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 1 General

(ii) Revoke Part 1 European Union: General 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 germplasm.

This OMAR shall be read in conjunction with the European Union Germplasm Export Requirements Part 0 and the part for the commodity being exported.

Part 1 General

1.1 Application

1.1.1 These requirements are restricted to germplasm from bovine, ovine/caprine, and equine animals.

1.1.2 These requirements apply to the export of germplasm to:

a. the European Union, being Austria, Belgium, Bulgaria, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Netherlands, Portugal, the Republic of Ireland (Eire), Spain, Sweden, the United Kingdom, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovakia and Slovenia
b. the French Departments, being Guadeloupe, French Guiana, Martinique, Mayotte, Réunion, St. Pierre et Miquelon
c. the Faroe Islands (Denmark), Canary Islands (Spain) and Madeira (Portugal).

1.1.3 References in this notice to EU requirements are deemed to include all the countries in clause 1.1.2 unless otherwise stated.

1.1.4 These requirements are based on the NZ/EU Veterinary Agreement and where appropriate other European Union legislation. Any additional requirements of Member States will be specifically referenced.

1.1.5 Statements contained within a border or appendix, other than tables in the body of the Part, are provided for guidance only. For example:

This statement is for guidance.

1.2 Interpretation

1.2.1 In these Export Requirements, unless the context otherwise requires:

Agency Technical Manager means the person with overall responsibility for the technical activities of the recognised agency, relating to the export of live animals and germplasm, and who acts as the recognised agency's point of contact with MAF

authorised person means a person employed by MAF and designated by the Director-General of MAF under section 65 of the Act as an authorised person for the purpose of issuing official assurances under section 61 of the Act, and for withdrawing and reissuing official assurances under section 64 of the Act

centre veterinarian means a veterinarian who is approved by the Director-General and responsible for day-to-day compliance of semen collection/processing/storage in accordance with the OAP

commercial risk means acceptance by the exporter that the export certificates are given in good faith based on the exporter's assurances that all due enquiries have been made and that there is no known impediment to entry of the product into the country concerned. It includes acceptance by the exporter that MAF may not necessarily intervene should the consignment be detained or rejected on arrival. Exporters presenting these certificates for approval are considered to have full knowledge of the potential risk of rejection of these certificates and/or their associated consignments by border inspectors in the EU. The exporter is further considered to have no claim against MAF for any losses that may result

embryo collection team, in the context of the European Union Germplasm Export Requirements, means an officially approved group of technicians supervised by a team veterinarian, competent to perform the collection, processing and storage of in-vivo derived embryos

embryo production team, in the context of the European Union Germplasm Export Requirements, means an officially approved embryo collection team for in-vitro fertilisation

enzootic bovine leukosis (EBL) free bovine herd means any herd classified as free in accordance with the New Zealand Dairy Industry Enzootic Bovine Leukosis Control Scheme

export certificate template is the template which is used to raise an official assurance as determined by the Director-General pursuant to section 62 of the Act. For the purposes of the OAP, once the export certificate template is completed, printed on security paper, numbered, signed and dated by an authorised person, and stamped with that authorised person's signatory seal, it becomes an official assurance

herd, in the context of the European Union Germplasm Export Requirements, means an animal or a group of animals kept on a property as an epidemiological unit; if more than one herd is kept on a property they may be distinct units but will have the same health status

ICAR is the International Committee for Animal Recording
http://www.icar.org/

IETS is the International Embryo Transfer Society
http://www.iets.org/

isolation facility means an area set apart on the collection centre that is specifically constructed for the purpose of physically isolating an animal (that is suspected of having a disease requiring quarantine), which has already entered the collection centre, from other animals on the centre. **Note:** These facilities cannot be used for quarantine prior to entry onto the centre

MAF Authorised Person, in the context of the European Union Germplasm Export Requirements, means a person recognised under section 103 of the Act i.e. an auditor from MAF Compliance and Enforcement Directorate

