**L.N. 351 of 2009**

# MALTA VETERINARY SERVICES ACT (CAP. 437 )

## 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

IN EXERCISE of the powers conferred by article 10 of the Veterinary Services Act, the Minister for Resources and Rural Affairs after consultation with the Minister for Finance, the Economy and Investment and after having consulted the Veterinary Services Authority, has made the following rules:-

Title, scope and commencement.

**1.** (1) The title of these rules is 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.

(2) The scope of these rules is to transpose Directive 92/65/EEC laying down 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 and shall apply without prejudice to the provisions adopted pursuant to other regulations and community rules which may apply in this regard and without prejudice to other national rules governing pet animals.

(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 7th December, 2009.

Interpretation.

**2.** (1) Unless otherwise provided in these rules, the definitions prescribed in the Act shall continue to apply and the definitions, other than those of approved centres and bodies, contained in in any other law or regulation governing trade shall mutatis mutandis apply, unless they are inconsistent with these rules.

(2) For the purpose of these rules and unless the context otherwise requires:

"the Act" means the Veterinary Services Act;

"animals" means specimens of animal species and shall not include such animals as referred to in other community legislation concerning animal health conditions governing intra-Community trade, and the movement and imports from third countries of animals and products of animal origin, animal health conditions governing the placing on the market of aquaculture and non-aquaculture animals and products as well as those referred to in legislation concerning animal health conditions for the production and the placing on the market of fishery products and live products;

"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" means and includes any person who is a trader or importer in terms of these rules and who is in possession of an authorisation issued in his favour by the Department of Trade to import and trade in animals and products of animal origin subject to trade from a Member State or third country to Malta;

"approved body, institute or centre" means any permanent, geographically limited establishment, approved in accordance with rule 13 of these rules, where one or more species of animal are habitually kept or bred, whether or not for commercial ends, and exclusively for one or more of the following purposes:

(a) display of the animals and education of the public;

(b) conservation of the species; and, or

(c) basic or applied scientific research or breeding of animals for the purposes of such research;

"the Community" means the Community of the European Union;

"competent Authority" means the Veterinary Services Authority as established by the Act;

"final consumer" means means any natural or legal person purchasing animals and animal products subject to trade for her own use and not for resale or transfer purposes;

"health certificate or commercial document" means a certificate properly issued by the competent Authority as an appropriate means of guaranteeing and monitoring compliance as regards animals and products of animal origin subject to trade with animal health requirements and any other requirements contained in these rules;

"importer" means a person who in terms of an authorisation issued in his favour by the Department of Trade is authorised to import in Malta animals and products of animal origin transported from any third country or other Member State in terms of these rules;

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

"monitoring program" means a control or monitoring programme drawn up by the competent Authority for the purpose of keeping of records of animals and products of animal of origin subject to trade with regard to the outbreak of notifiable diseases and of diseases referred to in Schedule B to these rules;

"notifiable diseases" means the diseases listed in Schedule A to these rules;

"official veterinarian" means a veterinarian of the approved body, institute or centre of origin appointed and approved by the competent Authority who, for the purpose of these rules shall be responsible to guarantee the animals' health;

"overriding reasons relating to public interest" means reasons recognised as such in case law of the European Courts of Justice and which reasons present a justification for the issue of an authorisation and, or the issue of a condition thereto and, or to any other policy decision taken in terms of such authorisation, when such authorisation, and, or condition and, or policy decision thereto could not have been issued or taken under normal circumstances but for such overriding reasons relating to public interest which include the following grounds:

(a) public policy, public security, public safety and public health, provided that, these grounds shall be interpreted within the meaning of Article 46 and Article 55 of the Treaty:

(b) the maintenance of order in society;

(c) social policy objectives;

(d) the protection of the recipients of services;

(e) consumer protection;

(f) the prevention of fraud;

(g) the protection of the environment;

"placing on the market" shall have the same meaning provided for in the Act;

"recipient" means any natural person who is a national of a Member State, who benefits from rights conferred upon him by community acts or any legal person established in a Member State, who for professional or non-professional purposes, uses, or wishes to use a service against non-economic considerations;

"service activity" means any self-employed activity performed for economic considerations;

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

"trade" means for the purpose of these rules, trade between Member States in animals and products, a business or occupation to make profit or gain, particularly in retail or wholesale sales and includes dealings in a particular business activity;

"the Treaty" means the treaty as established by the European Community;

"undertaking" shall have the same meaning as provided for under the Competition Act; and Cap. 379.

