recognised person in plenty of time prior to this audit.</p>
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Issue title	Implementation for audits not completed by 1 May 2009
Date received	17 March 2009
OAP reference	Sections 6.23.3 and 6.23.4 and 8.17.3 and 8.17.4
Issue details	Centres/teams that require a full audit prior to 1 May 2009 have been asked for updated work manuals to be sent to the recognised agency by 1 April so that they have time to complete the audit and approval prior to 1 May 2009. Manuals to the new OAP may take longer to review and semen centres/embryo teams should make provisions for this.
MAFBNZ Response	<p>From 1 May 2009, all semen centres and embryo teams will need to have been fully audited against the revised OAP.</p> <p>Semen centres and embryo teams were asked by the recognised agency to get their work manuals updated according to the new OAP and sent to the recognised agency by 1 April, so that the recognised agency would have time to carry out a full audit for approval prior to 1 May 2009. Work manuals updated according to the new OAP may take longer to review and semen centres/embryo teams should have made provisions for this. If work manuals were not submitted to the recognised agency by 1 April, there is no guarantee that they will be able to be checked, and a full audit conducted by the recognised agency prior to 1 May 2009. This may result in your centre's/team's approval expiring.</p> <p>If a currently approved semen centre/embryo team does not have a full audit completed before 1 May, their approval will remain provisional (if the first stage of an audit has</p>

	<p>been done according to 6.23.3 (a) or 8.17.3 (a)), or will expire if no audit has occurred.</p> <p>Prior to the centre's/team's expiry on 1 May 2009, any stored semen/embryos will need to be transferred to a fully approved semen centre/embryo team. Animals can be resident on the centre for the purposes of export testing to fulfill the export requirements during the provisional approval stage, but collection for export, and export of the species/commodity for which the semen centre/embryo team has provisional approval cannot occur until full approval has been given.</p> <p>However, if a semen centre/embryo team has full approval for another species, semen/embryos of the species which has provisional approval can be stored at or by this semen centre/embryo team as approval for storage is not species specific. Note: provisional approval can be no longer than three months. Alternatively, if the semen centre/embryo team has had the first stage of an audit done according to 6.23.3 (a) or 8.17.3 (a), and storage requirements have also been audited, then they may export stored semen/embryos (although not collect/process for export until the second stage has been audited.)</p> <p>In the situation where an early audit needs to occur i.e. the current approval expires after 1 May, the semen centre/embryo team has the discretion to decide whether to be approved from the date of the new audit (pre 1 May), or to remain with an expiry date taken 6 months from the centre's/team's previous expiry date.</p> <p>Where a semen centre/embryo team's approval has expired, approvals will be as per Clause 6.23.3 or 8.17.3 in the new OAP. Where the term of expiry is greater than two years, approvals will include the requirements of clause 6.23.4 or 8.17.4.</p>
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Issue title	“Fully vaccinated”
Date received	15 July 2009
OAP reference	Section 1.4.2 Interpretation of export requirements
Issue details	Please clarify the use of export certificate terms in relation to vaccination such as “correctly”, “properly”, “fully”, and “appropriately” vaccinated.
MAFBNZ Response	Fully vaccinated means according to the recommendations of the manufacture. Other terms such as “correctly”, “properly”, and “appropriately” will be taken to mean the same as “fully”, unless otherwise state.

Part 2 General requirements

Issue title	Verification of import permit number on official assurance for day-old-chicks.
Date received	10 February 2009
OAP reference	Section 2.1.12
Issue details	The OAP allows import permits for chicks/eggs to be presented to the AP after export - how can we verify the import permit number on the certificate?
MAFBNZ Response	Please note that all airlines now require (at least) the import permit number before they accept a consignment. In many situations exporters are now able to get the import permit for consignments prior to the consignment being exported. However, where they are not able to obtain the import permit prior to export, the importer will obtain the import permit number from the relevant overseas competent authority. This will then be sent to the exporter who passes it on to the recognised agency. The recognised agency then completes the number in the eligibility document.

Issue title	Translation service agreed with MAFBNZ
Date received	23 January 2009
OAP reference	Section 2.1.3
Issue details	How does MAFBNZ interpret "a translation service agreed with MAFBNZ"? What is acceptable?
MAFBNZ Response	<p>It is the exporter's responsibility to provide a translation from a translation service agreed with MAFBNZ, at the exporter's expense.</p> <ol style="list-style-type: none"> 1. A translation from an official translation service is acceptable and should be encouraged for more complex import permits i.e. lengthy import permits which obviously include import requirements. <p>There are five translation services in NZ that are government-approved to translate citizenship documents. These are:</p> <p>The Translation Service, Wellington</p>

	<p>NZ Translation Centre Limited, Wellington MLT Translating Centre, Christchurch Pacific International Translation Limited, Auckland Interpreting and Translation Service, Auckland.</p> <p>2. A suitably qualified/trained/experienced person who is proficient in English and the language of the import permit, may translate import permits upon agreement by MAFBNZ.</p> <p>MAFBNZ will take into account the following factors:</p> <ul style="list-style-type: none">○ does the person have a qualification in translation for that language into English○ the person's level of experience in technical translation in veterinary science. <p>3. A simple import permit (i.e. less than five sections in length) may be translated by a web-based service e.g. Babel Fish</p> <p>4. Exporters may also wish to request a translated import permit from the importing country upon application for the import permit.</p> <p>If in doubt about the accuracy of a translation, please contact MAFBNZ.</p>
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Part 3 Requirements for recognised agencies

Issue title	Status of an email
Date received	25 September 2008
OAP reference	Various sections
Issue details	Does the requirement "in writing" include emails? Does the email have to be confirmed as being received?
MAFBNZ Response	Yes, notification in writing includes an e-mail- refer section 165 in the animal Products Act 1999. This applies where a person must notify the Minister, the Director-General or delegate or where the Director-General or delegate must notify a person. This section provides for a presumption of receipt within 7 days after posting/sending. The presumption can be disproved by the person showing that they did not receive the notice and that the non-receipt was not their fault (refer 165(4)).

Issue title	Reporting requirements	
Date received	27 July 2009	
OAP reference	Table 3.1	
Issue details	The recognised agency is required to report under a heading "Eligibility documentation" identifying number completed / number verified. However, it is an eligibility document that is issued not a germplasm or bee declaration. Please clarify.	
MAFBNZ Response	We will split this requirement into two:	
	Report	Quarterly
	Eligibility documentation identifying: a. number completed b. issues	X _{summary}
	Germplasm declaration and bee declarations identifying:	X _{summary}

	<ul style="list-style-type: none">a. number of each type receivedb. number of each type verifiedc. non-compliance findings and corrective actions	
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Part 4 Requirements for recognised persons

Issue title	Conflict of interest
Date received	17 December 2008.
OAP reference	Sections 7.4.1 and 9.3.1 and Appendix 3
Issue details	Conflict of Interest - what are the roles and responsibilities for the recognised person with respect to the semen centre/embryo team veterinarian and MAFBNZ.
MAFBNZ Response	The semen centre/embryo team veterinarian has to complete the Conflict of Interest declaration, where they have a conflict, before getting approved. This has to be managed to the satisfaction of MAFBNZ. Once they are approved, the recognised person verifies at audit that the semen centre/embryo team veterinarian is carrying out roles according to the Conflict of Interest declaration. The recognised person is also a conduit for information if there are changes to the Conflict of interest position.

