VERŻJONI ELETTRONIKA

L.N. 481 of 2011

VETERINARY SERVICES ACT (CAP. 437)

Animal Health Conditions (Intra-Community Trade and Imports from Third Countries of Deep-Frozen Semen of Domestic Animals of the Porcine Species) Rules, 2011.

IN EXERCISE of the powers conferred by articles 9 and 10 of the Veterinary Services Act, the Minister for Resources and Rural Affairs after consultation with the Minister for Health, the Elderly and Community Care has made the following rules:-

Title, scope and commencement.

1. (1) The title of these rules is the Animal Health Conditions (Intra-Community Trade and Imports from Third Countries of Deep-Frozen Semen of Domestic Animals of the Porcine Species) Rules, 2011.

(2) The scope of these rules is to transpose Directive 90/429/EEC laying down animal health conditions applicable to intra-Community trade and imports from third countries of deep-frozen semen of domestic animals of the porcine species, and shall apply without prejudice to the provisions adopted pursuant to other regulations and community rules and other national legislation regarding domestic animals which may apply in this regard.

(3) These rules are being made for the safeguarding of the public interest and public safety. Any requirements and safeguard measures contained therein including those relating to authorisations are made for overriding reasons relating to public interest.

(4) These rules shall come into force on the XXXX, 2011.

Interpretation.

2. (1) Unless stated otherwise in these rules, the definitions in the Act, those contained under the Veterinary and Zootechnical Checks applicable in Trade with Member States in certain Live Animals and Products Regulations, 2003, those contained under the Animal Health Problems Affecting Intra-Community Trade in Bovine Animals and Swine Regulations, 2004, those contained under the Animal Health Requirements

L.N. 353 of 2003.

L.N. 505 of 2004.

Governing Trade and Imports into the Community of Animals, Semen, Ova and Embryos not Subject to Animal Health Requirements laid down in Specific Community Acts, Rules 2009, and those contained under the Animal Health Conditions Applicable to Intra-Community Trade and Imports from Third Countries of Deep-Frozen Semen of Domestic Animals of the Bovine Species, Rules 2010, shall apply as necessary.

L.N. 351 of 2009.

L.N. 554 of 2010.

(2) For the purposes of these rules and unless the context otherwise requires the following definitions shall apply:

"the Act" means the Veterinary Services Act;

"animals of the porcine species" means porcine animals whose semen is subject to intra-Community trade and imports from third countries to be produced for use in artificial insemination;

"approved laboratory" means a laboratory situated in Malta or a third country designated by the Competent Authority to carry out the tests laid down in these rules;

"authorisation" means any authorisation granted under these rules and in relation to authorised providers and services means a permit, licence, warrant, appointment, concession or any decision concerning access to a service activity or the exercise thereof;

"authorised provider" has the same meaning as that provided under the Animal Health Requirements Governing Trade and Imports into the Community of Animals, Semen, Ova and Embryos not Subject to Animal Health Requirements laid down in Specific Community Acts, Rules 2009;

"centre veterinarian" means the veterinarian responsible for day-to-day compliance in the centre with the requirements laid down in these rules;

"checks at origin" means veterinary checks which are carried out on semen of domestic animals of the porcine species imported from third countries by the Member State of collection prior to their dispatch to the Member State of destination for the purpose of intra-Community trade;

"collection" means a quantity of semen taken from a donor at any time;

VERŻJONI ELETTRONIKA

"the Commission" means the European Commission;

"the Community" means the European Community as established by the Treaty on the European Union as amended by subsequent treaties;

"the Competent Authority" means the department of veterinary services in Malta as established by article 3 of the Act;

"consignment" means a quantity of semen covered by a single certificate;

"country of collection" means the Member State or third country in which semen is collected and from which it is sent either directly from the third country of collection, or indirectly through a Member State to the Member State of destination;

"the Director" means the Director General of the Competent Authority or any veterinarian officer nominated by him;

"donor" means a domestic animal of the porcine species whose semen is used for artificial insemination;

"final consumer" has the same meaning as that provided for under the Animal Health Requirements Governing Trade and Imports into the Community of Animals, Semen, Ova and Embryos not Subject to Animal Health Requirements laid down in Specific Community Acts, Rules 2009;

"health certificate" means a certificate properly issued by the Competent Authority in accordance with Schedule IV to these rules, as a means of guaranteeing and monitoring compliance with animal health requirements as regards animals and products of animal origin subject to trade for the purpose of these rules;

