

CHAPTER 50: MODEL ANIMAL HEALTH CERTIFICATE FOR ENTRY INTO THE UNION OF CONSIGNMENTS OF OOCYTES AND EMBRYOS OF OVINE AND CAPRINE ANIMALS COLLECTED OR PRODUCED, PROCESSED AND STORED IN ACCORDANCE WITH REGULATION (EU) 2016/429 AND DELEGATED REGULATION (EU) 2020/692 AFTER 20 APRIL 2021, DISPATCHED BY THE EMBRYO COLLECTION OR PRODUCTION TEAM BY WHICH THE OOCYTES OR EMBRYOS WERE COLLECTED OR PRODUCED (MODEL ‘OV/CAP-OOCYTES-EMB-A-ENTRY’)

COUNTRY		Animal health certificate to the EU			
Part I: Description of consignment	I.1 Consignor/Exporter Name Address Country ISO country code	I.2 Certificate reference	I.2a IMSOC reference		
		I.3 Central Competent Authority	QR CODE		
		I.4 Local Competent Authority			
	I.5 Consignee/Importer Name Address Country ISO country code	I.6 Operator responsible for the consignment Name Address Country ISO country code			
	I.7 Country of origin ISO country code	I.9 Country of destination ISO country code			
	I.8 Region of origin Code	I.10 Region of destination Code			
	I.11 Place of dispatch Name Registration/Approval No Address Country ISO country code	I.12 Place of destination Name Registration/Approval No Address Country ISO country code			
		I.13 Place of loading			
	I.15 Means of transport <input type="checkbox"/> Aircraft <input type="checkbox"/> Vessel <input type="checkbox"/> Railway <input type="checkbox"/> Road vehicle Identification	I.14 Date and time of departure			
		I.16 Entry Border Control Post			
	I.18 Transport conditions	<input type="checkbox"/> Ambient		<input type="checkbox"/> Chilled	<input type="checkbox"/> Frozen
	I.19 Container number/Seal number		Container No Seal No		
I.20 Certified as or for	<input type="checkbox"/> Germinal products				
I.21 <input type="checkbox"/> For transit Third country ISO country code	I.22 <input type="checkbox"/> For internal market				
	I.23				

I.24 Total number of packages		I.25 Total quantity		I.26	
I.27 Description of consignment					
CN code	Species	Subspecies/Category		Identification number	Quantity
Type	Approval or registration number of plant/establishment/centre		Identification mark	Date of collection/production	Test

