OMARs with an uncertain status

These OMARs have not been used for a significant period of time. Therefore the requirements may have changed without the Ministry for Primary Industries knowledge.

If an exporter can provide the current import conditions, and the requirements still match, the certificate and the OMARs will be moved back into the published list of export certificates and OMAR's.

OVERSEAS MARKET ACCESS REQUIREMENTS NOTIFICATION
ANIMAL PRODUCTS ACT 1999
STANDARDS
MINISTRY OF AGRICULTURE AND FORESTRY NEW ZEALAND

Ref**:** AE-EU-00
Date**:** 7 July 2011

Statutory Authority

Pursuant to section 60 of the Animal Products Act 1999:

(i) I notify the following overseas market access requirements and specifications, entitled European Union Germplasm Export Requirements Part 6 Equine Semen

(ii) Revoke European Union Germplasm Export Requirements Part 6 Equine Semen: 1 June 2011.

This notice takes effect from date of signing.

Dated at Wellington this 12th day of July 2011.

Signed: Matthew Stone BVSc MACVSc MVS (Epidemiology)
Group Manager
Animal Imports and Exports Group
Imports & Exports Directorate
Standards Branch
MAF Biosecurity New Zealand
(pursuant to delegated authority)

Explanatory Note

These Export Requirements are the European Union Member States general requirements for Equine Semen.

This OMAR shall be read in conjunction with the European Union Germplasm Export Requirements Part 1.

Part 6 Equine Semen

Note: to be read in conjunction with Part 1: General

6.1 Application

6.1.1 This Part applies to the semen of domestic equine animals.

6.1.2 Where a semen storage centre is a stand-alone storage centre for storing EU eligible semen, it must be listed by both MAF and the EU.

6.1.3 Where the storage of semen is not limited to one (1) species, there must be separate approvals and listings for each species of semen that is stored at the centre.

6.2 Facility requirements

6.2.1 Collection centres must be physically separated from neighbouring properties by a solid wall of a building, or by a distance of separation of at least two (2) metres.

Separation implies the centre has control of the two (2) metre separation area.

6.2.2 Construction of collection, processing and storage facilities must be such that:

a. contact with livestock outside the centre is prevented

When paddocks are part of the centre, these should prevent unmanaged animal movements (be secure) and comply with the above.

b. all rooms and facilities (except the office rooms and exercise area) can be readily cleaned and disinfected

This is a constructional requirement; i.e. the lay-out and the materials used should allow for effective cleaning and disinfecting.

c. secure animal housing can be readily cleaned and disinfected, or managed effectively to prevent disease spread.

Where the centre accommodation includes paddocks or an exercise area that are not able to be readily cleaned and disinfected, the centre needs to have procedures to cover how this is managed effectively.

6.2.3 Collection centres must have:

a. animal housing, including isolation facilities. The isolation facilities accommodation on the centre must not have direct communication with the normal animal accommodation

Direct communication means nose-to-nose contact. The normal animal accommodation refers to the non-isolation accommodation on the centre.

b. semen collection facilities that may be open air, with non-slip flooring around the area of semen collection to reduce the risk of injury from a fall
c. a separate room for the cleaning and disinfection or sterilisation of equipment
d. a physically separate semen processing room, which may be located off-site
e. a physically separate semen storage room, which may be located off-site
f. a physically separate exercise area, if required.

Off-site located facilities should be operated with the same intensity of control as the EU listed collection centres.

6.2.4 All areas and buildings within the perimeter of the collection centre must be managed so that its status does not compromise the health status of the animals.

Waste areas and buildings used for storage etc should be kept tidy and have appropriate vermin control.

6.3 Operational requirements

6.3.1 Semen collection centres must be under the permanent supervision of a centre veterinarian, authorised by MAF as the competent authority.

6.3.2 Semen collection centres must be regularly inspected by a recognised person, at least once a year in the case of seasonal breeding centres or at least twice a year in the case of non-seasonal breeding centres, to verify the conditions of approval and supervision.

The verification would normally include records, standard operating procedures and internal audits, as well as compliance with the sanitary conditions regarding the collection, processing and storage of semen. Further inspections can occur in addition to the audits carried out once a year.