"importation" means the importation of animals and their products from a third country into the Community for the purpose of intra-Community trade;

"Member State" means a State which is a member to the European Union;

"Member State of destination" means such Member State to which semen is transported either indirectly from the Member State of collection where the semen collection centre or establishment of origin is situated, or directly from a semen collection centre or storage of a third country;

"official veterinarian" has the same meaning as that provided for under the Animal Health Requirements Governing Trade and Imports into the Community of Animals, Semen, Ova and Embryos not Subject to Animal Health Requirements laid down in Specific Community Acts, Rules 2009;

"pathogenic organisms" means bacteria which causes infectious diseases;

"the product" means any product of animal origin subject to trade and trading purposes;

"quarantine" means the voluntary or compulsory isolation of semen to contain the spread of hazardous or dangerous diseases;

"semen" means the ejaculate of a domestic animal of the porcine species, in the unaltered state or prepared or diluted;

"semen collection centre or centre" means an officially approved and supervised establishment situated in Malta, a member state or third country, in which semen is produced for use in artificial insemination;

"Standing Committee on the Food Chain and Animal Health" or "the Committee" means a Committee made up of representatives of Member States named committee members, who assist and consult the Commission by delivering an Opinion regarding safety measures with respect to animal health issues to be then formally adopted by the Commission in accordance with the appropriate procedure. Such committee procedure covers the entire food supply chain, ranging from animal health issues on the farm to the product which arrives to the final consumer, therefore significantly enhancing its ability to target risks to health wherever they arise in the production of food;

"third country" means a country which is not a member of the European Community;

VERŻJONI ELETTRONIKA

"trade" means intra-Community trade between Member States in animals and their products after being imported from a third country, a business or occupation to make profit or gain, particularly in wholesale or retail and includes dealings in a particular business activity;

"the Treaty" means the Treaty on the European Union establishing the European Community as amended by the Lisbon Treaty of 2007;

"veterinary checks" means veterinary checks or import controls carried out on semen imports from third countries via border inspection posts in accordance with the procedure laid down in terms of rule 15 of these rules, provided that import controls between Member States shall be carried out in conformity to the procedure determined for veterinary checks in intra-Community trade as provided in sub-rule (2) of rule 3 of the Animal Health Requirements Governing Trade and Imports into the Community of Animals, Semen, Ova and Embryos not Subject to Animal Health Requirements laid down in Specific Community Acts, Rules 2009.

Applicability.

3. (1) These rules shall apply to:

(a) the elimination, as far as possible, of the risk of animal disease spreading in the case of trade in semen by means of guarantees provided by third countries that animal health criteria have been fulfilled;

(b) national animal health provisions governing intra-Community trade in animals and animal products, in order to create a harmonized system for intra-Community trade and imports into the Community of semen of porcine animals;

(c) intra-Community trade in semen, whereby the Competent Authority ensures that semen has been collected and processed at approved and supervised semen collection centres, and that it has been obtained from animals whose health status is such as to ensure that the risk of spread of animal diseases is eliminated;

(d) semen which has been collected, processed, stored and transported in accordance with rules which preserve its health status and is accompanied during transport to the

Member State of destination by an animal health certificate in order to ensure that this obligation has been fulfilled;

(e) policies pursued within the Community with regard to vaccination against certain diseases, authorising the Competent Authority, in respect of certain diseases, to impose the requirement of additional protection against those diseases;

(f) imports of semen into the Community from third countries whereby a list of third countries should be drawn up taking into account animal health criteria;

(g) authorisation by the Competent Authority to the importation of semen only from semen collection centres which reach certain standards and which are officially supervised without prejudice to the list mentioned in paragraph (f) hereof;

(h) specific animal health conditions in respect of countries on such list which should be laid down according to circumstances;

(i) the verification of compliance with the standards mentioned in paragraph (g) hereof, by means of on-spot checks which may be carried out;

(j) rules and procedures concerning veterinary checks in intra-Community trade with a view to the completion of the internal market;

(k) prevent the transmission of certain contagious diseases, whereby import controls should be carried out when a consignment of semen arrives and is placed on the market of the Community and the measures to be taken by the Competent Authority or other competent authorities after establishing such controls in the case of internal transit; and

(l) emergency measures which should be sought and taken by the Competent Authority in the event of outbreaks of contagious diseases in another Member State or third country.

