

Questionnaire for the approval of ovine/caprine³embryo collection/production⁴ team			
Number	Reference	Question	Y = Yes N = No
1. General criteria			
1.1.	92/65/EEC Council Directive Article 17 Paragraph 2 (a)	Is the third country or parts of the territory of third country listed in Annex III to Commission Decision 2010/472/EU as authorised for imports to the EU of ova and embryos of animals of ovine and caprine species	
1.2.	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 Directive 90/425/EEC	
1.3.	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	
1.4.	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	
1.5.	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 storage centres have not been complied with or there is a doubt as for the quality of semen	
1.6	92/65/EEC Council Directive Article 12 Paragraph 6	Are administrative or penal measures available to penalize any infringement of the provisions governing semen storage centres in particular as for the certificates and the control of products concerned therefore	
2. Technical conditions to be applied for ovine/caprine⁵ embryo collection/production⁶ team			
2.1.	92/65/EEC Council Directive Annex D Chapter I(III) Point 1.1	Is the collection, processing and storage of embryos carried out either by a team veterinarian or under his responsibility by one or more technicians who are competent and trained by the team veterinarian in methods and techniques of hygiene and in techniques and principles of disease control	
2.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.2	Is the team veterinarian responsible for all team operations, including amongst others:	
2.2.1.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.2 (a)	<ul style="list-style-type: none"> • verification of the identity and health status of the donor animal, 	
2.2.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.2 (b)	<ul style="list-style-type: none"> • sanitary handling and surgery of donor animals, 	
2.2.3.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.2 (c)	<ul style="list-style-type: none"> • disinfection and hygienic procedures, 	

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2.2.4.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.2 (d)	<ul style="list-style-type: none"> • keeping records which shows: 	
2.2.4.1.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.2 (d)(i)	<ul style="list-style-type: none"> ○ the species, breed, date of birth and identification of each donor animal, 	
2.2.4.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.2 (d)(ii)	<ul style="list-style-type: none"> ○ the health history and all diagnostic tests and the results thereof, treatments and vaccinations carried out on donor animals, 	
2.2.4.3.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.2 (d)(iii)	<ul style="list-style-type: none"> ○ the place and date of collecting, processing and storing of oocytes, ova and embryos, 	
2.2.4.4.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.2 (d)(iv)	<ul style="list-style-type: none"> ○ the identification of embryos and details of their destination if known. 	
2.3.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.3	Is the team placed under the general supervision of the official veterinarian, who inspects it at least once every calendar year to ensure, where necessary based on records, standard operating procedures and internal audits, compliance with the sanitary conditions regarding collection, processing and storage of embryos and to verify all matters relating to the conditions of approval and supervision	
2.4.1.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.4	Does the team have at its disposal a permanently sited laboratory where embryos can be examined, processed and packed, consisting of at least a work surface, an optical or stereo microscope and cryogenic equipment where necessary	
2.4.2.1	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.5	If yes, does the permanently sited laboratory have:	
2.4.2.1.1.	92/65/EEC Council Directive Annex D Chapter I(III) Point 1.5 (a)	a room where embryos can be processed which is physically separate from the area used to handle the donor animals during collection,	
2.4.2.1.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.5 (b)	a room or area for cleansing and sterilising instruments, except when using only single-use equipment,	
2.4.2.1.3.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.5 (c)	a room for storing embryos.	
2.4.2.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.4	If not, does the team have at its disposal a mobile laboratory where embryos can be examined, processed and packed, consisting of at least a work surface, an optical or stereo microscope and cryogenic equipment where necessary	
2.5.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.6 (a)	Does the mobile laboratory have a specially equipped part of the vehicle consisting of two separate sections:	