Official Assurance Programme (OAP) means the current version of the *Official Assurance Programme Requirements for Export of Live Animals and Germplasm*
http://www.biosecurity.govt.nz/regs/exports/animals/oap

officially brucellosis free herd means any New Zealand herd, in accordance with New Zealand's brucellosis-free status

officially tuberculosis free herd, in the context of the European Union Germplasm Export Requirements, means any herd classified as C2 or greater for bovine tuberculosis (Tb), in accordance with the National Pest Management Strategy for Bovine Tuberculosis (NPMS), pursuant to the Biosecurity (National Bovine Tuberculosis Pest Management Strategy) Order 1998, and in which animals of a lower status have not been introduced since the last clear test

official veterinarian, in the context of the European Union Germplasm Export Requirements, means a veterinarian authorised by the competent authority of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of commodities. Where applicable, this term has been replaced in the EU Export Requirements by the term 'Recognised Person' as per the OAP

packaging means the placing of one or more wrapped or unwrapped products in a container, as well as the container itself

property, in the context of the European Union Germplasm Export Requirements, means any establishment, construction or, in the case of an open-air farm, any place in which animals are held, kept or handled, and is equivalent to the word 'holding' used in EU legislation

quarantine facility, in the context of the European Union Germplasm Export Requirements, means an area set apart from the collection centre that is specifically constructed for the purpose of pre-entry isolation of animals prior to entry to the centre

recognised agency means a person or body recognised as an agency under section 103 of the Act for the purpose of performing specified functions and/or activities required for export certification of animals and germplasm to which these Export Requirements apply

recognised person means a person recognised under section 103 of the Act for the purpose of performing specified functions and/or activities relating to the export of live animals and germplasm to which these Export Requirements apply

room means a space big enough to be entered, which is enclosed by a floor, walls and a ceiling, with a closable door

semen collection centre, in the context of the European Union Germplasm Export Requirements, means an officially approved and officially supervised establishment situated in the territory of a Member State or third country in which semen is produced for use in artificial insemination

semen storage centre, in the context of the European Union Germplasm Export Requirements, means an officially approved and officially supervised establishment situated in the territory of a Member State or third country in which semen is stored for use in artificial insemination

team veterinarian means a veterinarian approved by the Director-General and who is responsible for supervision of the embryo team and the day-to-day compliance of the embryo team with the OAP

1.2.2 Any term or expression that is defined in the Animal Products Act 1999 and used but not defined in this document has the same meaning as in that Act. This includes definitions included in the Official Assurance Programme (OAP).

1.2.3 European Community legislative documents referenced in this notice are available at the following website: http://europa.eu.int/eur-lex/en/search/search_lif.html.

1.3 Requirements for export

1.3.1 Animal germplasm intended for export to the EU must comply with:

a. all relevant generic export requirements issued under the Animal Products Act 1999;
b. the current Official Assurance Programme Requirements for Export of Live Animals and Germplasm; and
c. the relevant EU Germplasm Export Requirements.

New Zealand has a Veterinary Agreement (Treaty) with the EU. The agreement provides for equivalency in procedures for some products and replication of either EU or Member State requirements for other products. The equivalency agreement was made based on the operational and control regimes in place during the mid-1990s and is regularly reviewed and updated.

The scope of the agreement is limited to the sanitary measures applied by either party to the live animals and animal products specifically listed in the agreement.

1.4 Operational control

1.4.1 All EU-listed centres and teams must prepare, implement and maintain written procedures, covering the entire scope of operation, unless stated otherwise in these Export Requirements. The scope should be accurately described, including any off-site facilities.

1.4.2 Where more than one site relates to the listing, all sites must be clearly documented to show their geographical location.

An overview map, plus individual site plans, may fulfil this requirement.

1.4.3 Where on-farm collection of ova/embryos occurs, each site used for EU collection must be clearly documented.

A detailed physical address, plus individual site plans and photographs, may fulfil this requirement.

1.5 Laboratories

1.5.1 Where these Export Requirements require laboratory testing to be undertaken then, unless stated otherwise, the testing must be done in a laboratory recognised or approved by MAF in accordance with the Export Laboratory Programme: http://www.biosecurity.govt.nz/regs/exports/animals/oap/elp.

1.6 Listing of centres and teams

1.6.1 Centres/teams collecting, processing or storing germplasm intended for export to the EU must appear on the relevant centre/team lists specified in this Part and which are maintained by the EU, Member State or MAF, as appropriate, before the germplasm is collected, processed or stored.

1.6.2 Despite the previous clause, germplasm can be collected, processed or stored after the date of the successful EU listing audit by the recognised person (i.e. provisional EU listing), but must be detained in the relevant storage facility until the EU listing is confirmed.