(2) The Competent Authority shall apply all such necessary administrative measures conforming to the requirements of the Standing Committee on the Food Chain and Animal

VERŻJONI ELETTRONIKA

Health according to the requirements of these rules, to ensure that there is no breach of these rules and also to reduce the risk for final consumers and any additional risk to animals and to the environment.

(3) These measures include the direct confiscation of the product, the suspension of the activities carried out by the authorised provider when these are creating a risk to final consumers and to the environment, and the forfeiture of any authorisation, licence or permit in terms of article 60 of the Act in addition to the application of any other administrative penalty in terms of article 61 of the Act.

Measures to be adopted by the Authority for intra-Community trade.

4. The Competent Authority shall ensure that only semen meeting the following general conditions is intended for trade:

(a) it shall have been collected and processed, for the purpose of artificial insemination, in a semen collection centre approved from an animal health point of view for the purposes of intra-Community trade in accordance with sub-rule (1) of rule 5 of these rules;

(b) it shall have been collected from domestic animals of the porcine species whose health status complies with Schedule II to these rules;

(c) it shall have been collected, processed, stored and transported in accordance with Schedules I and III to these rules; and

(d) it shall be accompanied, during transport to the Member State of destination, by an animal health certificate complying with sub-rule (1) of rule 6 of these rules.

Semen collection centres.

5. (1) The Competent Authority shall ensure that, with regard to the semen collection centre, the approval provided for in rule 4 (a) of these rules is granted only where the conditions set out in Schedule I to these rules are observed and where the semen collection centre is able to satisfy the other provisions contained in these rules.

(2) The Competent Authority shall also ensure that the official veterinarian supervises the observance of these rules and shall withdraw its approval when one or more of the provisions contained in these rules are no longer observed.

VERŻJONI ELETTRONIKA

(3) All semen collection centres shall be registered, each centre given a veterinary registration number. The Competent Authority shall draw up and keep up to date a list of semen collection or storage centres and their veterinary registration numbers and make it available to other Member States and to the public.

(4) The general rules for applying this rule shall be adopted in accordance with the procedure referred to in the definition "Standing Committee on the Food Chain and Animal Health" under sub-rule (2) of rule 2 of these rules, where matters relating to semen collection centres shall be referred without delay to the Committee.

Admission or otherwise of imports of semen from Member States subject to an animal health certificate.

6. (1) The Competent Authority shall ensure that each consignment of semen is accompanied by an animal health certificate drawn up in accordance with the specimen in Schedule IV to these rules by an official veterinarian of the Member State of collection.

(2) This certificate shall:

(a) be drawn up in at least one of the official languages of the Member State of collection and one of those of the Member State of destination;

(b) accompany the consignment to its destination in its original form;

(c) be drawn up on a single sheet of paper; and

(d) be made out to a single consignee.

(3) In addition to measures provided for in regulation 8 of the Veterinary and Zootechnical Checks applicable in Trade with Member States in certain Live Animals and Products Regulations, 2003 concerning checks carried out at the place of destination of a consignment or during transport, the Competent Authority may:

(a) where the presence of agents responsible for a disease is established by the Competent Authority, or a zoonosis or a disease, or any cause is likely to constitute a serious hazard to animals or humans; or

VERŻJONI ELETTRONIKA

(b) in the case of products coming from a region contaminated by an epizootic disease, whereby the Competent Authority shall order that the animal or consignment of animals be put in quarantine at the nearest quarantine station or slaughtered and, or destroyed;

take the necessary measures, including storage in quarantine, provided this does not affect the viability of the semen, in order to obtain definite proof in cases where semen is suspected of being infected or contaminated by pathogenic organisms.

Importation of semen from third countries.

7. (1) The Competent Authority may authorise importation of semen only from those third countries which appear on a list drawn up in accordance with the procedure laid down in the definition "Standing Committee on the Food Chain and Animal Health" provided under sub-rule (2) of rule 2 of these rules, and which list may also be amended in accordance with the same procedure.