"veterinary checks" means any physical check and, or

administrative formality, verification, control, monitoring, organisation of checks and any follow-up thereto with regard to animals and products of animal origin made by official veterinarians, and which shall apply in particular, to checks at the point of origin and checks carried out on arrival by the Member State of destination to guarantee animals' health and to safeguard measures to be implemented in this regard, in order to ensure conformity with animal health requirements governing trade and which are intended for the protection, direct or otherwise, of public and, or animal health.

Applicability.

**3.** (1) The competent Authority shall ensure that the trade referred to in rule 1(2) hereof, is not prohibited or restricted for animal health reasons other than those arising from the application of these rules or from national legislation, and in particular any safeguard measures taken in this regard.

(2) The competent Authority shall ensure that the veterinary checks carried out on products of animal origin, which are intended for trade, are no longer carried out at frontiers but are carried out in accordance with Directive 89/662/EEC concerning veterinary checks in intra-Community trade with a view to the completion of the internal market, which shall apply in particular to checks at the place of origin, to the organisation of and follow-up to the checks to be carried out by the Member State of destination, and to the protective measures to be implemented in this regard.

(3) The provisions applicable to trade, shall in particular be applied by the competent Authority to:

(a) ensure that the placing on the market of such animals and their products constitute a considerable source of income for part of the farming population;

(b) ensure the rational development in this sector and increase productivity, as well as to ensure that animal health rules for the animals and their products are laid down at national law level;

(c) ensure that animal health rules are adopted for the placing on the market of animals and products of animal origin which are not covered by other community rules which are already into force;

(d) ensure that with regard to the organisation of checks and the follow-up thereto, as well as the safeguard measures to be implemented, reference is made to the general rules concerning veterinary checks applicable to national trade in

certain live animals and products with a view to the completion of the internal market;

(e) ensure, unless otherwise provided in these rules, that trade in animals and products of animal origin are liberalised, without prejudice to recourse to any possible safeguard measures;

(f) ensure, taking into account the significant risk of the spread of diseases to which animals are exposed, that for certain animals and products of animal origin, specific requirements are imposed when such animals and products of animal origin are placed on the market for the purposes of trade, particularly when intended for regions with a high health status;

(g) ensure that a health certificate is properly issued which is the most appropriate means of guaranteeing and monitoring compliance with the requirements of these rules; and

(h) ensure that provision is made for a procedure establishing close co-operation and mutual assistance with other authorities established in other Member States.

(4) The competent Authority shall establish and apply all such necessary administrative measures 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. The measures established in these rules shall conform with and be in accordance with the requirements of the food chain and animal health.

(5) These measures shall 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 application of an administrative penalty in terms of article 61 of the Act.

Measures to be adopted by the Authority.

**4.** The competent Authority shall take all necessary measures to ensure that, the animals referred to in rules 5 to 10 of these rules may without prejudice to rule 13 hereof and to the particular provision of rule 15 of these rules, be subject to trade only if they satisfy the conditions laid down in rules 5 to 10 hereof and that such animals come from the holdings or businesses referred to in rule 12 (1) and (3) of these rules, and which are duly registered with the Department of Trade and which undertakings shall:

(a) have the animals held examined regularly in accordance with animal health rules;

(b) notify the competent Authority, apart from the outbreak of notifiable diseases, of the outbreak of the diseases referred to in Schedule B to these rules for which the Authority has drawn up a control or monitoring programme in this regard;

(c) comply with the specific national measures to control a disease, and which measures are of particular importance to the competent Authority and are covered by a programme drawn up by the competent Authority;

(d) place on the market for the purposes of trade only animals which show no signs of disease and which come from holdings or areas not subject to any ban on animal health grounds, and with respect to animals not accompanied by a health certificate or a commercial document provided for in rules 5 to 11 hereof, only animals accompanied by self-certification by the trader, operator or authorised provider stating that the animals in question do not at the time of dispatch show any obvious signs of disease and that his holding is not subject to any animal health restrictions; and

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(e) comply with the requirements ensuring the welfare of the animals held in terms of the Animals Welfare Act.