Only germplasm collected after the date of approval by MAF is eligible for export to the EU.

1.6.3 In order to obtain an EU listing, the operator must determine that the centre/team complies with the notified requirements for the facilities and operation for the particular category(ies) of listing, and apply in writing to MAF.

Before applying for a listing, it is expected that the centre/team will carry out an internal audit as part of the process of determining that it complies with the requirements stated in the OAP and the relevant EU Germplasm Export Requirements.

1.6.4 All operations for a particular listing must be under the control of a single operator.

The EU does not permit more than one registration number for the same centre/team on each list.

1.6.5 Any assessment of the centre/team for compliance with the EU requirements must include all buildings, operations and environs within the perimeter of the facility, whether or not they are used for EU-related activities. All operations relevant to the EU listing must be within the perimeter, unless stated otherwise in the relevant EU Germplasm Export Requirements.

This clause is based on the standard rule that facilities must be listed and that a line of control exists around the listing (listings are usually for defined activities at a particular location). For details of what facilities may be located at other sites, see the Facility Requirements of the relevant species Part.

1.6.6 A centre/team must not appear in any of the lists unless the agency technical manager of the recognised agency confirms in writing that the centre/team complies with the relevant EU Germplasm Export Requirements.

1.6.7 A centre/team must not appear in any of the lists unless the listing of the centre/team is confirmed by MAF, the competent authority.

EU and/or Member State legislation specifies which lists are to be ratified by them. MAF will list premises or send applications to the EU, as appropriate, once the recommendations have been accepted as complying with the requirements.

1.6.8 The following centres/teams must be listed by MAF and also by the EU:

a. bovine semen collection centres
b. bovine semen storage centres
c. bovine embryo collection teams (in-vivo derived embryos)
d. bovine embryo production teams (in-vitro produced embryos)
e. bovine embryo storage centres
f. ovine and caprine semen collection centres
g. ovine and caprine semen storage centres
h. ovine and caprine embryo collection teams (in-vivo derived embryos)
i. ovine and caprine embryo production teams (in-vitro produced embryos)
j. ovine and caprine embryo storage centres
k. equine semen collection centres
l. equine semen storage centres.

1.6.9 For centres/teams to maintain their listing, they must re-apply through the recognised person, using the relevant application form, before the end of the approval period. Continuation of listing is subject to official supervision i.e. verification audits as per 1.13.

1.6.10 Centres/teams must be de-listed if:

a. there is consistent non-compliance with EU requirements (refer 1.14)
b. they are non-functional (dormant) for more than six (6) months

Non-functional for an embryo team means not collecting, processing or storing any product eligible for the EU. For a semen centre, non-functional additionally includes not having any eligible animals on centre.

c. they are functional but have not handled/stored EU-eligible products for more than one (1) year.

1.7 Biosecurity transitional facilities

1.7.1 Biosecurity transitional facilities must not be situated at any EU-listed centre/team facility.

1.8 Identification of animals

1.8.1 All EU-eligible donor animals, and any associated teaser animals, must be uniquely identified so that their eligibility for any activities associated with an EU listing can be clearly established.

Unique identification can include, but is not limited to; microchip, ear tag, brand, tattoo.

1.8.2 Centres/teams must ensure the physical separation of EU-eligible donor animals from donor animals ineligible for the EU.

For semen collection centres the physical separation applies from entry onto quarantine/centre. For embryo teams, the physical separation is during the embryo collection process.

1.9 Identification and separation of non-EU germplasm

1.9.1 Centres/teams must have procedures and methods to distinguish ineligible germplasm from EU-eligible germplasm. Where any EU-eligible germplasm is indistinguishable from ineligible germplasm, then the former is deemed to be ineligible and must be dealt with accordingly.

1.9.2 Centres/teams must ensure the physical separation of EU-eligible germplasm from germplasm ineligible for the EU.

1.9.3 EU eligible germplasm must not be stored in the same room with germplasm that is ineligible for the EU.

The EU eligible germplasm should be stored in a separate locked room, unless the germplasm is in transit, in which case it must be stored in a sealed shipper.

1.9.4 EU listed storage centres must not store germplasm other than EU eligible germplasm.

1.9.5 Where EU-eligible germplasm is transferred between centres/teams, it must be clearly labelled and secured in a manner that ensures it maintains its EU eligibility.