(2) In deciding whether a third country may appear on the list referred to in sub-rule (1) hereof, particular account shall be taken of:

(a) the state of health of the livestock, other domestic animals and wildlife in the third country, with particular reference to exotic animal diseases, and of the environmental health situation in that country, which might endanger animal health in Malta;

(b) the regularity and rapidity of the information supplied by the third country concerning the existence of contagious animal diseases in its territory, in particular those diseases mentioned in lists A and B of the International Office of Epizootic Diseases;

(c) such country's rules on animal disease prevention and control;

(d) the structure of the veterinary services in the country and their powers;

(e) the organization and implementation of measures to prevent and control contagious animal diseases; and

(f) the guarantees which the third country can give with regard to compliance with these rules.

VERŻJONI ELETTRONIKA

Conditions relating to semen collection or storage centres.

8. (1) The Competent Authority shall only authorise imports of semen dispatched from a semen collection or storage centre situated in one of the third countries appearing on the list referred to in rule 7 of these rules, and for which the competent authority of the third country concerned is able to give the guarantees that the following conditions relating to a semen collection or storage centre are met:

(a) it meets the conditions:

(i) for approval of semen collection centres or storage centres set out in Chapter I of Schedule I to these rules;

(ii) relating to the supervision of such centres set out in Chapter II of Schedule I to these rules;

(b) it has been officially approved by the competent authority of the third country for exports to the Community;

(c) it is placed under the supervision of a centre veterinarian;

(d) it is subject to inspections by an official veterinarian of the third country at least twice a year.

(2) The list of semen collection or storage centres which the competent authority of the third country appearing on the list referred to in rule 7 of these rules has approved, in accordance with the conditions set out in sub-rule (1) hereof, and from which semen may be dispatched to the Community, shall be communicated to the Commission.

(3) The approval of a semen collection or storage centre shall be immediately suspended or withdrawn by the competent authority of the third country where it no longer complies with the conditions set out in sub-rule (1) hereof and the Commission shall be immediately informed thereof.

(4) Detailed rules for the uniform application of this rule may be adopted in accordance with the procedure referred to in the definition "Standing Committee on the Food Chain and Animal Health" provided under sub-rule (2) of rule 2 of these rules, where matters relating to such authorisation and approval mentioned in this rule shall be referred without delay to the Committee.

VERŻJONI ELETTRONIKA

Conditions relating to semen from a third country.

9. (1) Semen shall come from animals which, immediately prior to collection of their semen, have remained for at least six months in the third country on the list drawn up in accordance with sub-rule (1) of rule 7 of these rules.

(2) Without prejudice to sub-rule (1) of rule 7 of these rules and sub-rule (1) hereof, the Competent Authority shall not authorise the importation of semen from a third country on the list, unless the semen complies with the animal health requirements adopted for imports of semen from that country, in accordance with the procedure laid down in the definition "Standing Committee on the Food Chain and Animal Health" provided under sub-rule (2) of rule 2 of these rules.

(3) In adopting the requirements referred to in the preceding sub-rule, special account shall be given to:

(a) the health situation in the area surrounding the semen collection centre, with particular reference to the diseases appearing on list A of the International Office of Epizootic Diseases;

(b) the state of health of the herd in the semen collection centre, including testing requirements;

(c) the state of health of the donor animal and testing requirements; and

(d) the testing requirements in relation to semen.

(4) The reference basis for fixing animal health conditions shall be the standards laid down in rules 4, 5 and 6 of these rules and their corresponding Schedules. The Competent Authority may, on a case-by-case basis, decide to waive these conditions in accordance with the procedure and requirements of the Standing Committee on Food Chain and Animal Health, where the third country concerned provides similar animal health guarantees which are at least equivalent.

Certification of semen imported from a third country of collection.

10. (1) The Competent Authority shall authorise the importation of semen only on submission of an animal health certificate drawn up and signed by an official veterinarian of the third country of collection.

(2) This certificate shall:

VERŻJONI ELETTRONIKA

(a) be drawn up in at least one of the official languages of the Member State of destination and one of those of the Member State where the import control provided for in rule 11 of these rules is carried out;

(b) accompany the semen in the original;

(c) be drawn up on a single sheet of paper; and

(d) be made out to a single consignee.

(3) The certificate shall correspond to a specimen drawn up in accordance with the procedure provided in the definition "Standing Committee on the Food Chain and Animal Health" provided under sub-rule (2) of rule 2 of these rules.

Control made on arrival of semen entering the customs territory of the Community.