Part II: Certification	II. Health information	II.a Certificate reference	II.b IMSOC reference
	<p>I, the undersigned official veterinarian, hereby certify that:</p> <p>II.1. The oocytes⁽¹⁾/ <i>in vivo</i> derived embryos⁽¹⁾/ <i>in vitro</i> produced embryos⁽¹⁾/ micromanipulated embryos⁽¹⁾ described in Part I are intended for artificial reproduction and were obtained from donor animals which originate from a third country, territory or zone thereof</p> <p>II.1.1. authorised for entry into the Union of oocytes⁽¹⁾/ embryos⁽¹⁾ of ovine⁽¹⁾/caprine⁽¹⁾ animals and listed in Annex X to Commission Implementing Regulation (EU) 2021/404;</p> <p>⁽¹⁾either [II.1.2. where foot-and-mouth disease was not reported for a period of at least 24 months immediately prior to collection⁽¹⁾/ production⁽¹⁾ of the oocytes⁽¹⁾/ embryos⁽¹⁾ and until their date of dispatch;]</p> <p>⁽¹⁾or [II.1.2. where foot-and-mouth disease was not reported for a period starting on the date⁽²⁾ (insert date dd/mm/yyyy) immediately prior to collection of the oocytes⁽¹⁾/ embryos⁽¹⁾ and until their date of dispatch;]</p> <p>II.1.3. where infection with rinderpest virus, infection with Rift Valley fever virus, infection with peste des petits ruminants virus, sheep pox and goat pox and contagious caprine pleuropneumonia were not reported for a period of at least 12 months immediately prior to collection⁽¹⁾/ production⁽¹⁾ of the oocytes⁽¹⁾/ embryos⁽¹⁾ and until their date of dispatch;</p> <p>II.1.4. where no vaccination against foot-and-mouth disease, infection with rinderpest virus, infection with Rift Valley fever virus, infection with peste des petits ruminants virus, sheep pox and goat pox and contagious caprine pleuropneumonia has been carried out for a period of at least 12 months immediately prior to collection⁽¹⁾/ production⁽¹⁾ of the oocytes⁽¹⁾/ embryos⁽¹⁾ and until their date of dispatch, and no vaccinated animals entered into the third country, territory or zone thereof during that period.</p> <p>⁽¹⁾[II.2. The <i>in vivo</i> derived embryos described in Part I have been collected, processed and stored, and dispatched by the embryo collection team⁽³⁾ which</p> <p>II.2.1. is approved and listed by the competent authority of the third country or territory;</p> <p>II.2.2. complies with requirements as regards responsibilities, operational procedures, facilities and equipment set out in Part 2 of Annex I to Commission Delegated Regulation (EU) 2020/686.]</p> <p>⁽¹⁾[II.2. The oocytes⁽¹⁾/ <i>in vitro</i> produced embryos⁽¹⁾/ micromanipulated embryos⁽¹⁾ described in Part I have been collected or produced, processed and stored, and dispatched by the embryo production team⁽³⁾ which</p> <p>II.2.1. is approved and listed by the competent authority of the third country or territory;</p> <p>II.2.2. complies with requirements as regards responsibilities, operational procedures, facilities and equipment set out in Parts 2 and 3 of Annex I to Delegated Regulation (EU) 2020/686.]</p> <p>II.3. The oocytes⁽¹⁾/ embryos⁽¹⁾ described in Part I were obtained from donor animals which originate from establishments</p> <p>II.3.1. free from infection with <i>Brucella abortus</i>, <i>B. melitensis</i> and <i>B. suis</i> and have never been kept previously in any establishment of a lower health status.</p> <p>⁽¹⁾⁽⁴⁾[II.3.2. in which infection with <i>Mycobacterium tuberculosis</i> complex (<i>M. bovis</i>, <i>M. caprae</i> and <i>M. tuberculosis</i>) has not been reported during the last 42 days;]</p> <p>⁽¹⁾⁽⁵⁾[II.3.2. in which surveillance for infection with <i>Mycobacterium tuberculosis</i> complex (<i>M. bovis</i>, <i>M. caprae</i> and <i>M. tuberculosis</i>) has been carried out on the caprine animals kept on the establishments during at least the last 12 months, in accordance with procedures provided for in points 1 and 2 of Part 1 of Annex II to Commission Delegated Regulation (EU) 2020/688, and in case, during this period, infection with <i>Mycobacterium tuberculosis</i> complex (<i>M. bovis</i>, <i>M. caprae</i> and <i>M. tuberculosis</i>) has been reported in caprine animals kept on the establishment, measures were taken in accordance with Part 1(3) of Annex II to that Delegated Regulation;]</p> <p>II.3.3. in which surra (<i>Trypanosoma evansi</i>) has not been reported during the last 30 days, and</p> <p>⁽¹⁾either [surra has not been reported in the establishments during the last 2 years.]</p> <p>⁽¹⁾or [surra has been reported in the establishments during the last 2 years and following the last outbreak the establishments have remained under movement restrictions until</p> <p>– the infected animals have been removed from the establishment, and</p>		