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2.5.1.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.6 (a)(i)	<ul style="list-style-type: none"> one for the examination and processing of embryos which shall be a clean section, and 	
2.5.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.6 (a)(ii)	<ul style="list-style-type: none"> the other for accommodating equipment and materials used in contact with the donor animals 	
2.5.3.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.6 (b)	Does the mobile laboratory use only single-use equipment, unless the sterilisation of its equipment and the provision of fluids and other products necessary for the collection and processing of embryos can be ensured by the contact with a permanently sited laboratory	
2.6.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.7	Is the design and layout of buildings and laboratories laid out and team operations carried out so as to ensure that cross-contaminations of embryos are prevented	
2.7.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.8	Does the team have at its disposal storage premises	
2.7.1.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.8 (a)	Do the storage premises comprise at least one lockable room for the storage of ova and embryos;	
2.7.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.8 (b)	Are the storage premises easy to cleanse and disinfect	
2.7.3.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.8 (c)	Do the storage premises have permanent records of all incoming and outgoing ova or embryos	
2.7.4.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.8 (d)	Do the storage premises have storage containers for ova and embryos which are stored in a place which is under the control of the team veterinarian and which is subject to regular inspections by an official veterinarian	
2.8.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.9	Is the team authorised by the competent authority for storage of semen in storage premises referred to in point 2.7	
2.8.1.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.9 (a)	If yes, does the semen meet the requirements of Directive 92/65/EEC for ovine and caprine species	
2.8.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 1.9 (b)	Is the semen stored only for the operation purposes of the team in separate storage containers in the premises for storing approved embryos	
3. Additional technical conditions to be applied for ovine/caprine⁷ embryo production team			
3.1.	92/65/EEC Council Directive Annex D Chapter I (III) Point 2.1	Does the team comply with all the requirements described in point 2 of this questionnaire	

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3.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 2.1	Have the team members received adequate training on disease control and laboratory techniques, particularly in procedures for working in sterile conditions	
3.3.	92/65/EEC Council Directive Annex D Chapter I (III) Point 2.2	Does the team have at its disposal a permanently sited laboratory	
3.3.1.	92/65/EEC Council Directive Annex D Chapter I (III) Point 2.2 (a)	Does the laboratory have adequate equipment and facilities	
3.3.2.	92/65/EEC Council Directive Annex D Chapter I (III) Point 2.2 (a)	Does the laboratory have separate room for recovering oocytes from ovaries	
3.3.3.	92/65/EEC Council Directive Annex D Chapter I (III) Point 2.2 (a)	Does the laboratory have separate room for processing oocytes, ova and embryos	
3.3.4.	92/65/EEC Council Directive Annex D Chapter I (III) Point 2.2 (a)	Does the laboratory have separate room for storing embryos	
3.3.5.	92/65/EEC Council Directive Annex D Chapter I (III) Point 2.2 (b)	Does the laboratory have a laminar-flow or other suitable facilities where all technical operations associated with specific sterile conditions (processing of ova, embryos and semen) are conducted	
3.4.1.	92/65/EEC Council Directive Annex D Chapter I (III) Point 2.3	Does the team collect ova and other tissues in a slaughterhouse	
3.4.2.		If yes, does the team have at its disposal suitable equipment for the collection and transport of the ovaries and other tissues to the processing laboratory in a hygienic and safe manner	
4. Health conditions to be applied for collection and processing of <i>in vivo</i> derived embryos			
4.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1	Are embryos conceived as a result of artificial insemination with semen meeting the requirements of Directive 92/65/EEC	
4.2.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.1	Are embryos collected and processed by an approved embryo collection team, without coming into contact with any other batch of embryos not complying with the requirements of Directive 92/65/EEC	
4.3.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.2	Are embryos collected in a place, which is: - separated from other parts of the premises or holding where the embryos are collected and - which is in good repair and constructed with materials which permit its effective and easy cleansing and disinfection	
4.4.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.3	Are embryos processed (examined, washed, treated and placed in identified and sterile straws, ampoules or other packages) in either a permanently sited laboratory or a mobile laboratory which, is situated in an area in which there has been no outbreak of foot-and-mouth disease for the past 30 days within a 10 kilometre radius	