11. (1) The Competent Authority shall ensure that each consignment of semen entering the customs territory of the Community is made subject to control before being released for free circulation or placed under a customs procedure and shall prohibit the introduction of the semen into the Community if the import control made on arrival reveals that:

(a) the semen does not come from the territory of a third country on the list drawn up in accordance with rule 7 (1) of these rules;

(b) the semen does not come from a semen collection centre on the list provided for in rule 8 (1) of these rules;

(c) the semen comes from the territory of a third country from which imports are prohibited in accordance with rule 15 of these rules; and

(d) the animal health certificate which accompanies the semen is not in conformity with the conditions laid down in rule 10 of these rules and fixed pursuant thereto.

(2) Sub-rule (1) hereof shall not apply to consignments of semen which arrive in the Community and are placed under a customs transit procedure for consignment to a destination situated outside the Community:

Provided that it shall be applicable where customs transit procedure is waived during transport through the Community.

VERŻJONI ELETTRONIKA

(3) The Competent Authority may take the necessary measures, including storage in quarantine provided that this does not affect the viability of the semen, in order to obtain definite proof in cases where semen is suspected of being infected or contaminated by pathogenic organisms.

(4) If the admission of semen has been prohibited on any of the grounds set out in sub-rules (1) and (2) hereof and the exporting third country does not authorize the return of the semen within 30 days in the case of deep-frozen semen, or immediately in the case of fresh semen, the Competent Authority may order it to be destroyed.

Authorised consignment of semen entering the Community.

12. Each consignment of semen authorised for introduction into the Community by the Member State of destination on the basis of the import control referred to in rule 11 (1) of these rules shall, when sent to another Member State, be accompanied by the original certificate or an authenticated copy thereof, suitably endorsed, in either case, by the Competent Authority responsible for controls carried out in accordance with rule 11 of these rules.

Costs relating to destruction measures.

13. If pursuant to rule 11 (4) of these rules, it is decided that destruction measures should be taken by the Competent Authority, any costs incurred shall be chargeable to the consignor or its agent or representitive, without any compensation thereto by the Competent Authority.

Veterinary checks and precautionary measures carried out by the Competent Authority for intra-Community trade.

14. The rules set out under the Veterinary and Zootechnical Checks applicable in Trade with Member States in certain Live Animals and Products Regulations, 2003 shall apply to intra-Community trade, in particular with regard to checks at origin, the organisation and the monitoring of the checks to be carried out by the Member State of destination. The precautionary measures set out in regulation 11 thereof shall apply to intra-Community trade.

Precautionary measures and veterinary checks carried out by the Competent Authority for importation from third countries.

L.N. 356 of 2003.

15. The provisions laid down in the Principles Governing the Organisation of Veterinary Checks on Products Entering the Territory of Malta from Third Countries Regulations, 2003 shall apply, in particular to the organisation of, and follow-up to the checks to be carried out by the Competent Authority, when Malta is the Member State of destination, and the safeguard measures to be applied in accordance with the procedure referred to in regulation 19 thereof, regarding a disease or any other phenomenon or circumstance liable to present a serious threat to animal or public health which manifests itself or spreads.

Veterinary experts.

16. (1) Veterinary experts from the Commission may, in cooperation with the Competent Authority and competent authorities of third countries, make on-the-spot checks in so far as that is indispensable for ensuring uniform application of these rules.

(2) The country of collection within whose territory a check is being carried out shall give all necessary assistance to the experts in carrying out their duties and shall be informed with the results of the checks.

(3) The country of collection concerned shall take any measures which may prove necessary to take account of the results of such check. Failure by the country of collection to take such measures, may lead the Competent Authority, after the situation has been examined by the Committee, to have recourse to the provisions of rule 5 and to sub-rule (2) of rule 6 of these rules.

(4) The general provisions for implementing this rule, especially as regards the frequency and method of carrying out the checks referred to in sub-rule (1) hereof shall be laid down in accordance with the procedure set out in the definition "Standing Committee on the Food Chain and Animal Health" provided under sub-rule (2) of rule 2 of these rules.

Offences and penalties.

17. (1) Any person who fails to abide by these rules shall be guilty of an offence in terms of the Act and the provisions and measures of sub-rules (2) and (3) of rule 3 of these rules shall apply to it.

(2) Any right given to the Competent Authority under these rules to apply all such necessary measures prescribed in sub-rules (2) and (3) of rule 3 of these rules, shall be given to the Authority without prejudice to other criminal procedures which may be taken under the Act or any other law when a person commits an offence by failing to abide by these rules.