Issue title	Who can issue an eligibility document for a Semen centre/Embryo team?
Date received	5 March 2009
OAP reference	Sections 4.1.3 and 5.1
Issue details	Where a recognised person, approved for the function of auditing semen centre and embryo teams and recommending their approval, issues an eligibility document for a semen centre/embryo team, does the recognised person always have to be the person who audits the semen centre/embryo team?
MAFBNZ Response	<p>To issue an eligibility document the recognised person should have first hand knowledge of:</p> <ul style="list-style-type: none"> ○ the work manual at audit ○ verification at audits that this was being followed, and ○ records <p>This knowledge combined with the supporting documentation should enable a germplasm recognised person to ascertain that the premise can or can not meet the export requirements. Therefore this does not limit the ability to sign an eligibility document solely to the recognised person who may audit the premise, but it does exclude recognised persons who are not recognised for the competency as per Section 4.13.</p>

Part 5 Requirements for certification

Issue title	Conditions for an exporter to hold security paper
Date received	30 January 2009
OAP reference	Section 5.11.12
Issue details	MAFBNZ have received a completed application form for use of security paper from a semen centre. What process should be followed?
MAFBNZ Response	The current OAP 5.11.2 states the conditions that must be met for an exporter to hold security paper. MAFBNZ's understanding is that most germplasm consignments (excluding fresh equine semen) are able to be finalised, inspected and loaded during normal working hours.

Issue title	Notification where an exporter holds security seals or paper.
Date received	29 January 2009
OAP reference	Sections 5.11 and 5.12
Issue details	How do NZFSA VA certifiers know by 1 February 2009 who is specifically approved to hold security seals and paper?
MAFBNZ Response	Security seals cannot be held by exporters from 1 February 2009. For security paper: exporters will send an application form – “Application Form 3 - Use of security paper: to MAFBNZ, who will then inform NZFSA VA if approval is given.

Issue title	Notification where an exporter holds security seals
Date received	29 January 2009
OAP reference	Section 5.12
Issue details	“Security seals are the domain of the authorised person, and there is no provision in the revised OAP for exporters to hold security seals, with the exception of exporters of fresh equine semen to Australia.” How will NZFSA VA be notified?
MAFBNZ	The conditions for them to hold seals is laid out in section 5.12.10 of the OAP. The

Response	NZFSA VA will know as an application form will be sent to MAFBNZ by the fresh equine semen exporters. MAFBNZ will then notify the NZFSAVA.
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Issue title	Discontinuation of the requirements to forward supporting documentation associated with germplasm exports to NZFSA VA.
Date received	12 March 09
OAP reference	Implementation and sections 5.3, 5.4 and 5.17
Issue details	Process for discontinuation of the requirements to forward supporting documentation associated with germplasm exports to NZFSA VA.
MAFBNZ Response	<p>From 1 February 2009, and as centres/teams are being audited and approved according to the new OAP, certification systems for germplasm revert to those specified in the OAP Part 5 - Requirements for Certification.</p> <p>In summary:</p> <ul style="list-style-type: none"> The semen centre/embryo team veterinarian (i.e. those without a conflict of interest) issues a germplasm declaration (in accordance with section 5.3 of the OAP), which is provided to NZFSA VA for the purpose of certification. A copy is forwarded to the recognised person who is responsible for the relevant semen centre/embryo team (section 5.4 of the OAP); <p>OR</p> <ul style="list-style-type: none"> Where the semen centre/embryo team veterinarian has a conflict of interest, a recognised person will review the supporting documentation and issue an eligibility document (section 5.3 of the OAP), which is provided to NZFSA NZFSAVA for the purpose of certification. <p>Thus, in the case where the semen centre/embryo team has been audited and approved according the new OAP, supporting documentation will no longer be required to be sent to and verified by NZFSA VA. The requirements and process for issuing the Official Assurance will be those specified in section 5.17 of the OAP</p> <ul style="list-style-type: none"> We emphasise the importance for recognised persons and Centre/Team Veterinarians of paying close attention to detail when completing eligibility documents and germplasm declarations, respectively. Please note that any errors detected by an Authorised Person may lead to the

	<p>delay of a consignment while the documentation is returned to the recognised person or Centre/Team Veterinarian in order to be raised correctly.</p> <ul style="list-style-type: none"> Furthermore, we have experienced an increase in the vigilance and rigour of overseas port veterinarians when clearing imported consignments of live animals and germplasm. This is an additional reason for making sure that all documentation can withstand full scrutiny by the overseas authorities.
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Issue title	Declaration forms
Date received	March 2009
OAP reference	Section 5.10
Issue details	Are the declaration forms in the OAP "set in concrete" i.e. a recognised agency cannot alter them? Or are they more flexible?
MAFBNZ Response	They are customisable but the information in the declaration forms is a minimum i.e. it cannot include less and cannot be altered and added to so that the intent or questions become confused. Section 5.10.4 has requirements for verification of identification. In addition the transport declaration has additional information, also the pre-export isolation declaration, so would want all this retained as a minimum, and true to intent. Section 1.4 has interpretations to be aware of in designing any other templates.

Issue title	Handwriting on Official Assurances
Date received	17 March 2009 and 17 June 2009
OAP reference	Section 5.14.1 (d)
Issue details	The new OAP makes it implicitly clear that handwriting is not permitted except where making amendments. This is different to the old OAP where handwriting was allowed in exceptional circumstances. NZFSA VA considered an exceptional circumstance to include adding the shoulder number to the export cert and supporting docs (where necessary) by hand. Can MAFBNZ please confirm whether or not this practice is acceptable, or whether a number stamp should be applied where the shoulder number cannot be typed in?
MAFBNZ	Section 5.14.1(c) provides for the situation where "the certificate number on the front page of the export certificate must be copied onto any subsequent pages in the space provided

Response	<p>(i.e. this allows handwriting).</p> <p>There may be other exceptional circumstances which are not provided for by the OAP currently e.g. official assurance for cats and dogs to EU member states.</p> <p>Section 5.14.1 (d) will be amended at the annual review of the OAP to say</p> <p>“all other information entered on the export certificate template must be in the same typeface style. Handwriting must not be used, with the following exceptions:</p> <ul style="list-style-type: none"> i) where an importing country requires a declaration to be included in the official assurance. The declaration must not be printed or copied onto security paper, but must be stamped, signed, dated and the AE number added by the authorised person. ii) where amendments are necessary (see also section 5.17.13) <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Examples of such declarations are those from practice veterinarians about pest treatments of cats and dogs being consigned to the UK; and owners/farm/veterinarian declarations. An example of a necessary amendment is amending a flight number where the export flight has been changed</p> </div>
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Issue title	Interpretation of section 5.17.4
Date received	March 2009
OAP reference	Section 5.17.4
Issue details	Section 5.17.4 requires the authorised person to ascertain that there are no issues that would render the product ineligible. It was thought that this could be accomplished in a simple fashion. What system is the recognised agency using to record any issues with germplasm declarations so that the authorised person may know?
MAFBNZ Response	Table 3.1 requires the recognised agency to notify MAFBNZ as an event within 48 hours of potential issues likely to compromise the integrity of export certification. The recognised agency will also notify NZFSA VA of the same. NZFSA VA should assume that if they are not contacted, there are no issues.