	<p>– the remaining animals on the establishment have been subjected to a test for surra (<i>Trypanosoma evansi</i>) with one of the diagnostic methods provided for in Part 3 of Annex I to Commission Delegated Regulation (EU) 2020/688, carried out, with negative results, on samples taken at least 6 months after the infected animals have been removed from the establishment.]</p>
II.4.	The oocytes ⁽¹⁾ / embryos ⁽¹⁾ described in Part I were obtained from donor animals which
II.4.1.	were not vaccinated against infection with rinderpest virus, infection with Rift Valley fever virus, infection with peste des petits ruminants virus, sheep pox and goat pox and contagious caprine pleuropneumonia;
II.4.2.	remained for a period of at least 6 months prior to the date of collection ⁽¹⁾ / production ⁽¹⁾ of the oocytes ⁽¹⁾ / embryos ⁽¹⁾ in a third country or territory or zone thereof referred to in Box I.7.;
II.4.3.	for a period of at least 30 days prior to the date of collection ⁽¹⁾ / production ⁽¹⁾ of the oocytes ⁽¹⁾ / embryos ⁽¹⁾ and during the collection ⁽¹⁾ / production ⁽¹⁾ period
II.4.3.1.	were kept on establishments not situated in a restricted zone established due to the occurrence of foot-and-mouth disease, infection with rinderpest virus, infection with Rift Valley fever virus, infection with peste des petits ruminants virus, sheep pox and goat pox or contagious caprine pleuropneumonia, or of an emerging disease relevant for ovine and caprine animals;
II.4.3.2.	were kept on a single establishment where infection with <i>Brucella abortus</i> , <i>B. melitensis</i> and <i>B. suis</i> , infection with <i>Mycobacterium tuberculosis</i> complex (<i>M. bovis</i> , <i>M. caprae</i> and <i>M. tuberculosis</i>), rabies, anthrax, surra (<i>Trypanosoma evansi</i>), infection with epizootic haemorrhagic disease virus, infection with bluetongue virus (serotypes 1-24) and, in case of ovine animals and those caprine animals which are kept together with ovine animals, ovine epididymitis (<i>Brucella ovis</i>) have not been reported;
II.4.3.3.	were not in contact with animals from establishments situated in a restricted zone due to the occurrence of diseases referred to in point II.4.3.1. or from establishments which do not meet the conditions referred to in point II.4.3.2.;
II.4.3.4.	were not used for natural breeding;
II.4.4.	were examined by the team veterinarian or a team member and did not show symptoms or clinical signs of transmissible animal diseases on the day of collection ⁽¹⁾ / production ⁽¹⁾ of the oocytes ⁽¹⁾ / embryos ⁽¹⁾ ;
II.4.5.	are individually identified as provided for in Article 21(1) of Commission Delegated Regulation (EU) 2020/692;
II.4.6.	comply with the following conditions as regards foot-and-mouth disease
II.4.6.1.	they come from establishments
	– situated in an area where foot-and-mouth disease has not been reported within a 10-km radius centred on the establishment for a period of at least 30 days immediately prior to the date of collection ⁽¹⁾ / production ⁽¹⁾ of the oocytes ⁽¹⁾ / embryos ⁽¹⁾ ;
	– in which foot-and-mouth disease has not been reported during a period of at least 3 months immediately prior to the date of collection ⁽¹⁾ / production ⁽¹⁾ of the oocytes ⁽¹⁾ / embryos ⁽¹⁾ ;
⁽¹⁾ either	[II.4.6.2. they were not vaccinated against foot-and-mouth disease;]
⁽¹⁾⁽⁶⁾ or	[II.4.6.2. they were vaccinated against foot-and-mouth disease during the period of 12 months prior to the date of collection of the embryos and
	II.4.6.2.1. have not been vaccinated against foot-and-mouth disease within the period of at least 30 days immediately prior to the date of collection of the embryos;

