

**Certificate for the approval in accordance with Council Directive 92/65/EEC<sup>1</sup> of an equine semen collection centre**

<b>Name and address of semen collection centre</b>	
<b>Owner</b>	
<b>Person in charge</b>	
<b>Name and address of the responsible centre veterinarian</b>	
<b>Name and address of the competent official veterinarian</b>  <b>I, the undersigned, certify that the equine semen collection centre detailed above has been inspected on the basis of the attached check-list and found in compliance with the requirements of Council Directive 92/65/EEC.</b>	
<b>Name and address of the central competent authorities</b>  <b>I, the undersigned, certify that the equine semen collection centre detailed above complies with the animal health requirements laid down in Council Directive 92/65/EEC for imports into the European Union of semen of animals of the equine species.</b>	
<b>Approval Date: [dd.mm.yyyy]</b>	
<b>Approval Number assigned to the centre</b>	

<sup>1</sup> Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC (OJ L 268, 14.9.1992, p. 54)

<b>Questionnaire for the approval of equine semen collection centres</b>			
<b>Number</b>	<b>Reference</b>	<b>Question</b>	<b>Y = Yes N = No</b>
<b>1. General criteria</b>			
<b>1.1.</b>	92/65/EEC Council Directive Article 17 Paragraph 2(a)	Is the third country or parts of the territory of third country listed in columns 2 and 4 of Annex I to Commission Implementing Regulation (EU) 2018/659 <sup>2</sup> and authorised for entry into the EU of semen of animals of the equine species in column(s) 11, 12 /and/or 13 thereof	
<b>1.2.</b>	Commission Implementing Regulation (EU) 2018/659, Annex I	Is the country listed for all categories of equidae <sup>3</sup>	
		Where the country is listed only for certain categories equidae please indicate appropriate letter <sup>3</sup> in right column (for example "(a)") <sup>4</sup>	
		Is the country listed for all types of entry of equidae	
		Where the country is listed only for certain of types of entry of equidae please indicate appropriate letter <sup>4</sup> in right column (for example "(i)")	
<b>1.3.</b>	92/65/EEC Council Directive Article 12 Paragraph 1 (measures equivalent)	Are the checks at origin carried out equivalent to the requirements laid down in Article 3 of Council Directive 90/425/EEC <sup>5</sup>	
<b>1.4.</b>	92/65/EEC Council Directive Article 12 Paragraph 2	Are the rules on disease notification established in Directives 90/425/EEC and 92/65/EEC applied and the diseases listed in Annex I to Council Directive 2009/156/EC <sup>6</sup> are compulsorily notifiable	
<b>1.5.</b>	92/65/EEC Council Directive Article 12 Paragraph 4 (measures equivalent)	Are arrangements in place to pre-notify the arrival of a consignment at an approved border inspection post for the checks required in accordance with Council Directive 97/78/EC <sup>7</sup>	
<b>1.6.</b>	92/65/EEC Council Directive Article 12 Paragraph 5	Does the competent authority have the legal power to carry out checks where it is suspected that the provisions governing semen collection centres have not been complied with or there is a doubt as for the health of the animals or the quality of semen	
<b>1.7.</b>	92/65/EEC Council Directive Article 12 Paragraph 6	Are administrative or penal measures available to penalise any infringement of the provisions governing semen collection centres in particular as for the certificates, state of animals, identification and marking of animals and semen and the control of animals and products concerned	
<b>2. Technical conditions to be applied for semen collection centre</b>			
<b>2.1.</b>	92/65/EEC Council Directive Annex D Chapter I (I), Point 1.1	Is the centre placed under the supervision of a centre veterinarian authorised by the competent authorities	
<b>2.2.</b>	92/65/EEC Council Directive Annex D Chapter I (I)	Has the centre lockable animal accommodation which is physically separated from the collection facilities, processing and storage rooms	

<sup>2</sup> Commission Implementing Regulation (EU) 2018/659 of 12 April 2018 on the conditions for the entry into the Union of live equidae and of semen, ova and embryos of equidae (OJ L 110, 30.4.2018, p. 1).

<sup>3</sup> Categories of equidae are: (a) registered horses, (b) registered equidae (i.e. horses or donkeys), (c) equidae for breeding and production (horses, donkeys, zebras and their crossings).

<sup>4</sup> Types of entry are (see Annex I to Commission Implementing Regulation (EU) 2018/659: (i) temporary admission of registered horses, (ii) re-entry after temporary export of registered horses, (iii) import of registered horses, (iv) import of registered equidae and equidae for breeding and production.