VERŻJONI ELETTRONIKA

Schedule I

CHAPTER I

Conditions for the approval of semen collection centres

Semen collection centres shall:

(a) be placed under the permanent supervision of a centre veterinarian;

(b) have a least:

(i) animal housing including isolation facilities;

(ii) semen collection facilities including a separate room for the cleaning and disinfection or sterilization of equipment;

(iii) a semen processing room which need not necessarily be on the same site;

(iv) a semen storage room which need not necessarily be on the same site;

(c) be so constructed or isolated that contact with livestock outside is prevented;

(d) be so constructed that the animal housing and the semen collecting, processing and storage facilities can be readily cleaned and disinfected;

(e) have isolation accommodation which shall have no direct communication with the normal animal accomodation;

(f) be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.

CHAPTER II

Conditions relating to the supervision of semen collection centres

The collection centres shall:

(a) be so supervised that they contain only male animals of the species whose semen is to be collected;

(b) be so supervised that a record, file or computer record is kept of all porcine animals at the centre, giving details of the breed, date of birth and identification of each of the animals, and also a record, file or computer record of all checks for diseases and all vaccinations carried out, giving also information from the disease/health file of each animal;

(c) be regularly inspected by an official veterinarian, at least twice a year, at which time checks on the conditions of approval and supervision shall be carried out;

(d) be so supervised that the entry of unauthorized persons is prevented. Furthermore, authorized visitors must be required to comply with the conditions laid down by the centre veterinarian;

(e) employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;

(f) be so supervised that:

(i) only semen collected at an approved centre is processed and stored in approved centres, without coming into contact with any other consignment of semen;

(ii) collection, processing and storage of semen takes place only on the premises set aside for the purpose and under conditions of the strictest hygiene;

(iii) all implements which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilized prior to use;

(iv) products of animal origin used in the processing of semen (including additives or diluents) are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;

(v) storage flasks and transport flasks are properly disinfected or sterilised before the beginning of each filling operation;

(vi) the cryogenic agent used has not been previously used for other products of animal origin;

VERŻJONI ELETTRONIKA

(vii) each collection of semen, whether or not it is separated into individual doses, is clearly marked in such a way that the date of collection of the semen and the breed and identification of the donor animal, as well as the name and the registration number of the centre, preceded by the name of the country of origin, where appropriate, in the form of a code, can be readily established;

(viii) the characteristics and form of this marking will be established under the procedure set out in the definition "Standing Committee on the Food Chain and Animal Health" provided under sub-rule (2) of rule 2 of these rules.

Schedule II

CHAPTER I

Conditions applying to the admission of animals to approved semen collection centres

1. All boars admitted to a semen collection centre must:

(a) have been subjected to a period of isolation of at least 30 days in accommodation specifically approved for the purpose by the Competent Authority and where only boars having at least the same health status are present;

(b) prior to their entering the isolation accommodation described in paragraph (a) have been chosen from herds or holdings:

(i) which are officially free of classical swine fever;

(ii) which are free of brucellosis;

(iii) in which no animal vaccinated against foot-and-mouth disease has been present in the preceding 12 months;

(iv) in which no clinical, serological or virological sign of Aujeszky's disease has been detected in the preceding 12 months;

(v) which are not covered by any prohibition in accordance with the requirements of the Animal Health Problems affecting Intra-Community Trade in Bovine Animals and Swine Regulations, 2004 with regard to African swine fever, swine vesicular disease, Teschen's disease and foot-and-mouth disease. The animals may not previously have been kept in other herds of a lower status;

(c) during the period of isolation specified in paragraph (a), and within the previous 30 days, have been subjected to the following tests with negative results:

VERŻJONI ELETTRONIKA

(i) a complement fixation test carried out in accordance with the provisions of Schedule C to the Animal Health Problems affecting Intra-Community Trade in Bovine Animals and Swine Regulations, 2004 in respect of brucellosis;

(ii) a serum neutralization or an ELISA test using all the viral antigens in the case of non-vaccinated pigs;

(iii) an ELISA test for GI antigens in the case of pigs vaccinated with a GI deleted vaccine;

(iv) pending the introduction of a Community policy to combat foot-and-mouth disease, an ELISA test for the presence of foot-and-mouth disease;