6.3.3 Collection, processing and storage of semen are carried out only in premises set aside for these purposes.

6.3.4 The centre veterinarian must inform the recognised person of any failure of compliance with these Export Requirements as soon as possible, and before affected semen is exported to the EU.

6.3.5 The semen collection centre must contain only animals of the species whose semen is to be collected. Other domestic animals may nonetheless be admitted, provided that they present no risk of infection to those species whose semen is to be collected, and that they fulfil the conditions laid down by the centre veterinarian.

6.3.6 Semen must be obtained from donor animals which show no clinical signs of disease on the day the semen is collected.

This excludes diseases which have no adverse effect on the requirements of these Export Requirements or cannot be transmitted through semen.

6.3.7 None of the animals kept in the centre is used for natural mating from thirty (30) days prior to the first semen collection until the end of the collection period.

6.3.8 Procedures and protocols must be in place for accommodation paddocks and shared facilities in the event of an incidence of any exotic disease of horses.

6.3.9 Feed and drinking water supplied must be so derived that it does not constitute an animal health risk.

6.3.10 Entry of unauthorised persons to the centre must be prevented. Authorised personnel, including visitors, must comply with the conditions specified by the centre veterinarian.

6.3.11 Staff employed must be technically competent and suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease.

6.3.12 All equipment used for the collection, processing, preservation or freezing of semen must be either disinfected or sterilised as appropriate for use, except for single-use equipment which must be discarded after use.

6.3.13 Where the collection centre shares a site with an equine breeding centre, there must be a strict separation between any instruments or equipment coming into contact with donor or teaser animals kept on the collection centre; and the semen, instruments and equipment used for artificial insemination and natural service.

6.3.14 Products of animal origin used in the processing of semen, including diluents, additives or extenders, must be obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented.

6.3.15 Where antibiotics or a mixture of antibiotics are added to semen, they should have a bactericidal activity in each ml of semen at least equivalent to one of the following combinations:

- gentamycin (250 µg), tylosin (50 µg), lincomycin-spectinomycin (150/300 µg);
- penicillin (500 IU), streptomycin (500 µg), lincomycin-spectinomycin (150/300 µg);
- amikacin (75 µg), divekacin (25 µg).

6.3.16 Each individual dose of semen must be clearly marked in such a way that the date of collection of the semen, and the species, breed and identification of the donor animal and the approval number of the centre can be readily established.

6.3.17 EU-eligible semen must not at any time come into contact with semen which is ineligible for the EU.

This means that EU eligible semen should not be stored in the same room with semen or embryos that are ineligible for the EU.

6.3.18 Records must be kept of all equine animals at the collection centre, giving details of:

a. the species, breed, date of birth and identification of each of the animals
b. any movement of animals entering or leaving the centre
c. a record of the health history, all diagnostic tests and results, and all vaccinations and treatments carried out on donor and teaser animals
d. the date of collection and processing of semen
e. the health status of the donor on the day of semen collection
f. the storage of semen
g. the destination of the semen.

6.3.19 Except for single-use containers, storage containers and transport containers must be either disinfected or sterilised before the commencement of each filling operation.

6.3.20 The cryogenic agent used must not have been previously used for other products of animal origin.

6.3.21 Semen must be transported to storage centres under conditions which maintain the health status of the semen and without contact with any other semen.

6.3.22 Semen must be exported in containers which have been cleaned and disinfected or sterilised before use, and which have been sealed and numbered prior to dispatch from the approved storage facility.

6.4 Semen storage centres

6.4.1 The storage of semen must take place only in a facility set aside for the purpose and under the strictest conditions of hygiene.

6.4.2 Semen storage centres must be under the permanent supervision of a centre veterinarian, authorised by MAF as the competent authority.

6.4.3 Semen storage centres must be regularly inspected by a recognised person, at least twice a year, to verify the conditions of approval and supervision.

> The verification would normally include records, standard operating procedures and internal audits. Further inspections can occur in addition to the audits carried out twice a year.