<sup>5</sup> Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market (OJ L 224, 18.8.1990, p. 29).

<sup>6</sup> Council Directive 2009/156/EC of 30 November 2009 on animal health conditions governing the movement and importation from third countries of equidae (OJ L 192, 23.7.2010, p. 1).

<sup>7</sup> Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organization of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

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			<b>N = No</b>
<b>2.3.</b>	Point 1.2 (a)	Is the exercise area of horses physically separated from the collection facilities, processing and storage rooms	
<b>2.4.</b>	92/65/EEC Council Directive Annex D Chapter I (I) Point 1.2 (b)	Has the centre isolation facilities which have no direct communication with the normal animal accommodation	
<b>2.5.</b>	92/65/EEC Council Directive Annex D Chapter I (I) Point 1.2 (c)	Has the centre semen collection facilities, that may be open air protected from adverse weather effects, with slip-proof flooring with protects from dramatic injury in case of fall, at and around the place of semen collection, without the prejudice to the requirements in point 2.10 of this questionnaire	
<b>2.6.</b>	92/65/EEC Council Directive Annex D Chapter I (I) Point 1.2 (d)	Has the centre a separate room for the cleansing and disinfection or sterilisation of equipment	
<b>2.7.</b>	92/65/EEC Council Directive Annex D Chapter I (I) Point 1.2 (e)	Has the centre a semen processing room separated from the collection facilities	
<b>2.8.</b>	92/65/EEC Council Directive Annex D Chapter I (I) Point 1.2 (f)	Has the centre a semen storage room	
<b>2.9.</b>	92/65/EEC Council Directive Annex D Chapter I (I) Point 1.3	Is the centre so constructed or isolated that contact with outside livestock is prevented	
<b>2.10.</b>	92/65/EEC Council Directive Annex D Chapter I (I) Point 1.4	Is the entire centre except the office rooms and the exercise area so constructed that it can be readily cleaned and disinfected	
<b>2.11.</b>		If not, can the outdoor accommodation facilities be quarantined for a sufficient time	
<b>3. Health conditions to be applied for semen collection centre</b>			
<b>3.1.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.1 (a)	Are only horses/equidae of the appropriate category <sup>8</sup> kept on the centre	
<b>3.2.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.1 (a)	What other species are kept on the centre:	
<b>3.2.1.</b>		Equidae	
<b>3.2.2.</b>		Cloven hooved animals	
<b>3.2.3.</b>		Pet animals (dog, cat)	
<b>3.3.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.1 (a)	Is the centre veterinarian satisfied that the health status of other domestic animals present on the centre sufficiently excludes risks pertaining to the animal health status of the equine animals used for semen collection	
<b>3.4.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.1 (a)	Are mares, teaser stallions or stallions for natural service kept on the same site	
<b>3.5.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.1 (a)	If yes, does their health state fulfil the requirements laid down in points 4.2.1 - 4.5 of this questionnaire	
<b>3.6.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.1 (b)	Is the entry of unauthorised persons prevented and are the authorised visitors required to comply with the conditions laid down by centre veterinarian	

<sup>8</sup> Registered horses, registered equidae or equidae for breeding and production; it should correspond to the category of horses/equidae authorised for importation into the Union as listed in Annex I to Commission Implementing Regulation (EU) 2018/659.

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<b>3.7</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.1 (c)	Is only competent staff who have received adequate training on disinfection and hygiene techniques to prevent the spread of disease employed by the centre	
<b>3.8</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (a)	Are records kept on the centre which show:	
<b>3.8.1.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (a)(i)	the species, breed, date of birth and identification of each animal present in the centre	
<b>3.8.2.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (a)(ii)	any movement of animals entering or leaving the centre	
<b>3.8.3.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.1 (a)(iii)	the health history and the diagnostic tests and results thereof, treatments and vaccinations carried out on animals kept	
<b>3.8.4.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (a)(iv)	the date of collecting and processing semen	
<b>3.8.5.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (a)(v)	the destination of semen	
<b>3.8.6.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (a)(vi)	the storage of semen	
<b>3.9.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (b)	Have the animals kept on the centre been used for natural breeding during the period of 30 days prior to first semen collection and during the collection period	
<b>3.10.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (c)	Is semen collection, processing, storage carried out in premises set aside for these purposes	
<b>3.11.1.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (d)	Are all instruments which come into contact with the semen or the donor animal during collection and processing properly disinfected or sterilized prior to use	
<b>3.11.2.</b>		If no, are only new and disposable utensils used which are discarded after use	
<b>3.11.3.</b>		Are the instruments and equipment for natural or artificial insemination strictly separated from instruments and equipment coming into contact with donor or other animals on the centre and the semen	
<b>3.12.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (e)	Are products of animal origin such as diluents, additives or extenders used in the processing of the semen obtained from the sources which present no animal health risk or are so treated prior to use that such risk is prevented	
<b>3.13.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (f)	Had cryogenic agents used for preservation or storage of semen been used previously for other products of animal origin	
<b>3.14.1.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (g)	Are storage and transport containers properly disinfected or sterilised before the commencement of each filling operation	
<b>3.14.2.</b>		If no, are only new and disposable receptacles used that are discarded after use	