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4.5.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.4	Is all equipment used to collect, handle, wash, freeze and store embryos sterilised or properly cleansed and disinfected prior to use according to the IETS Manual ⁸	
4.5.2		If not, is new single-use equipment used only and discarded after use	
4.6.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.5	Are all biological products of animal origin used in the media and solutions for collection, processing, washing or storage of embryos free of pathogenic micro-organisms	
4.7.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.5	Are media and solutions used for the collection, freezing and storage of embryos sterilised by approved methods according to the IETS Manual and handled in such a manner as to ensure that sterility is maintained	
4.8.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.5	Are antibiotics added to collection, processing, washing and storage media	
4.8.2.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.5	If yes, are they added in accordance with the IETS Manual	
4.9.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.6	Are procedures in place to ensure that the cryogenic agents used for the preservation or storage of embryos are not previously used for other products of animal origin	
4.10.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.7	Is each embryo straw, ampoule or other package clearly identified by labels according to the standardised system according to the IETS Manual	
4.11.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.8	Are the embryos washed according to the IETS Manual	
4.11.2.		Is the standard washing procedure modified to include additional washes with the enzyme trypsin, according to the IETS Manual, when inactivation or removal of certain viruses is required	
4.12.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.9	Are procedures in place to ensure that embryos from different donor animals are not washed together	
4.13.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.10	Is the <i>zona pellucida</i> of each embryo examined over its entire surface area at not less than 40X magnification and certified to be intact and free of adherent material after the washing	
4.14.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.11	Are embryos of a batch that has successfully undergone the examination set out in point 4.13. placed in a sterile straw, ampoule or other package marked in accordance with point 4.10. which is sealed immediately	
4.15.	92/65/EEC Council Directive Annex D Chapter III(II) Point 1.12	Is each embryo, where appropriate, frozen as soon as possible and stored in a place which is under the control of the team veterinarian	

⁸ Manual of the International Embryo Transfer Society – A procedural guide and general information for the use of embryo transfer technology emphasising sanitary procedures, published by the International Embryo Transfer Society 1111 North Dunlap Avenue, Savoy, Illinois 61874 USA (<http://www.iets.org/>).

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4.16.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.13	Does the team regularly submit for official examination for bacterial and viral contamination routine samples of non-viable embryos or ova, flushing fluids or washing fluids resulting from its activities according to the IETS Manual	
4.17.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.14	Is the team keeping a record of its activities in respect of embryo collection for a period of two years after the embryos have been the subject of trade or export	
4.17.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.14 (a)	Does the record include the breed, age and individual identification of the donor animals concerned	
4.17.2.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.14 (b)	Does the record include the place of collection, processing and storage of embryos collected by the team	
4.17.3.	92/65/EEC Council Directive Annex D Chapter III (II) Point 1.14 (c)	Does the record include the identification of the embryos together with details of the consignee of the shipment	
5. Health conditions to be applied for collection and processing of ova, ovaries and other tissues, with the aim of producing <i>in vitro</i> derived embryos			
5.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 2	Does the team comply with all the requirements described in point 2 of this questionnaire	
5.2.	92/65/EEC Council Directive Annex D Chapter III (II) Point 2.1	Does the competent authority have knowledge of, and authority over, the holding(s) of origin of the donor animals	
5.3.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 2.2	Are the ovaries and other tissues either from individual animals or from batches of donors ("batch collection") collected at a slaughterhouse	
5.3.2.	92/65/EEC Council Directive Annex D Chapter III (II) Point 2.2	If yes, is the slaughterhouse officially approved in accordance with: - Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ⁹ , or - equivalent under national legislation, and under the supervision of a veterinarian whose responsibility it is to ensure that <i>ante-mortem</i> and <i>post-mortem</i> inspections of potential donor animals are carried out and to certify them to be free of signs of the relevant contagious diseases transmissible to animals of the ovine and caprine species	
5.3.3.		Is the slaughterhouse situated in an area in which there has been no outbreak of foot and mouth disease for the past 30 days within a 10 kilometre radius	
5.4.	92/65/EEC Council Directive Annex D Chapter III (II) Point 2.3	Are procedures in place to ensure that batches of ovaries are not brought into the processing laboratory until <i>post-mortem</i> inspection of donor animals is completed	

⁹ OJ L 139, 30.4.2004, p. 206.