6.4.4 Storage centres must be supervised to ensure that they only store semen that was collected in accordance with these Export Requirements, and has not come into contact with any other semen.

6.4.5 When semen was transported to the semen storage centre, it was transported under conditions that maintained its EU-eligibility.

6.4.6 Construction must be such that:

a. the semen storage room is able to protect semen or embryos from adverse weather and environmental effects
b. contact with livestock outside the centre is prevented
c. the storage centre facilities (except the office rooms and exercise area) can be readily cleaned and disinfected
d. unauthorised access of persons is effectively prevented.

6.4.7 All equipment which comes into contact with the semen or the donor animal during collection and processing must be disinfected or sterilised prior to use, except for single-use equipment.

6.4.8 Each individual dose of semen must be clearly marked in such a way that the date of collection of the semen, and the species, breed and identification of the donor animal and the approval number of the centre can be readily established.

6.4.9 Except for single-use containers, storage containers and transport containers must be either disinfected or sterilised before the commencement of each filling operation.

6.4.10 The cryogenic agent used must not have been previously used for other products of animal origin.

6.4.11 Storage centres must keep records of all movement of semen in and out of the centre.

6.4.12 Frozen embryos may also be stored in the storage facilities of EU-listed storage centres provided that:

a. the facility is approved as an embryo collection/production team

b. the embryos comply with all EU requirements published in these Export Requirements
c. the embryos are stored in separate storage containers.

6.4.13 Where export is from a storage centre, the export certificate used must be the model health certificate appropriate to the premises of dispatch.

There is a model certificate specifically for equine semen exported from a storage centre.

6.5 Procurement of donor and teaser animals

6.5.1 The donor and teaser animals must have been born in New Zealand, or resided in New Zealand for at least three (3) months.

6.5.2 The donor and teaser animals originate from a property where they have been kept continuously for at least thirty (30) days prior to their entry into the collection centre.

6.5.3 The animals did not come from properties, and have not have been in contact with animals of a property, in which any of the following diseases have been clinically detected within the thirty (30) days prior to their entry into the semen centre:
a. Equine viral arteritis
b. Contagious equine metritis

6.5.4 The diseases stated in 6.5.3 above are included in an official system for notification of diseases.

6.5.5 The donor and teaser animals must not be used for natural mating during the thirty (30) days prior to the first semen collection, and during the collection period.

6.6 Admission to collection centres

6.6.1 Animals must only be admitted to the semen collection centre with the express permission of the centre veterinarian. All inward and outward movements of animals must be recorded.

6.6.2 The animals must have come directly from a property that has been free from any notifiable disease for at least thirty (30) days.

6.6.3 Animals must not show any clinical sign of disease on the day of admission.

6.6.4 Where an equine semen centre shares a site with an artificial insemination or service centre, any mares or stallions for teasing or natural service can be admitted provided they meet the requirements of clauses 6.5.1 to 6.5.4 above.

6.7 Fresh semen, or frozen semen from continuously resident stallion

6.7.1 The donor stallion must be continuously resident on the EU-listed semen centre for at least thirty (30) days prior to the date of the first semen collection.

6.7.2 The donor stallion must not have direct contact with any equidae of lesser health status.

6.7.3 At least fourteen (14) days after entry to the centre, and prior to the first semen collection, the donor stallion must be subjected to the following tests, with negative results;

a. Equine infectious anaemia using an AGID (Coggins test) or ELISA
b. Equine viral arteritis (EVA):
    i. a serum neutralisation test (VNT); or
    ii. virus isolation on an aliquot of an entire semen sample.
c. Contagious equine metritis, on two (2) occasions seven (7) days apart.

6.8 Frozen semen from non-resident stallion

6.8.1 The semen must be stored in approved conditions for a minimum period of thirty (30) days from the date of collection until dispatch.

6.8.2 The donor stallion must be tested at least once a year at the start of the breeding season, prior to the date of the first semen collection, with negative results;

a. Equine infectious anaemia using an AGID (Coggins test) or ELISA
b. Equine viral arteritis:
    i. a serum neutralisation test (VNT); or
    ii. virus isolation on an aliquot of an entire semen sample.
c. Contagious equine metritis, on two (2) occasions seven (7) days apart.