Trade restricted to certain animals.

**5.** The competent Authority shall ensure that trade in apes (*simiae* and *prosimiae*) is restricted solely to animals consigned from and to an approved body, institute or centre approved by the competent Authority in terms of rule 10 hereof, and that such animals are accompanied by a veterinary certificate corresponding to the specimen in Schedule E to these rules, the declaration in which shall be completed by the official veterinarian of the approved body, institute or centre of origin to guarantee the animals' health.

Ungulates of species subject to trade.

**6.** (1) The competent Authority shall ensure that ungulates of species are subject to trade only if generally:

(a) they are identified in accordance with rules established by Community law;

(b) they are not intended for slaughter under a programme for the eradication of an infectious disease;

(c) they have not been vaccinated against foot-and-

mouth disease and satisfy the relevant health requirements of other laws and regulations established by the Community;

(d) they come from a holding which is not the subject of animal health measures, particularly those taken under such regulations introducing Community measures for the control of classical swine fever and have been kept therein permanently since birth or for the last thirty days before dispatch;

(e) if imported, they come from a third country included in a column entitled 'other ungulates' to be inserted in the list provided in terms of such regulations on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries; and meet specific animal health conditions, which are at least equivalent to the requirements of this rule; and

(f) they are accompanied by a certificate corresponding to the specimen given in terms of the declaration laid down in Schedule E to these rules.

(2) The competent Authority shall ensure that ruminants of species are subject to trade only if:

(a) they come from an officially tuberculosis-free and officially brucellosis-free herd in accordance with community rules and satisfy, as regards animal health rules, the relevant requirements laid down for the bovine species; and

(b) when they do not come from a herd meeting the conditions laid down in paragraph (a), they come from a holding in which no case of brucellosis or tubercolosis has been recorded in the 42 days preceding loading of the animals and in which the ruminants have, in the 30 days prior to their dispatch, undergone with negative results:

(i) a tuberculosis reaction test; and

(ii) a test designed to show the absence of antibodies to brucellosis.

(3) The competent Authority shall ensure that suidae of species are subject to trade only if:

(a) they have not come from an area which is the subject of prohibition measures associated with the presence of African swine fever;

(b) they come from a holding which is not subject to any restrictions as a result of classical swine fever;

(c) they come from a brucellosis-free holding and satisfy the relevant animal health requirements in terms of these rules; and

(d) when they do not come from a herd meeting the conditions set out in paragraph (c), they have, in the 30 days prior to their dispatch, undergone with negative results a test designed to show the absence of antibodies to brucellosis.

(4) The testing requirements referred to in this rule and their criteria shall be established in accordance with the procedure concerning veterinary checks in terms of rule 3(2) of these rules. Without prejudice to the aforementioned sub-rules, other provisions shall continue to apply, particularly as regards tuberculosis.

Birds subject to trade.

**7.** (1) The competent Authority shall ensure that birds are subject to trade only if generally:

(a) they come from a holding in which avian influenza has not been diagnosed in the 30 days preceeding the dispatch;

(b) they come from a holding or an area not subject to restrictions under measures to be applied to combat Newcastle disease; and

(c) they have been quarantined, if they have been imported from a third country, in the holding to which they were taken after they entered the territory of the Community.

(2) Further to the provisions of sub-rule (1) hereof, psittacidae shall:

(a) not come from a holding nor have been in contact with animals from a holding on which psittacosis (*Chlamydia psittaci*) has been diagnosed. The period of prohibition since the last recorded case and the period of treatment under veterinary supervision in terms of these rules shall be of at least two months;

(b) be identified in accordance with the methods for identifying psittacidae, and in particular sick psittacidae, which shall be established under the procedure concerning veterinary checks in terms of these rules; and

(c) be accompanied by a commercial document signed by the official veterinarian or by the veterinarian responsible for the holding or business of origin and empowered for this purpose by the competent authority.