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<b>3.15.</b>	92/65/EEC Council Directive Annex D Chapter I (II) Point 1.2 (h)	Is each individual dose of semen indelibly identified showing data as follows:	
<b>3.15.2.</b>		date of collection	
<b>3.15.3.</b>		the species	
<b>3.15.4.</b>		the breed	
<b>3.15.5.</b>		the identification of the donor animal	
<b>3.15.6.</b>		approval number of semen collection centre	
<b>3.16.</b>	92/65/EEC Council Directive Annex D Chapter III (I) Point 1.1	Are antibiotics added to the diluents or semen	
<b>3.17.</b>	92/65/EEC Council Directive Annex D Chapter III (I) Point 1.3 (b)	Is frozen semen stored in approved conditions for a minimum 30 days period prior to dispatch	
<b>4. Health conditions to be applied to equidae in the semen collection centre</b>			
<b>4.1.</b>		Number of stallions in the centre:	
<b>4.2.1.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.1	Did they show any sign of an infectious disease at the time of admission	
<b>4.2.2.</b>		Did they show any sign of an infectious disease during semen collection period	
<b>4.3.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.2	Are the stallions coming from a country or part of the territory of a country regionalised in accordance with EU legislation and from a holding under veterinary supervision each of which satisfy the requirements of Directive 2009/156/EC	
<b>4.4.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.3	Have the stallions been kept for 30 days prior to semen collection in holding where no equine has shown any clinical sign of equine viral arteritis or contagious equine metritis during that period	
<b>4.5.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.4	Have the stallions been used for natural mating during 30 days prior to the first semen collection and during the collection period	
<b>4.6.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.5	Have the following laboratory tests been carried out and certified in a laboratory recognised by the competent authority, which has the tests included in its accreditation in accordance with Article 12 of Regulation (EC) No 882/2004 of the European Parliament and of the Council <sup>9</sup> , according to the program described in point 4.7 of this questionnaire	
<b>4.6.1.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.5 (a)	An agar immuno-diffusion test (Coggins-test) or an ELISA for equine infectious anemia (EIA) with negative result	
<b>4.6.2.1.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.5 (b)	Serum neutralisation test for equine viral arteritis (EVA) at a serum dilution of 1 in 4 with negative result	
<b>4.6.2.2.</b>		If not negative, a test for the isolation of the equine arteritis virus or the detection of its genome by polymerase chain reaction (PCR) or real-time PCR on an aliquot of the entire semen with negative result	

<sup>9</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

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<b>4.6.3.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.5 (c)	<p>An agent identification test for contagious equine metritis (CEM) with negative result in each case on three specimens (swabs) taken from the donor stallion on two occasions with an interval of not less than 7 days, and in no case earlier than 7 days (systemic treatment) or 21 days (local treatment) after possible antimicrobial treatment of the donor stallion, from at least the following sites:</p> <ul style="list-style-type: none"> <li>- the penile sheath (prepuce);</li> <li>- the urethra;</li> <li>- the fossa glandis.</li> </ul> <p>The specimens are placed in transport medium with activated charcoal, such as Amies medium, before dispatch to the laboratory.</p> <p>The specimens are subjected to at least one of the following tests:</p> <ul style="list-style-type: none"> <li>(i) culture under microaerophilic conditions for at least 7 days for the isolation of <i>Taylorella equigenitalis</i>, set up within 24 hours after taking the specimens from the donor animal, or 48 hours where the specimens are kept cool during transport; or</li> <li>(ii) PCR or real-time PCR for the detection of genome of <i>Taylorella equigenitalis</i>, carried out within 48 hours after taking the specimens from the donor animal</li> </ul>	
<b>4.7.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.6	Has one of the following testing procedures been carried out	
<b>4.7.1.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.6 (a)	if the donor stallion is continuously resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, and no equidae on the semen collection centre come into direct contact with equidae of lower health status than the donor stallion, the tests required in point 4.6 of this questionnaire are carried out on samples collected from the donor stallion at least once a year at the beginning of the breeding season or prior to the first collection of semen intended for imports into the European Union of fresh, chilled or frozen semen and at least 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection	