6.8.3 During the storage period as per 6.8.1 and before the semen is used or dispatched, between fourteen (14) and ninety (90) days after the date of semen collection the donor stallion must be subjected to the following tests, with negative results;

a. Equine infectious anaemia using an AGID (Coggins test) or ELISA
b. Equine viral arteritis :
    i. a serum neutralisation test (VNT); or
    ii. virus isolation on an aliquot of an entire semen sample.
c. Contagious equine metritis, on two (2) occasions seven (7) days apart.

6.8.4 If any of the tests listed in 6.8.3 is positive (except for EVA), the animal must be isolated and any semen collected from it since the last negative test declared ineligible for the EU. Should an animal become EVA positive, every ejaculate of that animal collected since the last negative test must be either declared ineligible for the EU or tested by virus isolation for EVA with negative results.

6.8.5 Semen collected from all other animals at the centre since the date on which the positive test was carried out shall be held in separate storage and must not be exported to the EU until the health status of the centre has been restored.

For information regarding the process required for restoring the health status of the centre, the Animal Imports and Exports Group of MAF should be consulted.

Appendix 1: Risk Analysis *Guidance Information*

Purpose / Scope
To identify the risk organisms relating to disease transmission that are reasonably likely to occur, and ensure that appropriate controls are included in the centre work manual so that the semen meets the EU Export Requirements.

Identification of Biological Hazards from Inputs and Process Steps

Process step	Inputs	Hazard reasonably likely to occur	Justification	Control Measures	Reference
1. Entry of donors and teasers to centre	Donors and teasers	EVA miscellaneous pathogens	Sporadic incidence of infection may occur	• Resident in NZ 3 months, present on property of origin for 30 days prior to entry, come from property of known disease status • No contact with animals from property with clinical EVA • Animals show no clinical sign of disease on day of admission • Express permission to enter centre	(a) Entry conditions 6.5, 6.6 6.5 6.6.3 6.6.1
2. Donors resident on centre	Donors continuously resident	EVA miscellaneous pathogens	Sporadic incidence of infection may occur	• Routine testing carried out • Donors must show no clinical disease on the day semen is collected • Facilities able to be cleaned and disinfected	(b) Centre facility and management conditions 6.7 6.3.6 6.2.2 b. 6.2.2 c.

Process step	Inputs	Hazard reasonably likely to occur	Justification	Control Measures	Reference
				• Isolation facilities	6.2.3 a.
	Donors (Frozen semen)	EVA miscellaneous pathogens	Sporadic incidence of infection may occur	• Routine testing prior to date of first collection	6.8.2
				• Post collection semen storage	6.8.1
				• Post collection testing	6.8.3
				• Donors must show no clinical disease on the day semen is collected	6.3.6
				• Facilities able to be cleaned and disinfected	6.2.2 b.,6.2.2c.
				• Isolation facilities	6.2.3 a.
	Animals admitted to a breeding centre sharing same site	EVA miscellaneous pathogens	Direct contact	• All equines admitted to site must meet same requirements	6.6.4
				• Resident in NZ 3 months, present on property of origin for 30 days prior to entry, come from property of known disease status	6.5, 6.6
				• No contact with animals from property with clinical EVA	6.5
				• Animals show no clinical sign of disease on day of admission	6.6.3
				• Express permission to enter centre	6.6.1
	Other animals	EVA miscellaneous pathogens	Direct contact	• Excluded by physical separation (2m boundaries)	6.2.1
				• Only animals of same species are allowed on centre unless they are necessary for managing stock (e.g. dogs)	6.3.5