Bees subject to trade.

**8.** The competent Authority shall ensure that bees (*Apis melifera*) may be subject to trade only if:

(a) they come from an area which is not the subject of a prohibition order associated with an occurrence of American foulbrood. The period of prohibition must continue for at least 30 days following the last recorded case and the date on which all hives within a radius of three kilometres have been checked by the competent authority and all infected hives burned or treated and inspected to the satisfaction of the said competent authority. In accordance with the procedure for veterinary checks in terms of these rules, the requirements applied to bees (*Apis melifera*) or equivalent requirements may be applied to bumble bees; and

(b) they are accompanied by a health certificate corresponding to the specimen in Schedule E to these rules, the declaration in which shall be completed by the competent authority to certify that the requirements laid down in paragraph (a) are met.

Lagomorphs subject to trade.

**9.** The competent Authority shall ensure that lagomorphs are subject to trade only if:

(a) they do not come from or have been in contact with animals from a holding in which rabies is present or is suspected of having been present within the last month; and

(b) they come from a holding in which no animal shows clinical signs of myxomatosis.

Prohibition on trade.

**10.** (1) The competent Authority shall ensure that there is a prohibition on trade in ferrets, mink and foxes which come from or have been in contact with animals from a holding in which rabies is present or is suspected of having been present within the previous six months, unless a systematic vaccination programme is applied.

(2) To be subject to trade, dogs and cats shall satisfy the following requirements:

(a) animals more than three months old shall:

(i) show no sign of disease, and particularly of contagious diseases of the species, on the day they are dispatched from the holding;

(ii) be tattooed or have a micro-chip identification system implanted in terms of specified rules which shall be established by means of the procedure regarding veterinary checks;

(iii) have after the age of three months, been vaccinated against rabies with an annual booster injection or, at intervals authorised by the competent Authority for that vaccine, by injection of an inactivated vaccine of at least one international antigenic unit (World Health Organisation standard) measured in accordance with the activity test by the method described by the European Pharmacopoeia and recognised by means of the procedure regarding veterinary checks in terms of these rules. The vaccination shall be certified by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent Authority. The vaccination certificate must bear the name of the vaccine and its batch number (self-adhesive label if possible);

(iv) in the case of dogs, have been vaccinated against canine distemper; and

(v) be accompanied by an individual passport allowing the animal to be clearly identified and showing the dates of vaccination and, or a certificate corresponding to the declaration laid down in the specimen shown in Schedule E to these rules, and which declaration shall be completed by an official veterinarian or by the veterinarian responsible for the holding of origin and empowered for this purpose by the competent authority; and

(b) animals less than three months old shall:

(i) satisfy the requirements of the first and fifth items of paragraph (a);

(ii) not come from a holding which is the subject of restrictions on the movement of animals on animal health grounds; and

(iii) have been born on the holding of origin and have been maintained in captivity since birth.

(3) The competent Authority shall ensure that the costs of applying the serological test are borne by the importers.

Semen, ova and embryos subject to trade.

**11.** (1) The competent Authority shall ensure that only semen, ova and embryos meeting the conditions laid down in sub-rules (2) and (3) hereof are subject to trade.

(2) Semen of the ovine, caprine and equine species shall, without prejudice to any criteria to be complied with for the entry of equids in stud books for certain specific breeds:

(a) have been collected and processed with a view to artificial insemination in a centre approved from the health point of view in accordance with Schedule D (I) to these rules, or, in the case of ovine and caprine animals by way of derogation from the above mentioned holding centre;

(b) have been collected from animals meeting the conditions laid down in Schedule D (II) - (admission and routine checks on animals);

(c) have been collected, processed and preserved in accordance with Schedule D (III); and

(d) have been accompanied during transport to another Member State by a health certificate corresponding to a specimen which shall be determined according to the procederure concerning veterinary checks established in rule 3(2) of these rules.