Issue title	Replacement official assurances
Date received	June 4 2009
OAP reference	Section 5.19.3
Issue details	Please clarify the process that occurs where an animal is exported with an incorrect

	official assurance.
MAFBNZ Response	<p>NZFSA VA is responsible for seeking MAFBNZ instructions on each case; sending the replacement official assurance to the importing country, and a letter requesting the return of the old export certificate and meeting associated costs, if NZFSA VA is the responsible party.</p> <p>The text box under 1.19.3 could have the additional clause:</p> <p>“Where an error is made by an authorised person a replacement official assurance fee, and any associated costs, will not be chargeable to another party(s). The authorised person is responsible for sending the replacement official assurance to the importing country.”</p>

Issue title	<i>Non-government official assurances</i>
Date received	<i>June 17 2009</i>
OAP reference	Section 5
Issue details	What is the legal requirement under the Animal Products Act (APA) for exporting germplasm to a country that doesn't require competent authority certification?
MAFBNZ Response	<p>It is MAFBNZ's responsibility to determine firstly if the importing country requires an official assurance. If the importing country doesn't require an official assurance, then it will not be an export requirement under section 60 of the APA.</p> <p>The exporter is free to give any other non-official assurance.</p> <p>However, MAFBNZ's concern would be to ensure that the non-official assurance did not give the impression that the assurance was given by MAFBNZ or had official status. Assurances so given could undermine the official assurance system and have trade implications for NZ.</p> <p>Some guidance as to what sort of non-official assurance would be acceptable is:</p> <ul style="list-style-type: none"> • the name of the entity giving the assurance should be clearly stipulated, • the words "official assurance" should not be used, • the assurance should state that it is not an assurance from the Crown or any government department of NZ etc. • use of the word MAF is regulated by the Flags, Emblems and Names Protection

	<p>Act 1981. The word MAF should not be used in conjunction with any non-official assurances</p> <ul style="list-style-type: none"> • there is nothing in the APA that restricts the use of words such as "country freedom" • the exporter number could be used to show they are a legally registered exporter, as long as they do not give the impression that the non-official assurance is official. <p>Regarding exporters making their own "arrangements" with countries that do not require competent authority certification, MAFBNZ's concern would be that these did not prejudice current or future trade negotiations that MAF is having or will have with those countries. Therefore it would be advisable to inform MAF prior to undertaking such arrangements (although there is no legal requirement for to do so.</p> <p>However, regardless of whether the importing country requires an official assurance, the APA would still apply in so far that:</p> <ul style="list-style-type: none"> • the exporter still needs to be registered under the APA to export • the live animals or germplasm still need to meet any relevant animal product standards or specifications issued under Part 4. • the exporter has duties e.g. to notify the DG (of NZFSA) if the product is refused entry, no longer fit for purpose. <p>An AWEC would still be necessary in respect of live animals.</p>
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Issue title	Exporter ID and address on official assurances
Date received	17 June 009
OAP reference	Section 5.1.5 (a)
Issue details	The eligibility document and the germplasm declaration require the exporter ID, but this is not provided for in the requirements for official assurances.
MAFBNZ Response	The exporter ID should occur after the name. Section 5.17.3 will be amended at the review of the OAP at the end of the year.

	The exporter's address should be the physical address.
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Issue title	Verification of germplasm declarations
Date received	27 July 2009
OAP reference	Section 5.4
Issue details	What verification frequency is expected in section 5.4? Are the germplasm declarations (GD) to be verified chosen as a proportion of GDs a team/centre issues or as a proportion of GDs issued by all centres/teams under the auspices of a particular recognised person?
MAFBNZ Response	The verification frequency relates to an individual semen centre or embryo team i.e. if a centre/team has issued 1-15 GDs per quarter at least one GD must be randomly chosen and verified; if a centre/team has issued 16+ GDs within the quarterly period, the recognised person who usually audits that centre/team will need to randomly choose 10% of these to verify.

Part 6 Requirements for semen centres

Issue title	Meaning of confirmed diagnosis
Date received	9 September 2008
OAP reference	Sections 6.11 and 6.12
Issue details	Everyone needs to be clear and in agreement about what a confirmed diagnosis means
MAFBNZ Response	MAFBNZ procedures are to be developed which specify how a "confirmed diagnosis" is established for applicable diseases

Issue title	Requirements in the event of an endemic disease occurrence
Date received	September 2009
OAP reference	Section 6.1.12
Issue details	Requirements need to be developed which are defensible for the regulator, and also practicable for the industry.
MAFBNZ Response	As of 9 December 2009 additional tests are carried out as per the export requirements (section 6.10.2). Section 6.12 now applies to the four diseases specified in the OAP, to take effect after a confirmed diagnosis.

Issue title	Process when no collection is occurring
Date received	7 October 2009
OAP reference	Section 6.23
Issue details	Use of semen centres at times of the year when no collection is going on.
MAFBNZ Response	Continuously approved semen centres cannot let their approval slip. Semen centres/embryo teams must be clear that if approval is not maintained they must have an exit audit.