(v) an ELISA test or a serum neutralization test for the presence of classical swine fever. The Competent Authority may give authorization for the tests referred to in paragraph (c) to be carried out in the isolation accommodation, provided that the results are known before the beginning of the 30-day isolation period laid down in paragraph (d);

(d) during the period of isolation of at least 30 days specified in paragraph (a), have been subjected to the following tests with negative results:

(i) a serum agglutination test complying with the procedure laid down in Schedule C to the Animal Health Problems affecting Intra-Community Trade in Bovine Animals and Swine Regulations, 2004 and showing a brucella count lower than 30 IU of agglutination per millilitre and a complement fixation test showing a brucella count lower than 20 EEC units per millilitre (20 ICFT units) in the case of animals coming from brucellosis-free herds;

(ii) a serum neutralization or an ELISA test using all the viral antigens in the case of non-vaccinated pigs;

(iii) an ELISA test for GI antigens in the case of pigs vaccinated with a GI deleted vaccine;

(iv) until the introduction of a Community policy on combating foot-and-mouth disease, an ELISA test for the presence of foot-and-mouth disease;

(v) a microscopic agglutination test for the presence of leptospirosis (sero-vars pomona, grippotyphosa, tarassovi, hardjo, bratislava and ballum serum viruses), or have been treated for leptospirosis with two injections of streptomycin at an interval of 14 days (25 mg per kg of live body weight).

Without prejudice to the provisions applicable in cases where foot-and-mouth disease and swine fever is found, if any of the above tests should prove positive, the animal must be removed forthwith from the isolation accommodation. In the case of group isolation, the Competent Authority must take all necessary measures to allow the remaining animals to be admitted to the collection centre in accordance with this Schedule.

2. All tests must be carried out in a laboratory approved by the Competent Authority.

3. Animals may only be admitted to the semen collection centre with the express permission of the centre veterinarian. All animal movements, both in and out, must be recorded.

4. No animal admitted to the semen collection centre may show any clinical sign of disease on the day of admission. All animals must, without prejudice to paragraph 5, have come from isolation accommodation as referred to in paragraph 1 (a) which, on the day of consignment, officially fulfils the following conditions:

(a) is situated in the centre of an area of 10 kilometres radius in which there has been no case of foot-and-mouth disease or swine fever for at least 30 days;

VERŻJONI ELETTRONIKA

(b) has for at least three months been free from foot-and-mouth disease and brucellosis;

(c) has for at least 30 days been free from Aujeszky's disease and from those porcine diseases which are compulsorily notifiable in accordance with Schedule E to the Animal Health Problems affecting Intra-Community Trade in Bovine Animals and Swine Regulations, 2004.

5. Provided that the conditions laid down in paragraph 4 are satisfied and the routine tests referred to in Chapter II of this Schedule have been carried out during the previous 12 months, animals may be transferred from one approved semen collection centre to another of equal health status without isolation or testing if transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used must have been disinfected before use. If the movement from one semen collection centre to another takes place between Member States, it must take place in accordance with the Animal Health Problems affecting Intra-Community Trade in Bovine Animals and Swine Regulations, 2004.

CHAPTER II

Compulsory routine tests for boars kept at an approved semen collection centre

1. All boars kept at an approved semen collection centre must be subjected when leaving the centre to the following tests with negative results:

(i) a serum neutralization or an ELISA test using all the viral antigens in the case of non-vaccinated pigs;

(ii) an ELISA test for GI antigens in the case of pigs vaccinated with a GI deleted vaccine;

B 5884

(iii) until the introduction of a Community policy on combating foot-and-mouth disease, an ELISA test for the presence of foot-and-mouth disease;

(iv) a complement fixation test conducted in accordance with Schedule C to the Animal Health Problems affecting Intra-Community Trade in Bovine Animals and Swine Regulations, 2004 regarding brucellosis;

(v) an ELISA test or serum neutralization test for the presence of classical swine fever.

In addition, boars kept more than 12 months at the collection centre must be subjected to the tests referred to in points (i) and (iii) not later than 18 months after their admission.

2. All tests must be carried out in a laboratory approved by the Competent Authority.

3. Without prejudice to the provisions applicable in cases where foot-and-mouth disease or swine fever is found, if any of the above tests should prove positive, the animal must be isolated and the semen collected from it since the last negative test may not be the subject of intra-Community trade. Semen collected from all other animals at the centre since the date when the positive test was carried out shall be held in separate storage and may not be the subject of intra-Community trade until the health status of the centre has been re-established.