	<p>II.4.6.2.2. the semen used for fertilisation was collected from a male donor that complies with the conditions set out in point 1(b) of Chapter I of Part 5 of Annex II to Delegated Regulation (EU) 2020/686 or the semen complies with the conditions set out in point 2 of Chapter I of Part 5 of Annex II to Delegated Regulation (EU) 2020/686;</p> <p>II.4.6.2.3. prior to freezing, the embryos have been subjected to trypsin washing carried out in accordance with the recommendations of the IETS Manual⁽⁷⁾;</p> <p>II.4.6.2.4. the embryos were stored deep frozen for a period of at least 30 days from the date of collection, and during this period the donor animal has not shown clinical signs of foot-and-mouth disease;]</p> <p>II.4.7. comply with at least one of the following conditions as regards infection with bluetongue virus (serotypes 1-24):</p> <p>⁽¹⁾either [II.4.7.1. they have been kept for a period of at least 60 days prior to and during collection⁽⁺⁾/ production⁽⁺⁾ of the oocytes⁽⁺⁾/ embryos⁽⁺⁾ in a third country, territory or zone thereof free from infection with bluetongue virus (serotypes 1-24) where no case of infection with bluetongue virus (serotypes 1-24) has been confirmed during the last 24 months in the targeted animal population;]</p> <p>⁽¹⁾and/or [II.4.7.2. they have been kept in a seasonally disease free zone, during the seasonally disease-free period, for a period of at least 60 days prior to and during collection⁽⁺⁾/ production⁽⁺⁾ of the oocytes⁽⁺⁾/ embryos⁽⁺⁾, in a third country, territory or zone thereof with an approved eradication programme against infection with bluetongue virus (serotypes 1-24);]</p> <p>⁽¹⁾and/or [II.4.7.3. they have been kept in a seasonally disease free zone, during the seasonally disease-free period, for a period of at least 60 days prior to and during collection⁽⁺⁾/ production⁽⁺⁾ of the oocytes⁽⁺⁾/ embryos⁽⁺⁾, in a third country, territory or zone thereof where the competent authority of the place of origin of the consignment of the oocytes⁽⁺⁾/ embryos⁽⁺⁾ has obtained the prior written consent of the competent authority of the Member State of destination to the conditions for establishment of that seasonally disease free zone and to accept the consignment of the oocytes⁽⁺⁾/ embryos⁽⁺⁾.]</p> <p>⁽¹⁾and/or [II.4.7.4. they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection⁽¹⁾/ production⁽¹⁾ of the oocytes⁽¹⁾/ embryos⁽¹⁾.];</p> <p>⁽¹⁾and/or [II.4.7.5. they have been subjected to a serological test to detect antibodies to the bluetongue virus serogroup 1-24, with negative results, between 28 and 60 days from the date of each collection⁽¹⁾/ production⁽¹⁾ of the oocytes⁽¹⁾/ embryos⁽¹⁾.];</p> <p>⁽¹⁾and/or [II.4.7.6. they have been subjected to an agent identification test for bluetongue virus (serotypes 1-24), with negative results, on blood sample taken on the day of collection of the oocytes⁽¹⁾/ embryos⁽¹⁾.];</p> <p>II.4.8. comply with at least one of the following conditions as regards infection with epizootic haemorrhagic disease virus (serotypes 1-7) (EHDV 1-7):</p> <p>⁽¹⁾either [II.4.8.1. they have been kept for a period of at least 60 days prior to and during collection⁽¹⁾/ production⁽¹⁾ of the oocytes⁽¹⁾/ embryos⁽¹⁾ in a third country, territory or zone thereof where EHDV 1-7 has not been reported for a period of at least the preceding 2 years within a radius of 150 km of the establishment;]</p> <p>⁽¹⁾and/or [II.4.8.2. they have been kept in a vector-protected establishment for a period of at least 60 days prior to and during collection⁽¹⁾/ production⁽¹⁾ of the oocytes⁽¹⁾/ embryos⁽¹⁾.];</p> <p>⁽¹⁾and/or [II.4.8.3. were resident in the exporting country in which according to official findings the following serotypes of EHDV exist: and have been subjected with negative results in each case to the following tests carried out in an official laboratory:</p>