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5.5.	92/65/EEC Council Directive Annex D Chapter III (II) Point 2.4	Is equipment for removal and transport of ovaries and other tissues cleansed and disinfected or sterilised before use and exclusively used for these purposes	
6. Health conditions to be applied for processing of <i>in vitro</i> derived embryos			
6.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 3	Does the team comply with all the requirements described in point 5 of this questionnaire	
6.2.	92/65/EEC Council Directive Annex D Chapter III (II) Point 3.1	Are <i>in vitro</i> derived embryos conceived as a result of <i>in vitro</i> fertilisation with semen meeting the requirements of Directive 92/65/EEC	
6.3.	92/65/EEC Council Directive Annex D Chapter III (II) Point 3.2	Are the embryos, after the <i>in vitro</i> culture period is completed but prior to freezing, storage and transport washed and subjected to the treatments referred to in points 4.11., 4.13. and 4.14.	
6.4.	92/65/EEC Council Directive Annex D Chapter III (II) Point 3.3	Are procedures in place to ensure that embryos from different donor animals, in the case of individual animal recovery, or from different batch collections washed together	
6.5.	92/65/EEC Council Directive Annex D Chapter III (II) Point 3.4	Are procedures in place to ensure that embryos from different donor animals, in the case of individual animal recovery, or from different batch collections are not stored in the same straw, ampoule or other package	
7. Health conditions to be applied for processing of micromanipulated embryos			
7.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 4	Does the team comply with all the requirements described in points 4,5 and 6 of this questionnaire	
7.2.	92/65/EEC Council Directive Annex D Chapter III (II) Point 4.1	Where micromanipulation of the embryo which involves penetration of the <i>zona pellucida</i> is carried out, is it done in suitable laboratory facilities under supervision of an approved team veterinarian	
7.3.	92/65/EEC Council Directive Annex D Chapter III (II) Point 4.2	Is the team keeping records of its activities according to point 4.17, including details of micromanipulation techniques which involve penetration of the <i>zona pellucida</i> and which have been performed on the embryos.	
7.4.1.		In the case of embryos derived by <i>in vitro</i> fertilisation, is the identification of the embryos done on the basis of a batch	
7.4.2.		If yes, does it contain details of the date and place of collection of ovaries and/or ova and is it possible to identify the holding of origin of the donor animals	
8. Health conditions to be applied for storage and transport of embryos			
8.1.	92/65/EEC Council Directive Annex D Chapter III (II) Point 5.1	Does the team ensure that the embryos are stored at suitable temperatures in storage premises referred to in point 2.7	
8.2.	92/65/EEC Council Directive Annex D Chapter III (II) Point 5.2	Are frozen embryos, prior to dispatch, stored in approved conditions for a minimum period of 30 days from the date of their collection or production	

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8.3.	92/65/EEC Council Directive Annex D Chapter III (II) Point 6.1	Are procedures in place to ensure that embryos intended for export to the EU are transported to the destination in containers which have been cleansed and disinfected or sterilised before use or are new single-use containers, and are sealed and numbered prior to dispatch from the approved storage premises	
8.4.	92/65/EEC Council Directive Annex D Chapter III (II) Point 6.2	Are the straws, ampoules or other packages marked in such a way that the number on the straws, ampoules or other packages coincides with the number on the health certificate referred to in Article 17(2)(b) of Directive 92/65/EEC and with the container in which they are stored and transported	