Issue title	Germplasm centre register
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Date received	30 October 2008
OAP reference	Section 6.12
Issue details	The register of germplasm approvals needs to capture the possibility of suspension of a semen centre as per section 6.12
MAFBNZ Response	<p>This has been added to the NZ semen centre register only. Category for suspension of semen centres: see section 6.12 of OAP</p> <p>If the category of suspension affects the eligibility of the semen, this suspension and the date of commencement needs to be recorded. MAFBNZ is not recording single animal suspensions.</p>

Issue title	Sample collection method for preputial samples for detection of campylobacteriosis and trichomonas
Date received	13 January 2008
OAP reference	Section 6.10.1
Issue details	On reading section 6.10.1 (a) iii of the OAP, do we have to change our sample collection method for preputial samples for detection of campylobacteriosis and trichomonas to comply with the OAP from 1 February 2009? At the centre we have always done preputial scraping which is as outline in the OIE manual for collection of samples for both these diseases. Should this section read “using culture of preputial sample”? As it is currently written we cannot comply with the OAP unless we change our sample collection method.
MAFBNZ Response	<p>No, there is no need to change your sample collection method for preputial samples for detection of Campylobacter and Trichomonas organisms. We agree that there is a difference between washing and scraping, with the latter being the preferred method collecting a sample. The recognised agency for testing has recently recommended the use of a new sampling device (mainly to be used in combination with their newly developed PCR), i.e. the so called 'Tricamper'. This corrugated plastic device, when attached to the end of a plastic rod, is scraped across the glands of the prepuce. Mucus, debris and any bacteria are caught in the corrugated grooves. On withdrawal from the prepuce, the grooves of the device are flushed with phosphate buffered saline to collect the smegma sample. For the PCR test, the 'tricamper' device can be simply cut off and placed in a vacutainer for transport to the laboratory, without the need for transport medium. When the OAP is due for updating, we will amend the relevant sections (6.9.1.a.iii and</p>

	6.10.1.a.iii) by changing it to: "....., using culture of a preputial sample."
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Issue title	Clarification of “physically separated”
Date received	December 2008
OAP reference	Section 6.6.1 (c)
Issue details	“Physically separated” – what does this mean? Physical barrier vs. distance; especially with respect to use of mobile processing laboratories at collection locations.
MAFBNZ Response	Processing has to be in an “envelope”. If distance only was used, the walls and ceiling of the processing area would have to be of the standard required in the OAP, and this is highly unlikely in a wool shed. But processing could occur in the wool shed in an envelope such as a tent, which met the requirements of the OAP. Mobile processing laboratories represent such an envelope.

Issue title	Germplasm centres and presence of semen centre/embryo team veterinarian.
Date received	March 2009
OAP reference	Section 6.3.1, 7.3.1. (b), 8.3.1 and 9.2.1 (b)
Issue details	Can MAFBNZ develop the scope of acceptable interpretations of section 6.3.1, 7.3.1? (b), 8.3.1 and 9.2.1 (b) “ensure that he/she has adequate knowledge of what is happening on the centre on a day to day basis and is able to be present at a reasonable notice”.
MAFBNZ Response	<p>MAFBNZ believes that the expectation is clear in the OAP - See section 7.3.1.(b), states under responsibilities of a Semen Centre Veterinarians that "ensure that he/she has adequate knowledge of what is happening on the centre on a day-to-day basis and is able to be present at reasonable notice". The centre needs to provide evidence that they do comply with the above requirement.</p> <p>There are a range of circumstances with the industry, such that a “horses for courses” approach is appropriate. There are also inherent risks with specifying a minimum because people will fall back to that minimum rather than working to a higher and more appropriate level for the circumstances. The frequency of visits really depends on how much activity the centres are involved with - For example: for a centre that only collects twice a year - prescribing a required visit frequency of every 3 weeks would be unnecessary, whereas for a centre collecting daily this may not be frequent enough. An</p>

	alternative approach is for auditors to develop questions that enable an informed assessment of the adequacy of the veterinarian's knowledge.
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Issue title	Approach to non-compliances at audit.
Date received	22 March 2009
OAP reference	Sections 6.23 .3 and 8.17.3
Issue details	If a semen centre/embryo team has non-compliances at an audit, should approval be withheld until they are worked through, or should they be approved subject to the non-compliance being closed out by next audit. What is the preferred approach to take?
MAFBNZ Response	Minor/major non-compliances do not hold up the approval of a semen centre/embryo team as long as corrective actions and timeframes have been agreed to by the auditor and semen centre/embryo team veterinarian.

Issue title	Are 'mock' collections acceptable for audit purposes?
Date received	22 March 2009
OAP reference	Sections 6.23 .3 and 8.17.3
Issue details	If a semen centre/embryo team has a failure of collection at an audit because an animal does not perform, can a 'mock' collection be used?
MAFBNZ Response	A full reality procedure is required at an audit, such that the germplasm is 'export eligible'. Where real observation of collection does not occur, e.g. because the collection fails, then this should be regarded in the same light as a non-compliance and a corrective action will be required, to be closed out within two months. Therefore, the recognised person must follow up with a proper collection and processing procedure to close out the corrective action for that particular audit.

Issue title	Are collections from an animal not intended for export, acceptable for audit purposes?
Date received	April 2009
OAP reference	Sections 6.23 .3 and 8.17.3

Issue details	Where breeding is seasonal and a semen centre/embryo team has low volumes for export, can collection/processing at an audit be from an animal whose germplasm is not intended for export?
MAFBNZ Response	A full reality procedure is required at an audit, such that the germplasm is 'export eligible'. The animal must be export eligible and collection and processing must meet all the applicable requirements of the OAP, irrespective of its final destination.

Issue title	Auditing collection and processing at other centres
Date received	March 2009
OAP reference	NA
Issue details	A centre has approval to collect and store cervine semen. However they do not collect the semen at their centre, but have it collected at other registered centres, and then taken to their centre for processing and then storage. This causes a problem in that the recognised agency can never observe collection at the centre itself, but it is not possible to register them just for processing and storage. Clearly the registration just for storage of cervine semen isn't appropriate either. What is the answer?
MAFBNZ Response	MAFBNZ believe that the semen centre can be observed collecting semen at another approved semen centre, as long as this observation occurs annually and fully complies with the relevant parts of the OAP. The recognised person will need to reference this observation in the semen centre audit reports.

Issue title	Approval of cervine semen collection centre.
Date received	19 March 2009
OAP reference	Section 6.23
Issue details	Can a cervine semen centre be continuously approved for storage, and seasonally approved for cervine semen collection
MAFBNZ Response	This can be managed as one approval. The centre will have one registration number. The register will record the dates of approval for cervine collection separately from the dates of storage. The centre must be compliant at all times with the requirements for storage that are contained in sections: 6.2, 6.3, 6.4, 6.5.1 and 6.5.2 a,b,c,d,viii,xi,xii,xiii,xvi,xvii,xviii,

	6.5.3, 6.5.4,a.b.c.d.e.f.g., 6.5.5, 6.5.6, 6.6.1.d, 6.6.6, 6.16, 6.17, 6.20, 6.21, 6.22, 6.23, 6.24.
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Issue title	Please clarify: ‘cleaned prior to the start of each day's collection’.
Date received	23 March 2009
OAP reference	Section 6.14.1(a)
Issue details	This section states "Collection must be carried out in a facility that has been cleaned prior to the start of each day's collection....." Does this have to be on that day, or can it also be prior to that day?
MAFBNZ Response	Prior to does not mean immediately before, but can be the previous day or even the previous week if the facility has been maintained in that same clean condition.

Issue title	Recording of day-of-collection examinations
Date received	March 2009
OAP reference	Section 6.5.5 i (i)
Issue details	Section 6.5.5 i (i) requires the centre to make a record of day-of-collection examinations in accordance with export requirements. Should this be a record of all or by exception only?
MAFBNZ Response	The requirement is “as per the export requirements” rather than an absolute requirement. However, if they did not make a positive record, a centre may preclude future exports through an absence of requisite information.