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	<p>⁽¹⁾<i>either</i> [II.4.8.3.1. a serological test to detect antibodies to EHDV 1-7, with negative results, on blood sample taken between 28 and 60 days from the date of the collection⁽¹⁾/ production⁽¹⁾ of the oocytes⁽¹⁾/ embryos⁽¹⁾.];]</p> <p>⁽¹⁾<i>and/or</i> [II.4.8.3.2. an agent identification test for EHDV 1-7, with negative results, on blood sample taken on the day of collection⁽¹⁾/ production⁽¹⁾ of the oocytes⁽¹⁾/ embryos⁽¹⁾.]]</p> <p>⁽⁸⁾[II.4.9. comply with the following conditions as regards classical scrapie:</p> <p>II.4.9.1. have been kept continuously since birth in a country where the following conditions are fulfilled:</p> <p>II.4.9.1.1. classical scrapie is compulsorily notifiable;</p> <p>II.4.9.1.2. an awareness, surveillance and monitoring system is in place;</p> <p>II.4.9.1.3. ovine and caprine animals affected with classical scrapie are killed and completely destroyed;</p> <p>II.4.9.1.4. the feeding to ovine and caprine animals of meat-and-bone meal or greaves of ruminant origin, as defined in the Terrestrial Animal Health Code of the World Organisation for Animal Health, has been banned and effectively enforced in the whole country for a period of at least the last seven years;</p> <p>And</p> <p>⁽¹⁾<i>either</i> [II.4.9.2. have been kept continuously for the last three years preceding the date of the collection of the embryos to be exported in a holding or holdings which has/have fulfilled during that period all the requirements set out in points 1.3. (a) to (f) of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001, except during the period when they were kept at a semen collection centre that complied during that period with the conditions set out in the four indents of point 1.3.(c)(iv) of that Section;]</p> <p>⁽¹⁾<i>or</i> [II.4.9.2. they are ovine animals and the embryos ⁽¹⁾<i>either</i> [are of the ARR/ARR prion protein genotype;] ⁽¹⁾<i>or</i> [carry at least one ARR allele.]]]</p> <p>II.5. The oocytes⁽¹⁾/ embryos⁽¹⁾ described in Part I</p> <p>II.5.1. has been collected, processed and stored in accordance with animal health requirements set out in Part 2⁽¹⁾/Part 3⁽¹⁾/Part 4⁽¹⁾/Part 5⁽¹⁾ and Part 6 of Annex III to Delegated Regulation (EU) 2020/686;</p> <p>II.5.2. are placed in straws or other packages on which the mark is applied in accordance with requirements provided for in Article 83(a) of Delegated Regulation (EU) 2020/692 and that mark is indicated in Box I.27;</p> <p>II.5.3. are transported in a container which:</p> <p>II.5.3.1. was sealed and numbered prior to the dispatch by the embryo collection or production team under responsibility of the team veterinarian, or by an official veterinarian, and the seal bears the number as indicated in Box I.19;</p> <p>II.5.3.2. has been cleaned and either disinfected or sterilised before use, or is single-use container;</p> <p>⁽¹⁾⁽⁸⁾[II.5.3.3. has been filled in with the cryogenic agent which not have been previously used for other products;</p> <p>⁽¹⁾⁽¹⁰⁾[II.5.4. are placed in straws or other packages which are securely and hermetically sealed;</p> <p>II.5.5. are transported in a container where they are separated from each other by physical compartments or by being placed in secondary protective bags.]</p> <p>⁽¹⁾⁽¹¹⁾[II.6. The <i>in vivo</i> derived embryos⁽¹⁾/ <i>in vitro</i> produced embryos⁽¹⁾/ micromanipulated embryos⁽¹⁾ described in Part I were conceived by artificial insemination using semen coming from a semen collection centre, germinal product processing establishment or germinal product storage centre approved for the collection, processing and/or storage of semen by the competent authority of a third country, territory or zone</p>
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thereof listed in Annex X to Implementing Regulation (EU) 2021/404 for semen of ovine and caprine animals or by the competent authority of a Member State.]