(3) Ova and embryos of the ovine or caprine and equine species and of swine shall:

(a) have been removed by a collection team approved by the competent authority in Malta and processed in an appropriate laboratory from donor females meeting the conditions laid down in Schedule D (IV) to these rules;

(b) have been treated and stored in accordance with Schedule D (III) to these rules; and

(c) be accompanied during transport to another Member State by a health certificate in accordance with the procedure concerning veterinary checks established in rule 3(2) of these

rules. Semen used for the insemination of donor females must comply with the provisions of sub-rule (2) hereof in the case of sheep, goats and equids and with the provisions for swine.

Veterinary checks.

**12.** (1) The rules on checks shall continue to apply, in particular as regards the organisation of and follow-up to the checks to be carried out, to the animals, semen, ova and embryos being referred to in these rules, which are accompanied by a health certificate. Other animals shall come from holdings subject to the principles regarding checks at the point of origin and at those carried out by the Member State of destination.

(2) The communication of the place of destination shall, with respect to animals, semen, ova or embryos accompanied by a health certificate in accordance with these rules, take place using the Animo system.

(3) For the purposes of trade, the general rules applicable to veterinary checks shall extend to dealers who keep, on a permanent or temporary basis, animals referred to in rules 7, 9 and 10 hereof.

(4) Without prejudice to the specific provisions of these rules, the competent Authority shall, where it is suspected that these rules have not been complied with or there is doubt as to the health of the animals or the quality of the semen, ova and embryos referred to in sub-rule (1) hereof, carry out any checks as it deems appropriate.

(5) The competent Authority shall take the appropriate administrative or penal measures to penalise any infringement of these rules, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the animals referred to in sub-rule (1) hereof, that the identification of the animals or the marking of the semen, ova and embryos in question does not comply with these rules or that the animals or products in question have not undergone the necessary checks provided for in these rules.

Trade in animals of species susceptible to the diseases.

**13.** (1) Trade in animals of species susceptible to the diseases listed in Schedule A or to the diseases listed in Schedule B, where the Member State of destination applies the guarantee provided by the control or monitoring program drawn up by the competent Authority, and trade in semen, ova or embryos of such animals consigned to and from bodies, institutes or centres approved in accordance with Schedule C to these rules, shall be subject to

production of a transport document corresponding to the specimen in Schedule E to these rules. Such document, which shall be completed by the veterinarian responsible for the body, institute or centre of origin, must specify that the animals, semen, ova or embryos come from a body, institute or centre approved in accordance with Schedule C and must accompany them during transport.

(2) To be approved, bodies, institutes or centres shall, as regards notifiable diseases, submit to the competent Authority all relevant supporting documents relating to the requirements contained in Schedule C to these rules.

(3) After receiving the file relating to the request for approval or for renewal of approval, the competent Authority shall examine it in the light of the information it contains and, where appropriate, of the results of the tests conducted on the spot.

(4) The competent Authority shall withdraw approval in accordance with point 3 of Schedule C to these rules.

Conditions applicable to imports into the Community of animals.

**14.** The conditions applicable to imports into the Community of animals, semen, ova and embryos covered by these rules shall be at least equivalent to those laid down in the aforementioned provisions.

Powers of the Authority.

**15.** The competent Authority shall have the power to make the entry into the Maltese territory of animals, including cage birds, semen, ova and embryos referred to in these rules, which have passed through the territory of a third country, subject to the production of a health certificate certifying compliance with the requirements of these rules.

Offences and penalties.

**16.** (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 rule 3 (4) and (5) 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 (4) and (5) of rule 3 hereof, 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.

## Schedule A

Regulations 2(2) and 13(1)

NOTIFIABLE DISEASES IN THE CONTEXT OF THESE RULES [a]

| Diseases | Species concerned |
|---|---|
| Newcastle disease, avian influenza | Birds |
| Psittacosis | Psittacidae |
| American foulbrood | Bees |
| Foot-and-mouth disease | Ruminants |
| Brucellosis (Brucella ssp.) | |
| Tuberculosis | |
| Classical swine fever | Suidae |
| African swine fever | |
| Foot-and-mouth disease | |
| Rabies [b] | All susceptible species |

[a] Without prejudice to the notifiable diseases provided for in Annex I to Directive 82/894/EEC.

[b] In accordance with Article 2 of Directive 89/455/EEC.