Issue title	Presence of a cipher with the consignment
Date received	March 2009
OAP reference	Section 16.15.2 (a)
Issue details	Where a date of collection is not on the straw but a cipher is used, does the cipher need to be available to vets at both borders, so that the date is able to be deciphered? It is not sufficient to have that information held only at the centre.

MAFBNZ Response	Agree. Where a code is used, as per Section 16.15.2 (d), a cipher must also be available at both borders e.g. with the official assurance.
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Issue title	Checking germplasm declarations for semen centres and embryo teams
Date received	18 March 2009
OAP reference	Sections 6.23.6 (c) and 8.17.7 (b)
Issue details	At audits, should the recognised agency be checking two eligibility documents per species-germplasm combination or two overall? If the latter, should they be rotating so that eventually all species are covered?
MAFBNZ Response	Only two export consignments need to be checked per embryo team and two per semen centre, not two per species. The recognised person should ensure that the supporting documentation that is checked reflects the species that is most commonly exported, and that all species for which the team/centre is approved, are covered. However, if a centre or team is predominantly exporting from one species (even though they are approved for more than one), export consignments from this species would be checked more regularly than the other species.

Issue title	List of Official Assurances from NZFSA VA to allow AsureQuality to audit Germplasm Declarations
Date received	March 2009
OAP reference	6.23.6 and 8.17.7
Issue details	Recognised agency auditors need access to the lists of official assurances so that they can undertake an independent audit of the germplasm declarations. How will this occur?
MAFBNZ Response	<p>The lists of germplasm declarations can be provided to the recognised agency but NZFSA VA would need some notice e.g. 3 days. However, where a consignment has been consolidated, the export certificate may not necessarily reference all the germplasm declarations. Therefore, all germplasm declarations used to form a consolidated consignment should be sent to NZFSA VA (and AsureQuality for random verification as per Section 5.4.1 of the OAP).</p> <p>Section 6.23.1 and 8.17.1 need to be reviewed and amended by requesting that the</p>

	<p>information be presented by the semen centre/embryo team itself.</p> <p>Note also that MAFBNZ can always supply obsolete export certificates should the recognised agency need to reference these.</p>
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Issue title	Notification of test results
Date received	April 29 2009
OAP reference	Section 5.10.2 and 5.10.3
Issue details	Where test results are required for an export certificate, and they are not readily available, will a declaration of those results be sufficient?
MAFBNZ Response	<p>A copy of the test results is required.</p> <p>The OAP provides for originals or legible copies of supporting documentation and appears to exclude laboratory reports from declarations. A copy of the laboratory reports ensures that all information is correctly reported, and can be referenced to the standing of the laboratory.</p>

Issue title	Testing prior to animal entry to a semen centre
Date received	June 4 2009
OAP reference	Section 6.9.1 (c) (i)
Issue details	The OAP asks for donor stags to be Tb tested prior to entering the centre. Please clarify “prior to”.
MAFBNZ Response	<p>Tb testing is according to the national pest management strategy (NPMS). Therefore a stag needs to have a negative test result prior to entry. For Tb, testing is annual. There may also be additional export specific requirements which need to be met.</p> <p>The semen centre also needs to be aware of section 6.12.1, whereby if a stag gives a positive test result when on centre, even if it was negative when tested prior to entering the centre, the centre could lose its approval status.</p>

Part 7 Requirements for semen centre managers and semen centre veterinarians

Issue title	Frequency of assessment of semen centre veterinarian
Date received	2 December 2008
OAP reference	Section 7.5.4
Issue details	Please confirm the interpretation: ‘Once the centre veterinarian has been approved, the recognised person must re-assess him/her at least once every 12 months’.
MAFBNZ Response	Agree, this is confirmed.

Issue title	Conflict of interest
Date received	January 2009
OAP reference	Section 7.4.1 and 9.3.1
Issue details	Can a semen centre/embryo team veterinarian who has a conflict of interest provide clinical services and sign declarations for those services that lead to official assurances?
MAFBNZ Response	<p>A semen centre/embryo team veterinarian with a conflict of interest can carry out:</p> <ul style="list-style-type: none"> o testing o clinical examinations o supporting documentation <p>providing that his/her conflict of interest is managed by another approved and non-conflicted semen centre/embryo team veterinarian or recognised person signing the respective germplasm declarations or eligibility documents that are required for the official assurances.</p>

Issue title	Auditing of semen centre veterinarians
Date received	June 4 2009
OAP reference	Sections 7.5.2 and 7.5.3
Issue details	What level of audit should occur when an additional centre veterinarian commences

	<p>supervision of an approved centre?</p> <p>Also what happens if the original centre vet leaves before the new veterinarian has been present at an audit, i.e. part-way between routine centre audits? Would this mean that the centre needs to have an audit within 10 days of the original vet leaving?</p>
MAFBNZ Response	<p>Since there is no required division of responsibility between a sole centre veterinarian and an additional semen centre veterinarian, the level of auditing should be the same for all centre veterinarians.</p> <p>Yes, when a new centre veterinarian commences sole supervision of an approved centre, an audit of the centre must be carried out within 10 working days. One would expect the new sole centre veterinarian to be audited at the same time as the centre audit.</p> <p>Note 7.5.3 refers to 6.21.6. This is incorrect. It should be 6.23.6.</p>

Part 8 Requirements for embryo teams

Issue title	Requirement for audit of collection on farms/facilities
Date received	7 January 2009
OAP reference	Section 8.5.1
Issue details	Do any of the farms/facilities used by an embryo team to collect on farm need to be visited by the recognised person during an audit? Or if not, what assessment of the list of collection places used by the team needs to be made?
MAFBNZ Response	<p>Approval is of embryo teams not facilities, but teams need to work in compliant facilities to be approved. So the question is “how do you know facilities are compliant?”</p> <p>There are collection facility requirements in section 8.5.1, which are minimal.</p> <p>The work manual has to have procedures for on farm collection, including a description or photographic record of each on farm facility collected from section 8.4.2 (d). This is where the embryo team defines how they know when facility is acceptable for collection and what they look for.</p> <p>At the first approval audit, representative facilities need to be assessed to see that they comply with the work manual and OAP section 8.17.3 (a). Representative facility is defined in part 1. If collection is on farm, then one would expect that the recognised person would visit a representative facility for that species. There is an element of judgement here by the recognised person about whether the core of the collection facility e.g. crush, head bail, type of flooring is any different in the types of farms proposed to collect from.</p> <p>Records have to be kept of each on farm facility including description or photographic record section 8.4.4. (c).</p> <p>For continuous approval audits section 8.17.7, the records should provide guidance as to the type of farm collected from and its compliance with the work manual and the OAP.</p> <p>Every 12 months collection needs to be observed for each species. This may be at a permanent facility, in which case on farm would not necessarily be observed. The recognised person may be of the view from the records that he/she will observe collection at a farm as well or instead. The OAP does not require on farm to be observed every 12 months in continuously approved teams. So apart from first approval audit there is no requirement set down to visit on farm, but if based on the assessment of work manual and</p>