VERŻJONI ELETTRONIKA

Schedule III

Conditions which semen collected at approved centres must satisfy for the purposes of intra-Community trade

1. Semen must be obtained from animals which:

(a) show no clinical signs of disease on the day the semen is collected;

(b) have not been vaccinated against foot-and-mouth disease;

(c) satisfy the requirements of Chapter I of Schedule II to these rules;

(d) are not allowed to serve naturally;

(e) are kept in semen collection centres which have been free from foot-and-mouth disease for at least three months prior to dispatching of the semen, and are situated in the centre of an area of 10 kilometres radius in which for at least 30 days there has been no case of foot-and-mouth disease;

(f) are kept in collection centres which must not be situated in a restricted area designated under the provisions of national legislations or any other applicable Community law relating to contagious diseases of the porcine species;

(g) have been kept in semen collection centres which, during the 30-day period immediately prior to collection, have been free from those porcine diseases which are compulsorily notifiable in accordance with Schedule E to the Animal Health Problems affecting Intra-Community Trade in Bovine Animals and Swine Regulations, 2004 and from Aujeszky's disease.

2. An effective combination of antibiotics, in particular against leptospires and mycoplasmas, must be added to the semen after final dilution. This combination must produce an effect at least equivalent to the following dilutions:

not less than:

500 IU per ml streptomycin;

500 IU per ml penicillin;

150 mg per ml lincomycin;

B 5886

300 mg per ml spectinomycin.

Immediately after the addition of the antibiotics the diluted semen must be kept at a temperature of at least 15°C for a period of not less than 45 minutes.

3. Semen for intra-Community trade must:

(i) be stored as laid down in Chapters I and II of Schedule I prior to dispatch;

(ii) be transported to the Member State of destination in flasks which have been cleaned and disinfected or sterilized before use and which have been sealed prior to dispatch from the approved storage facilities.

VERŻJONI ELETTRONIKA

Schedule IV

ANIMAL HEALTH CERTIFICATE

No. ORIGINAL

1. Consignor (name and full address)
2. Member State of collection
3. Consignee (name and full address)
4. Competent authority of country of collection
5. Competent Authority of Malta
6. Place of loading
7. Name and address of semen collection centre
8. Means of transport
9. Place and Member State of destination
10. Registration number of semen collection centre
11. Number and code-mark of semen containers
12. Identification of semen:-
    (a) Number of doses
    (b) Date(s) of collection
    (c) Breed
    (d) Identification of donor animal

13. I, the undersigned official veterinarian, certify that:

    (a) the semen described above was collected, processed and stored under conditions which comply with the standards laid down in the Animal Health Conditions (Intra-Community Trade and Imports from Third Countries of Deep-Frozen Semen of Domestic Animals of the Porcine Species) Rules, 2011;

    (b) the semen described above was collected from boars:

B 5888

(i) on a collection centre which only contains animals that have not been vaccinated against Aujeszky's disease and which have reacted negatively to the serum neutralization test or to the ELISA test for Aujeszky's disease, in accordance with the provisions of these rules; or

(ii) on a centre in which some or all the boars have been vaccinated against Aujeszky's disease using a GI deleted vaccine; such boars having been sero-negative with regard to Aujeszky's disease before vaccination and subjected three weeks later to a further serological examination which did not reveal the presence of antibodies induced by the disease virus; and, in that case, the semen of each batch has been subjected to a virus isolation test for Aujeszky's disease in the laboratory ....., and gave a negative reaction;[1]

(c) the semen described above was sent to the place of loading in sealed containers under conditions which comply with the provisions of the Animal Health Conditions (Intra-Community Trade and Imports from Third Countries of Deep-Frozen Semen of Domestic Animals of the Porcine Species) Rules, 2011.

Done at .....

Signature

Name and qualification (in block letters).

[1]Delete whichever of points (i) or (ii) does not apply.

VERŻJONI ELETTRONIKA

B 5889

Stamp

Notes

(a) A separate certificate must be issued for each consignment of semen

(b) The original of this certificate must accompany the consignment to the place of destination

B 5890

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — ***Published by the Department of Information (doi.gov.mt) — Valletta***
Mitbugħ fl-Istamperija tal-Gvern fuq karta riċiklata — ***Printed at the Government Printing Press on recycled paper***

Prezz/*Price*
€2.52