Security of a shipper can be by use of a unique seal.

1.9.6 Where germplasm produced by an EU-listed centre/team is exported but not destined for the EU, comes into contact with germplasm of a lesser health status, or is held in a facility that is not EU-listed when it is required to be, then the germplasm becomes ineligible for export to the EU and must be subject to inventory controls so that it cannot mistakenly be exported to the EU.

1.10 Labels

1.10.1 Labels must display in a legible manner the marks, descriptions and other indicators required by the relevant EU Germplasm Export Requirements and any export certificates.

1.10.2 Germplasm labels must include the centre/team registration number, date of collection, breed and identification of the donor(s).

A code may be used in such a way that the information can be readily established, but the code must be internationally accepted i.e. follow IETS or ICAR.

1.11 Use of export certificates

1.11.1 Exporters must use the MAF export certificates specified for each commodity, and premises of dispatch.

Stand-alone storage centres must use the relevant export certificate for dispatch from a storage centre, with the original certificates from the collection centre/team attached.

1.11.2 All export certificates must be in English and, where relevant, an official language of the country where the commodity is inspected (i.e. commonly the Border Inspection Post port of entry into the EU).

1.11.3 Where an export certificate is unavailable, or is not in the appropriate language for the Member State where the commodity is inspected, (i.e. commonly the Border Inspection Post port of entry into the EU) then the relevant germplasm must not be exported to the EU.

1.11.4 MAF export certificates for germplasm to the EU must not be signed by an authorised person until the commodity has been loaded out or sealed at the final centre/team facility.

1.11.5 Export certificates must not be signed after the commodity has left New Zealand, unless approval is granted elsewhere in these Export Requirements for specific export certificates for specific products and subject to any conditions applied in each case.

1.11.6 The name and address of the consignee must be shown. The words ‘To order’ in lieu of the consignee details must not be used.

1.11.7 Export certificates for the EU can be signed at the operator’s commercial risk if the address of the consignee is in a different Member State from that of the intended destination of the commodity.

1.11.8 Export certificates must also show all relevant additional certificate declarations that have been notified for the Member State where the consignment receives border clearance, even when the consignment is intended for another Member State.

1.12 Shipping containers for the export of germplasm

1.12.1 Germplasm must be exported in shipping containers which have been cleaned and disinfected or sterilised before use.

1.12.2 Shipping containers must be marked in such a way that the identification of the shipping container coincides with the number on the export certificate.

1.12.3 All shipping containers of germplasm for export must be sealed with a MAF security seal before leaving the control of the relevant centre/team.

A MAF security seal can be applied at a VA operating location if the shipper is transported there under the direct supervision of the centre/team (i.e. seal applied and shipper transported by centre/team staff).

The relevant centre may be a separate storage centre.

Embryos may only be exported from facilities approved as part of the collection/production teams approval.

1.13 Official supervision

1.13.1 All requirements in these Export Requirements, other than those applying to MAF, are subject to verification audit by the recognised agency.

Any EU verification frequencies or procedures specified in this notice take precedence over any other programme such as the OAP.

1.13.2 The recognised agency must apply the frequencies in Table 1.

Table 1: Verification Frequencies

Activity	Frequency	Official
Bovine semen		
Semen collection centres	Twice yearly	recognised person
Semen storage centres	Twice yearly	recognised person
Bovine embryos		
Embryo teams	Twice yearly	recognised person
Embryo storage teams	Twice yearly	recognised person
Ovine and caprine semen		
Semen collection centres	Once yearly*	recognised person
Semen storage centres	Twice yearly	recognised person
Ovine and caprine ova and embryos		
Embryo teams	Once yearly	recognised person
Embryo storage teams	Twice yearly	recognised person
Equine semen		
Semen collection centres	Once yearly*	recognised person
Semen storage centres	Twice yearly	recognised person
* in the case of non-seasonal breeding centres the verification frequency must be increased to twice yearly		

1.13.3 The frequencies in Table 1 provide the maximum period between each verification activity in situations where the centre/team has a good record of compliance with any New Zealand requirements and with the EU requirements.