	<p>records the recognised person has cause for concern, then the recognised person can visit an on farm facility, or more if there is sufficient concern.</p> <p>MAFBNZ has tried to focus on the outcome and avoid being prescriptive about the number of visits. The embryo team has the opportunity to reduce costs at audit by being thorough in their work manual and recording.</p> <p>On farm collection is not a significant disease risk, so this needs to be reflected in the requirements.</p>
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Issue title	Clarification of requirements for supervision
Date received	17 December 2008.
OAP reference	Section 8.3.1 and definition in 14.3
Issue details	“Direct supervision” needs to be clarified. The definition in 1.4.3 stands. Where should this requirement apply?
MAFBNZ Response	At the annual review of the OAP the word “direct” will most likely be removed from 8.3.1. The embryo team veterinarian will then have some flexibility according to competency of the person.

Issue title	List of Official Assurances from NZFSA VA to allow AsureQuality to audit Germplasm Declarations
Date received	March 2009
OAP reference	6.23.6 and 8.17.7
Issue details	Recognised agency auditors need access to the lists of official assurances so that they can undertake an independent audit of the germplasm declarations. How will this occur?
MAFBNZ Response	The lists of germplasm declarations can be provided to the recognised agency but NZFSA VA would need some notice e.g. 3 days. However, where a consignment has been consolidated, the export certificate may not necessarily reference all the germplasm declarations. Therefore, all germplasm declarations used to form a consolidated consignment should be sent to NZFSA VA (and AsureQuality for random verification as per Section 5.4.1 of the OAP).

	<p>Section 6.23.1 and 8.17.1 need to be reviewed and amended by requesting that the information be presented by the semen centre/embryo team itself.</p> <p>Note also that MAFBNZ can always supply obsolete export certificates should the recognised agency need to reference these.</p>
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Issue title	Requirements for <i>in-vitro</i> derived embryos
Date received	18 March 2009
OAP reference	Sections 8.4.2 and 8.4.5
Issue details	Part 8 purports to cover both <i>in-vivo</i> derived embryos and <i>in-vitro</i> produced embryos but, apart from section 8.1.1 (which mentions collection/production); reference is made only to collection and always to embryos with no mention of oocytes or ovaries.
MAFBNZ Response	<p>When the OAP was drafted, we realised from the onset that there were the two commodities as far as embryos are concerned, i.e.:</p> <ol style="list-style-type: none"> 1. <i>in-vivo</i> derived embryos (recovered as embryos from donor cows) 2. <i>in-vitro</i> produced embryos (<i>in-vitro</i> fertilised oocytes, which are sourced either by ultrasound guided transvaginal ovum pick-up from live cows or at slaughter by recovering ovaries from cull cows). <p>We have referred to these <i>in-vivo</i> and <i>in-vitro</i> options only twice, once in the text box under 8.1 and again under section 8.1.1. Doing this consistently through all of Part 8 of the OAP would have made this section very cumbersome.</p> <p>So, yes, if embryo teams are doing <i>in-vitro</i> production then there need to be:</p> <ul style="list-style-type: none"> • procedures for collection of ovaries and production of embryos • animal records of animals slaughtered for recovery of ovaries, including am and pm inspections.

Issue title	When can an embryo team move to 12 monthly audits?
Date received	9 March 2009
OAP reference	Section 8.17.5

Issue details	<p>Under the old OAP embryo collection centres were audited every 6 months.</p> <p>The revised OAP allows for embryo teams to be audited once every 12 months, after 2 consecutive 6 monthly audits without any major or critical non-compliance.,</p> <p>For existing embryo centres, will previous audit performance as a centre count in assessing the requirements for audit as an embryo team? That is, if the centre has had no major or critical non-compliances will this be taken into account when determining the next audit date? If so what do you expect in the way of assessment at what would have been the due date for the 6 monthly audit?</p>
MAFBNZ Response	<p>No. The new OAP is a new system, and the team has to show first (twice) that all is in order, before their audit should be extended to once every 12 months.</p> <p>There are two consecutive 6-monthly audits i.e. audits are done and then there is a six-month approval period after these audits. This means that there is a minimum period of 12 months and two audits before an embryo team has an audit to move to a 12-month audit frequency. This is shown pictorially below:</p> <p style="text-align: center;">● → ● → ● → —————→</p> <p style="text-align: center;">6 - 6 - 12 months</p>

Issue title	Approach to non-compliances at audit.
Date received	22 March 2009
OAP reference	Sections 6.23 .3 and 8.17.3
Issue details	<p>If a semen centre/embryo team has non-compliances at an audit, should approval be withheld until they are worked through, or should they be approved subject to the non-compliance being closed out by next audit. What is the preferred approach to take?</p>
MAFBNZ Response	<p>Minor/major non-compliances do not hold up the approval of a semen centre/embryo team as long as corrective actions and timeframes have been agreed to by the auditor and semen centre/embryo team veterinarian.</p>

Issue title	Pre-export isolation requirements – embryo teams
Date received	March 2009
OAP reference	Section 8.6

Issue details	<p>Q1. If an embryo team generally exports to places that do not require isolation - so does not have isolation looked at during an approval audit - then decides to go collecting on-farm for export to a market that does require isolation, does the embryo team have to get the place it has its donors isolated audited before it uses it?</p> <p>Q2. If an embryo team does all its collecting on-farm, including some to markets that require isolation, must all the isolation facilities be audited before use?</p> <p>Q3 If isolation is being audited retrospectively, would it be a good idea to require the certificates that are checked during audit to include one that uses isolation?’</p>
MAFBNZ Response	<p>Q1 Yes</p> <p>Q2 No. An embryo team has to show one example of isolation and the rest are checked retrospectively through the records (pictures/descriptions) the embryo team is required to keep.</p> <p>Q3. This would be advisable (although not mandatory).</p>

Issue title	Checking germplasm declarations for semen centres and embryo teams
Date received	18 March 2009
OAP reference	Sections 6.23.6 (c) and 8.17.7 (b)
Issue details	At audits, should the recognised agency be checking two eligibility documents per species-germplasm combination or two overall? If the latter, should they be rotating so that eventually all species are covered?
MAFBNZ Response	Only two export consignments need to be checked per embryo team and two per semen centre, not two per species. The recognised person should ensure that the supporting documentation that is checked reflects the species that is most commonly exported, and that all species for which the team/centre is approved, are covered. However, if a centre or team is predominantly exporting from one species (even though they are approved for more than one), export consignments from this species would be checked more regularly than the other species.