Process step	Inputs	Hazard reasonably likely to occur	Justification	Control Measures	Reference
				• Facilities able to be cleaned and disinfected	6.2.2 b., 6.2.2 c.
	Feed (pasture)	contamination with miscellaneous pathogens	Endemic disease occurrence	• Donors must show no clinical disease on the day semen is collected • Antibiotics added to semen	6.3.6 6.3.15
	Supplementary feed	contamination with miscellaneous pathogens such as lepto	Feed contaminated by rodents, hedgehogs	• Feed sourced from centre, or from property of known health status • Donors must show no clinical disease on the day semen is collected • Antibiotics added to semen	6.3.9 6.3.6 6.3.15
	Water supply	None	Controlled water supply	• Water supply must not be an animal health risk	6.3.9
	Staff	EVA	Disease transmission may be indirect	• Staff trained in disease and disinfection procedures	6.3.10, 6.3.11
	Visitors	EVA	Disease transmission may be indirect	• Authorised personnel only	6.3.10
3. Semen collection	Donors and teasers	EVA miscellaneous pathogens	Sporadic incidence of infection may occur	• Donors must show no clinical disease on the day semen is collected • Facilities able to be cleaned and disinfected • Antibiotics added to semen	(c) Control of collection 6.3.6 6.2.2 b., 6.2.2 c. 6.3.15
	Equipment	EVA	Disease transmission may be indirect	• Equipment must be single-use disposable, or disinfected prior to use • Separation of equipment between collection centre and breeding centre	6.3.12 6.3.13
4. Semen	Semen	EVA	Disease may be present in semen		(d) Control of processing

Process step	Inputs	Hazard reasonably likely to occur	Justification	Control Measures	Reference
processing		miscellaneous pathogens		• Equipment must be single-use disposable, or disinfected prior to use • Separation of equipment between collection centre and breeding centre • Antibiotics added to semen	6.3.12 6.3.13 6.3.15
	Equipment	None	Single-use disposable, or disinfected prior to use	• Equipment must be single-use disposable, or disinfected prior to use • Separation of equipment between collection centre and breeding centre	6.3.12 6.3.13
	Media	None	Free of pathogenic organisms	• Products of animal origin do not represent an animal health risk	6.3.14
	Packaging	None	Single-use disposable, or disinfected prior to use	• Equipment must be single-use disposable, or disinfected prior to use • Separation of equipment between collection centre and breeding centre	6.3.12 6.3.13
5. Storage	Packaging	None	Disinfected prior to use	• Storage and transport containers must be disinfected prior to use	(e) Control of storage 6.3.19
	Cryogenic agent	None	New	• Must not have been used for other products of animal origin	6.3.20

Control measures

(a) Entry conditions

Risks associated with donors and teasers entering the centre is managed by:

- The donors and teasers must be resident in NZ for 3 months
- Donors and teasers present on property of origin for 30 days prior to entry to collection centre, and come from property of known disease status

- No contact with animals from properties with known EVA during 30 days prior to entry to collection centre
- No natural mating for 30 days prior to collection, and during collection period
- Animals show no clinical sign of disease on day of admission to the centre
- Require the express permission of the centre veterinarian to enter the centre
- All animals on site of collection centre must meet same requirements.
- Contagious equine metritis and Equine infectious anaemia not considered a risk organism as NZ has disease freedom.

(b) Centre facility and management conditions

Risks associated with donors continuously resident on the centre is managed by:

- Routine testing carried out
- Regular visual checks of resident animals
- Donors show no clinical sign of disease on day of semen collection, records kept
- Facilities able to be easily cleaned and disinfected - non-porous surfaces on structures in direct contact with donors during collection (i.e. wood painted/sealed, concrete in good condition), flooring material in collection area either easily washable or able to be replaced (i.e. sand/bark), non-porous internal surfaces in processing areas, non-porous internal surfaces in storage areas with floor coverings able to be easily cleaned and disinfected or replaced (carpet can be used for safety reasons but must be able to be managed effectively). Other structures such as yards, building exteriors and fencing must be maintained in good repair so that they can be cleaned down or replaced as appropriate in the event of an endemic or exotic disease occurrence
- Isolation facilities available for isolation of sick animals
- Procedures in place for exotic disease occurrence - if exotic disease occurs, MAF notified; EU notified; animals isolated on centre with possible destruction; EU exports suspended; any semen isolated/destroyed; all areas cleaned and disinfected; accommodation paddocks disinfected or topsoil removed
- CEM and EIA not considered a risk organism as NZ has disease freedom.