**Schedule B**

Regulations 2(2), 4(b) and 13(1)

LIST OF DISEASES FOR WHICH NATIONAL PROGRAMMES MAY BE RECOGNIZED UNDER THESE RULES

| | |
|---|---|
| Mink | Viral enteritis<br>Aleutian disease |
| Bees | European foulbrood<br>varroasis and acariasis |
| Apes and felids | Tuberculosis |
| Ruminants | Tuberculosis |
| Lagomorphs | Myxomatosis<br>Viral haemorrhagic disease<br>Tularaemia |

## Schedule C

Regulation 13 (1) and (4)

CONDITIONS GOVERNING APPROVAL OF BODIES, INSTITUTES OR CENTRES

1. In order to be granted official approval under rule 13 (2) of these rules, a body, institute or centre as defined in rule 2 (2) hereof must:

(a) be clearly demarcated and separated from its surroundings;

(b) be situated at a reasonable distance from agricultural establishments whose health status might be jeopardized by the presence of the approved body, institute or centre;

(c) be under the control of a veterinarian ([1]) who monitors the animals, which it must be possible to catch, confine and cage at any time;

(d) have adequate quarantine facilities;

(e) have one or more appropriate premises to practise post-mortem examination;

(f) be free of the diseases listed in Schedule A and, as regards the diseases covered in the country concerned by a monitoring programme, the diseases listed in Schedule B;

(g) keep up-to-date records indicating:

- the number of animals of each species present in the establishment, with information as to their ages,

- the number of animals arriving in the establishment or leaving it, together with information on their transport and the animals' health,

- observations made during the quarantine period,

- the results of regular examinations of excreta,

- the results of blood tests or any other diagnostic procedures,

([1]) Responsible for day-to-day compliance with the animal health requirements of these rules.

- cases of disease and, where appropriate, the treatment administered,

- the results of the dissection of any animals that die in the establishment, including still-born animals;

(h) have facilities for appropriate disposal of the bodies of animals which die of a disease;

(i) be monitored by an official veterinarian who must carry out at least two health checks per year.

Health checks must include at least:

- one inspection of all the animals in the establishment,

- representative samples taken from all the species susceptible to the diseases referred to in Schedules A and B (2) or detection of these diseases by other methods.

These samples must be analysed by an approved laboratory to check whether they contain agents of the diseases for each species in Schedule A. Samples may be taken throughout the year.

The results of the laboratory tests on the samples taken during the health checks must reveal no evidence of the pathogens in question;

- examination of the records which must be kept.

2. Approval shall be retained where the following requirements are met:

(a) the animals brought into the establishment must come from another approved centre, institute or body;

(b) if animals covered by Directive 64/432/EEC are held in an approved centre, institute or body, they may leave the establishment only under official control;

(c) health checks in the approved centre, institute or body must be carried out twice a year, in accordance with point 1 (h) of this Schedule.

(d) the results of the laboratory tests on the samples must reveal no trace of agents of the diseases referred to in Schedules A and B (2);

(2) Inasmuch as one of these diseases is notifiable in the Malta.

(e) any suspect deaths or the presence of any other symptom suggesting that animals have contracted one or more of the diseases referred to in Schedules A and B (1) must be notified without delay to the competent authority.

3. Approval may be suspended, restored or withdrawn in the following circumstances:

(a) where notification is given within the meaning of 2 (d) of this Schedule, the competent authority shall temporarily suspend approval of the approved centre, body or institute;

(b) a sample taken from a suspect animal is forwarded to the approved laboratory to test for the presence of the pathogens in question. The test results shall immediately be forwarded to the competent authority;

(c) where the official department has been informed of suspicions as to the presence of one of the diseases referred to in Schedules A and B (1), it shall reacts, as regards the laboratory tests, the epizootiological examination, the measures to be taken against the disease and the withdrawal of approval, as if the disease had been notified, in accordance with these rules' governing measures in this field to be taken against the diseases and trade in animals;

(d) where the test results show no signs of the pathogens concerned, the official department shall reinstate approval;

(e) the body, institute or centre shall again be approved only where, after eradication of the sources of infection, the conditions laid down in point 1 of this Schedule, with the exception of point 1 (f), are again fulfilled;

(f) the competent authority shall inform the Commission of the suspension, restoration or withdrawal of approval.