Issue title	Are collections from an animal not intended for export, be acceptable for audit purposes?
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Date received	April 2009
OAP reference	Sections 6.23 .3 and 8.17.3
Issue details	Where breeding is seasonal and a semen centre/embryo team has low volumes for export, can collection/processing at an audit be from an animal whose germplasm is not intended for export?
MAFBNZ Response	A full reality procedure is required at an audit, such that the germplasm is ‘export eligible’. The animal must be export eligible and collection and processing must meet all the applicable requirements of the OAP, irrespective of its final destination.

Issue title	Embryos stored at an alternative location
Date received	April 2009
OAP reference	Part 8
Issue details	Where embryos are stored at a physical location other than the embryos teams registered site, whose responsibility are they?
MAFBNZ Response	Where embryos from one registered embryo team (team A) are currently stored at a physical location registered under another embryo team (team B), the storage of these embryos is the responsibility of the Team Veterinarian of team A. These responsibilities need to be clearly documented in team A’s Work Manual. As long as team B remains fully approved (including storage), and team A continues to store embryos at team B, MAFBNZ will not require team A’s storage facilities to be audited. This will be done as part of the audit of team B. Embryo team A needs to be aware that any major/critical non-compliances of the storage of embryos at team B are the responsibility of both team A’s and team B’s Team Veterinarians. MAFBNZ highly recommends that a contingency plan is put into place to cover such an event should it occur.

Issue title	Approval of embryo team for pre-collection isolation
Date received	June 4 2009
OAP reference	8.4.2 d (iv)
Issue details	Please clarify how embryo teams should be approved where they carry out pre-collection

	isolation?
<p>MAFBNZ Response</p>	<p>The embryo team must be approved for these activities, although the facilities themselves are not approved. This is analogous to collection facilities.</p> <p>An embryo team must have in their work manual:</p> <ul style="list-style-type: none"> • documented procedures for isolation of animals and how this isolation is maintained, where applicable (as per 8.4.2 d (iv) of the OAP); • an up-to-date list of pre-collection isolation facilities and the description or photographic record of each pre-collection isolation facility, where applicable (comparable to 8.4.4.c) • records of visitor entry to the pre-collection isolation facility (8.4.4 (d)) <p>Note: A clause to clarify the requirements for the list of facilities and record of each (as above) will be added to the OAP at the next review in December.</p> <p>It is at the recognised person's discretion to decide whether or not an audit of the physical location of the pre-collection isolation facility is necessary.</p> <p>As is the case for collection facilities, where there are multiple pre-collection isolation facilities, it is not necessary to audit each and every one either before or at the 6 or 12 monthly audits.</p> <p>Note this is in contrast to a semen centre, where who must have in their work manual: documented procedures for isolation of animals and how isolation is maintained, where applicable (as per 6.5.2 (d) (v) of the OAP); and have a physical audit of the pre-entry isolation facility audited during six-monthly audits.</p>

Issue title	Export certificate requirements for “on-centre collection”
Date received	28 July 2009
OAP reference	Export certificate requirements for on-farm collection of bovine embryos to South Africa.
Issue details	<p>Can we collect on-farm when the export certificate explicitly refers to, or implies for the animal to be on centre?</p> <p>The relevant clause in the export certificate, dated 13 May 2005, reads as follows:</p>

	"Prior to entering the embryo collection centre, the donor cows were tested with negative results for the following diseases:"
MAFBNZ Response	MAFBNZ has set up Part 8 of the OAP so it applies to approved embryo teams. Approval as an embryo team is taken to be equivalent to approval as a "centre". In situations where an export certificate specifically mentions or implies "on centre", the embryo team's registration number should be provided where the certificate asks for the centre's approval number.

Issue title	<i>Procedures for "on-farm" collection</i>
Date received	<i>12 July 2009</i>
OAP reference	<i>Section 8.4.2 (d) (ii)</i>
Issue details	<i>Where on-farm collection is not being carried out, is it necessary to provide procedures for this in the quality manual?</i>
MAFBNZ Response	<i>Section 8.4.2 (d) (ii) requires procedures to be detailed, where applicable. Therefore, if no on-farm collection is being carried out, procedures are not required in the quality manual. However, where on-farm collection is anticipated, this would involve a significant change to the procedures and section 8.15 requires that any significant changes to procedures must be notified to the recognised person, and may be audited.</i>

Issue title	<i>Details of semen donors</i>
Date received	<i>August 12 2009</i>
OAP reference	<i>Sections 8.4.2 (d), 8.4.5 (j), and 8.13.</i>
Issue details	<i>Do work manuals need to include references to the semen that has been used to inseminate embryo donor cows?</i>
MAFBNZ Response	<i>Yes, frozen semen needs to be compliant with export requirements, and where fresh semen is used, the donor male has to have the same export status as the donor female. Records have to be kept of these animals so that compliance can be traced and assured.</i>

	<p><i>Documented procedures for collection of embryos would also include a procedure to ensure that all semen used is compliant.</i></p>
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Part 9 Requirements for embryo team veterinarians

Issue title	Conflict of interest
Date received	January 2009
OAP reference	Sections 7.4.1 and 9.3.1
Issue details	Can a semen centre/embryo team veterinarian who has a Conflict of Interest provide clinical services and sign declarations for those services that lead to official assurances?
MAFBNZ Response	<p>A semen centre/embryo team veterinarian with a conflict of interest can carry out</p> <ul style="list-style-type: none"> o testing o clinical examinations o supporting documentation <p>PROVIDING THAT his/her conflict of interest is managed by another approved and non-conflicted semen centre/embryo team veterinarian or recognised person signing the respective germplasm declarations or eligibility documents that are required for the official assurances.</p>

Issue title	Conflict of interest
Date received	April 2009
OAP reference	Section 9.2.1 (e)
Issue details	Where an embryo team has two embryo team veterinarians, are both required to be present at provisional and full approval audits (as per 8.17.3)?
MAFBNZ Response	Yes, the embryo team veterinarian(s) must be present at every approval audit.

Issue title	Internal audits by veterinarians
Date received	June 4 2009
OAP reference	Section 9.2.1
Issue details	Where team veterinarians are required to undertake internal audits, can these audits be delegated to other parties?

MAFBNZ Response	A team veterinarian may delegate audits as long as he/she understands that they are personally responsible for the quality of the audit and the outcomes. MAFBNZ suggests that sections 9.2.1(c), 8.4.3, 6.5.3, and 10.14.1 be amended to say “ensure that annual internal audits are undertaken”, to allow for external engagement of an auditor.
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Part 10 Requirements for pre-export isolation facilities associated with export of live animals

Issue title	Provision to be made for animals over-nighting under PEI
Date received	November 2008
OAP reference	Sections 10.6.1 (b); 10.18.12; 10.19.2
Issue details	Some facilities e.g. South Island have animals over-nighting at another approved PEI prior to being loaded at the port of departure. As the OAP is currently such facilities would not be compliant.
MAFBNZ Response	Omit sections 10.6.1 (b), and 10.18.12. In section 10.12.2 and 10.19.2 add the modifications: "Where off-loading of the animals is required, it must be into MAF-approved pre-export isolation facilities"; and "Where off-loading of the animals is required, it must be into facilities that meet the requirements of sections 10.16 to 10.19 of the OAP". In the isolation plan 10.7 must have additional point vii for "management of any off-loading during the transport to the port of departure".