Risks associated with donors temporarily resident on centre is managed by

- Testing carried out prior to start of collection period

- Donors show no clinical sign of disease on day of semen collection
- Testing carried out between 14 and 90 days post collection period
- Semen stored at least 30 days from date of collection
- Facilities able to be easily cleaned and disinfected
- Isolation facilities available for isolation of sick animals
- Procedures in place for exotic disease occurrence - if exotic disease occurs, MAF notified; EU notified; animals isolated on centre with possible destruction; EU exports suspended; any semen isolated/destroyed, all areas cleaned and disinfected, accommodation paddocks disinfected or topsoil removed
- CEM and EIA not considered a risk organism as NZ has disease freedom.

Risks associated with other animals admitted to a breeding centre on same site

- All animals on site of collection centre must meet same requirements
- The animals must be resident in NZ for 3 months
- Animals present on property of origin for 30 days prior to entry to collection centre, and come from property of known disease status
- No contact with animals from properties with known EVA during 30 days prior to entry to collection centre
- Animals show no clinical sign of disease on day of admission to the centre
- Require the express permission of the centre veterinarian to enter the centre
- Facilities able to be easily cleaned and disinfected
- Isolation facilities available for isolation of sick animals
- Procedures in place for exotic disease occurrence – if exotic disease occurs, MAF notified, EU notified, animals isolated on centre with possible destruction, EU exports suspended, any semen isolated/destroyed, all areas cleaned and disinfected, accommodation paddocks disinfected or topsoil removed
- CEM and EIA not considered a risk organism as NZ has disease freedom.

Other animals not directly associated with the centre are excluded from entry

- Excluded by physical separation (2m boundaries)
- Only animals of same species are allowed on centre unless they are necessary for managing stock (e.g. dogs) and do not pose a disease risk
- Facilities able to be cleaned and disinfected.

Feed and supplementary feed

- Normal farming practices discourage wildlife and vermin
- Supplementary feed sourced from centre pasture, or property of known health status
- If commercially prepared feeds are used, they meet NZ manufacturing standards and do not contain ruminant protein
- Stored feed is protected from vermin
- Donors must show no clinical disease on the day semen is collected
- Antibiotics added to semen diluent/extender.

Water supply

- From secure water supply (town water, bore, or local supply)
- Use of back-flow preventers when reticulation shared with water troughs animals external to centre.

Risks associated with staff entering the centre is managed by:

- Staff trained in disease recognition, disease control, and disinfection procedures
- Use of clean protective clothing on entry to centre
- Limited contact to off-centre animals that may pose a risk of indirect disease transmission.

Risks associated with visitors entering the centre is managed by:

- Authorised personnel only, and must be accompanied/supervised by staff when on centre

- Use of clean protective clothing on entry to centre
- Limited contact to off-centre animals that may pose a risk of indirect disease transmission i.e. biosecurity stand-down period prior to visit.

(c) Control of collection

Risks associated with donors and teasers managed by:

- Donors must show no clinical disease on the day semen is collected
- Donors and teasers adequately prepared
- Good hygiene during teasing and mounting to minimise risk of cross-contamination of semen/artificial vagina
- Facilities able to be cleaned and disinfected
- Antibiotics added to semen diluent/extender.

Equipment must be single-use disposable, or disinfected prior to use.

Strict separation of equipment that comes in contact with donor and teaser animals, and semen and equipment used on a breeding centre, located at the same site.

(d) Control of processing

Collection area physically separated from processing area

Equipment must be single-use disposable, or disinfected prior to use

Strict separation of equipment that comes in contact with donor and teaser animals and semen and equipment used on a breeding centre located at the same site

Separate room for cleaning and disinfecting laboratory equipment

Animal products of animal origin (e.g. milk powder) from commercially prepared/pasteurised ingredients or disease free source so do not represent an animal health risk

Equipment for packaging, including straws, must be single-use disposable, or disinfected prior to use.

(e) Control of storage

Storage area physically separated from collection and processing areas

Storage and transport containers must be disinfected prior to use
Cryogenic agent must not have been used for other products of animal origin.

Appendix 2: Testing *Guidance Information*