(1) Inasmuch as one of these diseases is notifiable in the Malta.

**Schedule D**

Regulation 11 (2) (a)(b)(c) and (3) (a) (b)

CHAPTER I

I. *Conditions governing the approval of semen collection centres*

Semen collection centres must:

1. be placed under the supervision of a 'centre veterinarian';

2. have different and physically separate premises for:

- accommodating and isolating animals,

- collecting semen,

- cleaning and disinfecting equipment,

- processing semen,

- storing semen;

3. be built or kept separate in such a way as to prevent any contact with animals outside the centre;

4. have premises such as described at 2 which are easily cleaned and disinfected,

II. *Conditions for the supervision of semen collection centres*

Semen collection centres must:

1. be monitored to ensure that only animals whose semen is to be collected are kept there. However, other domestic animals may stay in these centres provided they meet the general conditions set out below.

2. be monitored to ensure that a register is kept showing

- the identity of the animals present in the centre,

- any movements of animas (entering and leaving),

- the health checks made,

- the health history,

- the destination of the semen,

- the storage of the semen;

3. be inspected at least twice a year by an official veterinarian to ensure that the approval and supervision conditions are met;

4. employ competent staff who have received adequate training on disinfection and hygiene techniques to allow the spread of disease to be avoided;

5. be monitored to ensure that

- the collection, processing and storage of semen is carried out only in premises set aside for these purposes,

- all utensils coming into contact with the semen or the donor animal during collection or processing are properly disinfected or sterilized before each use,

- any recipient for the storage or transport of semen is disinfected or sterilized before use;

6. be sure to use:

- products of animal origin used in the processing of the semen (additive or diluent) which present no health risks or which have undergone prior processing to preclude such risks,

- a cryogenic agent which has not previously been used for other products of animal origin;

7. ensure that each quantity of semen is adequately identified in such a way that the date of collection, the breed and the identity of the donor animal may be established as well as the name of the approved centre which made the collection.

## CHAPTER II

## **Conditions applicable in collection centres**

*Requirements as regards the admission of donor males*

A. STALLIONS

Only stallions which, to the satisfaction of the official veterinarian, meet the following requirements may be used for the collection of semen:

1. they must be in good health at the time of collection;

2. they must satisfy the requirements of Directive 90/426/EEC and come from holdings which also satisfy those requirements;

3. during the 60 days before the first collection they must have undergone with negative results the following tests:

(a) to detect equine infectious anaemia, an agar-gel immunodiffusion test, known as the 'Coggins test':

(b) to detect viral artheritis, a sero-neutralization test (dilution < 1/4) supplemented, in the event of a positive result, by virological examination of total semen with a negative result;

(c) to detect contagious equine metritis by isolating the Taylorella equigenitalis germ, at least a test of samples taken from the urethra and the pre-ejaculatory fluid.

The result of these tests must be certified by a laboratory recognized by the competent authority.

During the period mentioned in the first paragraph of 3 above, and during the collection period, stallions may not be allowed do serve naturally.

B. SHEEP AND GOATS

1. Only sheep and goats from centres or holdings which, to the satisfaction of the official veterinarian, meet the following requirements may be used for the collection of semen:

(a) they are in good health on the day the semen is collected;

(b) they meet the requirements laid down in Articles 4, 5 and 6 of Directive 91/68/EEC on intra-Community trade.

In addition, donor animals must undergo, during the thirty days before the collection, with negative results:

- a test to detect brucellosis (B. melitensis) in accordance with Annex C to Directive 91/68/EEC,

- a test for contagious epididymitis (B. ovis) in accordance with Annex D to Directive 91/68/EEC,

- a test for the Border disease virus;

(c) they have undergone the relevant tests or checks designed to guarantee compliance with the requirements set out in (a) and (b) above.

2. The tests referred to in 1. must be carried out by a laboratory approved in Malta.

C. If any of the tests referred to in A or B proves positive, the animal must be isolated and the semen collected from it since the last negative test may not be placed on the market. The same applies to semen collected from the other animals at the holding or collection centre since the date on which the positive test was carried out. Trade may not resume until the health status of the centre has been re-established.