The recognised person must:

a. increase the verification frequencies when the centre/team's level of compliance is considered by the recognised person to be unsatisfactory. The modified frequencies must be such that the recognised person is confident that the germplasm remain eligible for export from New Zealand to the EU

b. suspend the issue of official assurances, and germplasm declarations or eligibility documents, when the eligibility of the germplasm for export from New Zealand to the EU is in doubt or confirmed to be ineligible
c. recommend that the premises or place be removed from any list of EU-eligible centres/teams when the centre/team repeatedly fails to maintain all relevant EU requirements.

1.14 Non-compliance

1.14.1 Where an EU listed centre/team no longer complies with these Export Requirements, or a critical or multiple major non-compliances occur, the EU listing may be suspended or withdrawn by MAF.

Appendix 1: EU listing process *Guidance Information*

A listing for the EU comprises of two audit stages, which may be undertaken separately:

a. In the first stage, the recognised person will carry out an audit of the written procedures (work manual), facilities (including the quarantine facility if applicable) and the centre/team veterinarian(s). A MAF Authorised Person will normally have oversight of the listing process.

   Following a successful first stage audit, the centre/team will be given its provisional EU registration number. Collection for export to the EU cannot be undertaken at this stage.

   In the case of semen centres, EU eligible animals can then be resident on the centre for the purposes of semen collection and processing to fulfil the second stage of the listing.

b. In the second stage, which must occur within three (3) months of the provisional approval, the recognised person must observe and assess the collection, processing and storage of germplasm as applicable to the listing sought. A MAF Authorised Person will normally be present, and have oversight of the listing process.

   Following a successful EU listing audit, the centre will be recommended for EU listing.

   Germplasm subject to EU listing can be collected, processed or stored after the date of the successful EU listing audit, but must be detained in storage until the EU listing is confirmed i.e. the centre/team is listed on the EU website (http://ec.europa.eu/food/animal/semen_ova/index_en.htm).

Under the OAP, germplasm collected and processed on the day of the audit is eligible for export, but this is not the case for the EU. This means that the germplasm collected and processed on the day of the audit is eligible under the MAF registration, but not the EU registration.

Where a quarantine facility is required for the pre-entry isolation of animals, the quarantine facility must be audited as part of the listing audit.

For the initial EU listing audit, an EU Checklist is currently required by the EU for:

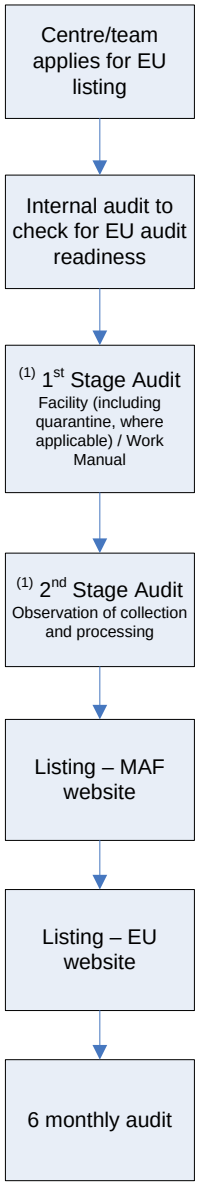
- bovine semen collection centres
- bovine semen storage centres
- ovine and caprine semen collection centres
- ovine and caprine semen storage centres
- ovine and caprine embryo collection teams
- ovine and caprine production teams
- equine semen collection centres
- equine semen storage centres

Where it is required, the recognised person must complete the appropriate EU Checklist (available from MAF or on the EU website) and forward it to MAF as part of the listing process.

The EU Checklist is a questionnaire based on the relevant Council Directive, and is sent to the EU to support the listing.

Once EU listed, the re-approval audits can be carried out by a recognised person.

EU listing flowchart:



Collection, processing and storage of germplasm for export can start after successfully completing both stages of the audit. No exports can take place until the centre / team is listed on the EU website

Once a centre is listed on the EU website exports of germplasm, including those collected, processsed and stored since the audit, can begin.

(1) The stages of the audit may be carried out on the same day if donor/teaser animals do not have to undergo a period of quarantine prior to entering the listed centre/team (eg embryo teams, equine semen centres).

If the donor/teaser animals do have to undergo a period of quarantine (eg bovine/ovine/caprine semen centres) this period may start on the day of the successful 1st stage audit. The 2nd stage audit must then take place as soon as practical after the animals have completed their quarantine and within 3 months of the 1st stage audit.