^{(1)/(12)}[II.7. The following antibiotic or mixture of antibiotics⁽¹³⁾ has been added to the collection, processing, washing or storage media:]

Notes

This certificate is intended for entry into the Union of oocytes and embryos of ovine and caprine animals, including when the Union is not the final destination of the oocytes and embryos.

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland / Northern Ireland in conjunction with Annex 2 to that Protocol, references to European Union in this certificate include the United Kingdom in respect of Northern Ireland.

This animal health certificate shall be completed according to the notes for the completion of certificates provided for in Chapter 4 of Annex I to Commission Implementing Regulation (EU) 2020/2235.

Part I:

Box reference I.11: “*Place of dispatch*”: Indicate the unique approval number and the name and address of the embryo collection or production team of dispatch of the consignment of oocytes or embryos. Only embryo collection or production teams listed in accordance with Article 233(3) of Regulation (EU) 2016/429 on the Commission website:

http://ec.europa.eu/food/animal/semen_ova/ovine/index_en.htm .

Box reference I.12: “*Place of destination*”: Indicate the address and unique registration or approval number of the establishment of destination of the consignment of oocytes or embryos.

Box reference I.19: “*Seal number*” shall be indicated.

Box reference I.24: Total number of packages shall correspond to the number of containers.

Box reference I.27: “*Type*”: specify if *in vivo* derived embryos, *in vivo* derived oocytes, *in vitro* produced embryos or micromanipulated embryos.

“*Species*”: select amongst “*Ovis aries*” or “*Capra hircus*” as appropriate.

“*Identification number*”: Indicate the identification number of each donor animal.

“*Identification mark*”: Indicate the mark on the straw or other packages where oocytes or embryos of the consignment are placed.

“*Date of collection/production*”: Indicate the date on which oocytes or embryos of the consignment were collected or produced.

“*Approval or registration number of plant/establishment/centre*”: Indicate the unique approval number of the embryo collection or production team by which the oocytes or embryos were collected or produced.

“*Quantity*”: Indicate the number of straws or other packages with the same mark.

“*Test*”: Indicate for BTV-test: II.4.7.5. and/or II.4.7.6., and/or for EHD-test: II.4.8.3.1. and/or II.4.8.3.2., if relevant.

Part II:

⁽¹⁾ Delete if not applicable.

⁽²⁾ Only for a third country, territory or zone thereof with an opening date in accordance with column 9 of the table in Part I of Annex II to Implementing Regulation (EU) 2021/404.

⁽³⁾ Only embryo collection or production teams listed in accordance with Article 233(3) of Regulation (EU) 2016/429 on the Commission website:

http://ec.europa.eu/food/animal/semen_ova/ovine/index_en.htm.

<p>(4)</p> <p>(5)</p> <p>(7)</p> <p>(8)</p> <p>(10)</p> <p>(11)</p> <p>(12)</p> <p>(13)</p>	<p>Applicable for ovine animals.</p> <p>Applicable for caprine animals.⁽⁶⁾ Option available only for the consignment of <i>in vivo</i> derived embryos.</p> <p>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, 1 111 North Dunlap Avenue, Savoy, Illinois 61 874 USA (http://www.iets.org/).</p> <p>Delete if the Union is not the final destination of the oocytes and embryos.⁽⁹⁾ Applicable for frozen oocytes or embryos.</p> <p>Applicable for the consignment where in one container oocytes, <i>in vivo</i> derived embryos, <i>in vitro</i> produced embryos and micromanipulated embryos of ovine or caprine animals are placed and transported.</p> <p>Does not apply to oocytes.</p> <p>Mandatory attestation in case antibiotics were added.</p> <p>Insert the name(s) of the antibiotic(s) added and its(their) concentration.</p>				
<p>Official veterinarian</p> <p>Name (in capital letters)</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Date</td> <td style="width: 50%; border: none;">Qualification and title</td> </tr> <tr> <td style="border: none;">Stamp</td> <td style="border: none;">Signature</td> </tr> </table>		Date	Qualification and title	Stamp	Signature
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