## CHAPTER III

### Requirements applicable to semen, ova and embryos

Semen, ova and embryos must have been collected, processed, washed and preserved with a biological product free of living micro-organisms in accordance with the following principles:

(a) the washing of ova and embryos must be carried out in accordance with rule 11 (3) of these rules. Their pellucid zone must remain intact before and after washing. Only ova and embryos from one and the same donor may be washed at any one time. After washing, the pellucid zone of each ovum or embryo must be examined over its entire surface area under a magnification of at least 50 and be certified as being intact and free of any foreign body adhering to it;

(b) the medium and solutions used for the collection, freezing and conservation of ova and embryos must be sterilized in accordance with approved methods as laid down in rule 11 (3) and handled in such a way that they remain sterile. Antibiotics must be added to the collection, washing and conservation mediums;

(c) all materials used for the collection, handling, washing, freezing and conservation of ova or embryos must be sterilized before use;

(d) they must have been subjected, in accordance with rule 11 (2), to additional tests, in particular of the collection or washing liquids, so as to establish that no pathogens are present;

(e) they must be kept in sterile recipients:

- containing only products from one male or female donor,

- sealed at the time of freezing in alcohol or fresh liquid nitrogen, and labelled,

and be placed in sterilized liquid nitrogen containers which present no risk of contamination to the products;

(f) they must be stored in approved conditions for a minimum period of 30 days prior to dispatch;

(g) they must be transported in flasks which have been cleaned, disinfected or sterilized before use.

## CHAPTER IV

## **Donor females**

Females may be used for the collection of embryos or ova only if they meet, to the satisfaction of the official veterinarian, the requirements of the relevant Directives on intra-Community trade in live animals for breeding and production for the breed concerned, viz. Directive 64/432/EEC for swine, Directive 90/426/EEC for equids and Directive 91/68/EEC for ovine and caprine animals and come from herds which also meet the said requirements.

**Schedule E**

Regulations 6 (1) (f) and 10 (2) (a) (v)

**CERTIFICATE**

**EUROPEAN COMMUNITY**

<table>
<tr><td>1. Name and address of the consignor<br><br>3. Name and address of the consignee</td><td>HEALTH CERTIFICATE<br>No ORIGINAL ([a])<br><br>2. MEMBER STATE OF ORIGIN<br><br>4. COMPETENT AUTHORITY</td></tr>
<tr><td></td><td>5. Address<br>- of holding of origin or of an officially approved body, institute or centre of origin ([b])<br><br>- of holding or business of destination or of an officially approved body, institute or centre of origin ([b])</td></tr>
<tr><td colspan="2">6. Place of loading<br><br>7. Means of transport</td></tr>
</table>

| |
|---|
| 8. Species |
| 9. Number of animals/hives/queens (with attendants)) ([b]) |
| 10. Batch Identification |
| 11. ATTESTATION ([c])<br>Made in …… on the …… Signature:<br>Name in capital letters:<br>Title and position: |

([a]) A separate certificate shall be provided for every delivery and the original shall be sent together with the delivery to the final destination, which validity period is of 10 days.

([b]) Delete as applicable.

([c]) Complete according to Articles 5 to 11 of Directive 92/65/EEC within 24 hours prior to the loading of animals.

Declaration to be filled as per rule 6 (1) (f)

I, the undersigned (official veterinarian) certify that the ruminant/suida[1] other than that covered by Directive 64/432/EEC:

(a) belongs to the . . . . . species;

(b) at the time of examination, does not show any clinical sign of any disease to which it is susceptible;

(c) comes from an officially tuberculosis-free/officially brucellosis-free or brucellosis-free herd/a holding not subject to swine-fever restrictions (a) or from a holding where it was subjected with negative results to the tests laid down in rule 6 (f) of these rules.

[1]Delete as appropriate.

Declaration to be filled as per rule 10 (2) (a) (v)

I, the undersigned . . . . . certify that the cats/dogs[1] covered by this certificate satisfy the requirements of rule 10 (2) (a) (v) of these rules and come from a holding in which no case of rabies has been recorded in the last six months.

[1]Delete as appropriate.

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