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<b>4.7.2.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.6 (b)	<p>if the donor stallion is resident on the semen collection centre for at least 30 days prior to the date of the first semen collection and during the collection period, but may leave the centre occasionally under the responsibility of the centre veterinarian for a continuous period of less than 14 days, and/or other equidae on the collection centre come into direct contact with equidae of lower health status, the tests required in point 4.6 of this questionnaire are carried out as follows:</p> <p>(i) at least once a year on samples taken from the donor stallion at the beginning of the breeding season or prior to the first collection of semen intended for imports into the European Union of fresh, chilled or frozen semen and at least 14 days following the date of the commencement of the residence period of at least 30 days prior to the date of first semen collection; and</p> <p>(ii) during the period of collection of semen intended for imports into the European Union of fresh, chilled or frozen semen as follows:</p> <ul style="list-style-type: none"> <li>- for the test required in point 4.6.1 of this questionnaire (EIA) on samples taken not more than 90 days prior to the collection of semen for trade;</li> <li>- for the test required in point 4.6.2 of this questionnaire (EVA) on samples taken not more than 30 days prior to the collection of semen for imports into the European Union , unless the non-shedder state of a donor stallion is confirmed by virus isolation test, PCR or real-time PCR carried out on samples of an aliquot of the entire semen taken not more than 6 months prior to the collection of semen for imports into the European Union and the donor stallion has reacted with positive result at a serum dilution of at least 1 in 4 in a serum neutralisation test for equine viral arteritis,</li> <li>- for the test required in point 4.6.3 of this questionnaire (CEM) on samples taken not more than 60 days prior to the collection of semen for imports into the European Union , which in the case of PCR or real-time PCR may be carried out on three specimens (swabs) taken on a single occasion</li> </ul>	

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<b>4.7.3.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.6 (c)	<p>if the donor stallion does not meet the conditions in points 4.7.1 and 4.7.2 of this questionnaire and the semen is collected for trade in frozen semen, the tests required in point 4.6 of this questionnaire are carried out on samples collected from the donor stallion as follows:</p> <p>(i) at least once a year at the beginning of the breeding season; and</p> <p>(ii) during the storage period provided for in point 3.17 of this questionnaire and before the semen is dispatched to the European Union , on samples taken not earlier than 14 days and not later than 90 days following the date of collection of the semen.</p> <p>By way of derogation from point (ii), post-collection sampling and testing for equine viral arteritis as described in 4.6.2 of this questionnaire is not required in case the non-shedder state of a seropositive donor stallion for EVA is confirmed by virus isolation test, PCR or real-time PCR carried out with negative result on samples of an aliquot of the entire semen of the donor stallion taken twice a year at an interval of at least four months and the donor stallion has reacted with positive result at a serum dilution of at least 1 in 4 in a serum neutralisation test for equine viral arteritis.</p>	
<b>4.7.4.1.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.7	If any of the tests provided for in point 4.6 of this questionnaire was positive, was the donor stallion isolated, and the semen collected from it since the date of the last negative test has not been exported to the European Union, with the exception, for equine viral arteritis, of semen from every ejaculate which has undergone the equine arteritis virus isolation test with negative result	
<b>4.7.4.2.</b>		Was semen collected from all other stallions at the semen collection centre since the date when the last sample was collected that gave a negative result in one of the tests provided for in point 4.6 of this questionnaire kept in separate storage and was not exported to the European Union until the health status of the semen collection centre has been restored and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases mentioned in point 4.6 of this questionnaire	
<b>4.7.5.</b>	92/65/EEC Council Directive Annex D Chapter II (I) Point 1.8	Is semen collected from stallions at a semen collection centre subject to a prohibition order in accordance with Article 4 or 5 of Directive 2009/156/EC kept in separate storage and not be intended for imports into the European Union until the health status of the semen collection centre has been restored by the official veterinarian in accordance with Directive 2009/156/EC and the semen stored has undergone the appropriate official investigations to rule out the presence in the semen of pathogens causing diseases listed in Annex I to Directive 2009/156/EC	