Issue title	Diseases present during pre-export isolation in non MAF approved facilities
Date received	14 April 2009
OAP reference	Sections 10.16-10.19 and declaration 4.
Issue details	Where there is a disease outbreak in the facility, does an exporter have to let the recognised person know before the eligibility document is prepared?
MAFBNZ Response	The exporter is required to present for export only animals that have met the export requirements and the OAP (section 2.1.11). There is an expectation, although this is not explicitly stated, that if a disease occurrence compromises the export eligibility of the animal or indicates circumstances such that this may have occurred, the exporter should notify the recognised person. For the end of year review, consider an additional bullet point in Declaration 4: “there has been no breach in the isolation status of the animal”.

Issue title	Whose responsibility is it to develop the isolation plan and get it approved?
Date received	April 28 2009
OAP reference	Sections 10.3.2 and 10.7.1
Issue details	There is an apparent contradiction between sections 10.3.2 and 10.7.1 with respect to whose responsibility the isolation plan is.
MAFBNZ Response	<p>It is the exporter's responsibility, to ensure the isolation plan is approved and the facility operator's responsibility to implement it. However, one would expect both to collaborate on developing a suitable isolation plan.</p> <p>At the annual review of the OAP, section 10.7.1 will be amended to clarify this, and a text box may be added.</p>

Issue title	Interpretation of "clean and disinfected" for avian PEI
Date received	June 17 2009
OAP reference	Section 10.18.4; Definitions of "cleaning" and "disinfection"; section 1.4.2
Issue details	Is sand an acceptable surface in a non MAF approved avian PEI, and does it meet the requirements of the OAP?
MAFBNZ Response	The OAP requirements are that the surface needed to be hard, e.g. concrete or wood. Bare earth is not acceptable. Sand can be on top.

Issue title	<i>Non-MAF approved pre-export isolation facility</i>
Date received	<i>August 12 2009</i>
OAP reference	<i>Section 10.16-10.19</i>
Issue details	<i>For non- MAF- approved PEI, where an export certificate does not require MAF approval, can you clarify how this is to be managed e.g. is there a minimum number of times a recognised person visits, and when?</i>
MAFBNZ	<i>When the export requirements are for an animal to be in isolation, but do not specify this to be in a MAF-approved PEI facility, then the pre-export isolation can be carried out in</i>

Response	<p><i>a non-MAF-Approved PEI Facility.</i></p> <p><i>Approval per se, of a <u>non</u>-MAF-approved PEI Facility is NOT required. However, inspection of the facility is required prior to the animals entering the isolation facility as per clause 10.17.1 (b).</i></p> <p><i>Note currently it is not clear that function 4.15 applies only to approving MAF-approved PEI facilities. Therefore a recognised person can inspect non MAF-approved PEI facilities.</i></p> <p><i>The recognised person visits and inspects the non-MAF approved facility to ensure it meets the requirements of the OAP (Section 10.16-10.19) and the relevant export requirements prior to or at the start of the isolation period (10.17 b). The export requirements may necessitate more visits by the recognised person.</i></p> <p><i>We consider that the word “prior” means within 72 hours prior to commencement of isolation.</i></p> <p><i>At the end of the isolation period the exporter must supply to the recognised person, as supporting documentation, a declaration based on Declaration Form 4 in Appendix I (10.19.1). The declaration states, amongst other things “that the isolation has been carried out in the facilities that meet the requirements of section 10.16 to 10.19 of the OAP” and “a recognised person inspected the facility prior to, or at, the beginning of the required isolation period”. Additional details can be added to Declaration Form 4 in Appendix I to cover export requirements in regard to the non-MAF-approved PEI.</i></p> <p><i>The recognised person uses the declaration by the exporter as supporting documentation for the required PEI, unless they have concerns in regard to the pre-export isolation. If the recognised person has concerns about the export or supporting documentation then it is appropriate to investigate the concern before signing any eligibility documents.</i></p> <p><i>Therefore the minimum number of visits by a recognised person to a non-MAF-approved PEI Facility, if the export requirements do not require more than the first approval inspection, is one. Recognised persons may need to make additional visits related to the export or certification requirements.</i></p>
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Part 11 Requirements for live bees

Part 12 Appendix I: Application and declaration forms

Application Form 1:	Recognised Agency (live animals and germplasm)
Application Form 2:	Recognised Person (live animals and germplasm) Consent to Disclosure of Information Comments of the New Zealand Police
Application Form 3:	Use of security paper
Application Form 4:	Use of security seals
Application Form 5:	Approval for access to export template certificates
Application Form 6:	Approval of a semen centre
Application Form 7:	Approval of a semen centre veterinarian
Application Form 8:	Approval of an embryo team and embryo team veterinarian
Application Form 9:	Approval for continuously approved pre-export isolation centre
Application Form 10:	Approval of a bee team
Conflict of Interest Form	
Declaration Form 1:	Export certification
Declaration Form 2:	Export certification for farm/premises/herd/flock of origin
Declaration Form 3:	Transportation
Declaration Form 4:	Pre-export isolation in non-MAF-approved facilities
Template 1:	Audit Report
Template 2:	Non-compliance report

Issue title	Declarations 1-3 in appendix
Date received	7 October 2009
OAP reference	Appendix 1
Issue details	Section 127 must be on all declarations “I have read section 127(1) of the Animal Products Act 1999, and I am aware that section 127(1) makes it an offence for a person to deceive under this Act.” The consequence of this for the recognised agency is that the wording of section 127 (1) will need to be on back of recognised agency declarations, and this may involve additional paper then faxing is used.
MAFBNZ Response	Accept the consequence, but MAFBNZ need to be assured that the person has read it.

Issue title	Transport declaration
Date received	7 October 2009
OAP reference	Appendix 1
Issue details	Use of declarations. Traceability of animals is important but declarations may relate to property or cleaning of a truck but not all animals per se. Verification of identification of animal(s) is not required in all circumstances
MAFBNZ Response	Declaration for farm/premises/herd/flock or origin has been added to appendix. Redraft transport declaration and section 5.10.3.

Issue title	Re-sending of application forms prior to audits
Date received	March 2009
OAP reference	Appendix
Issue details	Please notify whether EU application forms need to be submitted prior to 6 monthly audits as per OAP application forms.
MAFBNZ Response	Application forms i.e. for semen centres, semen centre veterinarians, embryo teams and embryo team veterinarians, should be completed and sent to recognised agency prior to every audit not just an initial audit. This also applies to the EU application form.