

CHAPTER 42: MODEL ANIMAL HEALTH CERTIFICATE FOR ENTRY INTO THE UNION OF CONSIGNMENTS OF OOCYTES AND EMBRYOS OF BOVINE 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 ‘BOV-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.14 Date and time of departure		
	I.15 Means of transport <input type="checkbox"/> Aircraft <input type="checkbox"/> Vessel <input type="checkbox"/> Railway <input type="checkbox"/> Road vehicle Identification	I.16 Entry Border Control Post I.17		
	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

COUNTRY

Certificate model BOV-OOCYTES-EMB-A-ENTRY

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 bovine animals and listed in Annex IX 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⁾ (<i>insert date dd/mm/yyyy</i>) 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, contagious bovine pleuropneumonia and lumpy skin disease 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 and contagious bovine 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⁾ 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 the donor animals which originate from establishments</p> <p>II.3.1. free from infection with <i>Mycobacterium tuberculosis</i> complex (<i>M. bovis</i>, <i>M. caprae</i> and <i>M. tuberculosis</i>), and they have never been kept previously in any establishment of a lower health status;</p> <p>II.3.2. free from infection with <i>Brucella abortus</i>, <i>B. melitensis</i> and <i>B. suis</i> and they have never been kept previously in any establishment of a lower health status;</p>		

⁽¹⁾ either [II.3.3.	free from enzootic bovine leukosis and they have never been kept previously in any establishment of a lower health status;]
⁽¹⁾ or [II.3.3.	not free from enzootic bovine leukosis and the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of enzootic bovine leukosis during a period of at least the preceding 3 years;]
⁽¹⁾ either [II.3.4.	free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis and they have never been kept previously in any establishment of a lower health status;]
⁽¹⁾ or [II.3.4.	not free from infectious bovine rhinotracheitis/infectious pustular vulvovaginitis and the official veterinarian responsible for the establishment of origin has certified that there has been no clinical case of infectious bovine rhinotracheitis/infectious pustular vulvovaginitis during a period of at least the preceding 12 months;]
II.3.5.	in which surra (<i>Trypanosoma evansi</i>) has not been reported during the last 30 day period prior to collection ⁽¹⁾ / production ⁽¹⁾ of the oocytes ⁽¹⁾ / embryos ⁽¹⁾ , and
⁽¹⁾ either	[surra has not been reported in the establishments during the last 2 years prior to collection ⁽¹⁾ / production ⁽¹⁾ of the oocytes ⁽¹⁾ / embryos ⁽¹⁾];]
⁽¹⁾ or	[surra has been reported in the establishments during the last 2 years prior to collection ⁽¹⁾ / production ⁽¹⁾ of the oocytes ⁽¹⁾ / embryos ⁽¹⁾ and following the last outbreak the establishments have remained under movement restrictions until <ul style="list-style-type: none"> – the infected animals have been removed from the establishment, and – 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;]
II.4.	The oocytes ⁽¹⁾ / embryos ⁽¹⁾ described in Part I were obtained from the donor animals which
II.4.1.	were not vaccinated against infection with rinderpest virus, infection with Rift Valley fever virus, contagious bovine pleuropneumonia and lumpy skin disease;
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 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, contagious bovine pleuropneumonia or lumpy skin disease, or of an emerging disease relevant for bovine 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>), enzootic bovine leukosis, infectious bovine rhinotracheitis/infectious pustular vulvovaginitis, bovine viral diarrhoea, infection with epizootic haemorrhagic disease virus and infection with bluetongue virus (serotypes 1-24) 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

	<p>II.4.6.1. they come from establishments</p> <ul style="list-style-type: none"> – 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⁾; <p>⁽¹⁾either [II.4.6.2. they were not vaccinated against foot-and-mouth disease;]</p> <p>⁽¹⁾⁽⁴⁾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</p> <p>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> <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⁽⁵⁾;</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>⁽¹⁾⁽⁶⁾[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 of the oocytes 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 of the oocytes, 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 of the oocytes, in a third country, territory or zone thereof where the competent authority of the place of origin of the consignment of oocytes⁽⁴⁾/in vitro produced embryos⁽⁴⁾ 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 oocytes⁽⁴⁾/in vitro produced embryos⁽⁴⁾;</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 of the oocytes;]</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 of the oocytes;]</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;]</p> <p>⁽¹⁾⁽⁶⁾[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 of the oocytes 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>
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- ⁽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 of the oocytes;]
- ⁽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:
 - ⁽¹⁾either [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 of the oocytes;]
 - ⁽¹⁾and/or [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 of the oocytes.]]
- ⁽¹⁾/⁽⁶⁾[II.4.9. comply with animal health requirements laid down in Chapter III of Part 1 of Annex II to Delegated Regulation (EU) 2020/686;]
- II.5. The oocytes⁽¹⁾/ embryos⁽¹⁾ described in Part I
 - 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;
 - 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;
 - II.5.3. are transported in a container which:
 - 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;
 - II.5.3.2. has been cleaned and either disinfected or sterilised before use, or is single-use container;
 - ⁽¹⁾/⁽⁷⁾[II.5.3.3. has been filled in with the cryogenic agent which not have been previously used for other products;]
 - ⁽¹⁾/⁽⁸⁾[II.5.4. are placed in straws or other packages which are securely and hermetically sealed;
 - 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.]
- ⁽¹⁾/⁽⁹⁾[II.6. The *in vivo* derived embryos⁽¹⁾/ *in vitro* 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 thereof listed in Annex IX to Implementing Regulation (EU) 2021/404 for semen of bovine animals or by the competent authority of a Member State.]
- ⁽¹⁾/⁽¹⁰⁾[II.7. The following antibiotic or mixture of antibiotics⁽¹¹⁾ has been added to the collection, processing, washing or storage media:]

Notes

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

<p>Box reference I.12:</p> <p>Box reference I.19:</p> <p>Box reference I.24:</p> <p>Box reference I.27:</p> <p>Part II:</p> <p>(1) Delete if not applicable.</p> <p>(2) Only for a third country, territory or zone thereof with opening date in accordance with column 9 of the table in Part 1 of Annex II to Implementing Regulation (EU) 2021/404.</p> <p>(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/bovine/ova_embryos_en.htm.</p> <p>(4) Option available only for the consignment of <i>in vivo</i> derived embryos.</p> <p>(5) 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>(6) Applicable for the consignment of oocytes and <i>in vitro</i> produced embryos.</p> <p>(7) Applicable for frozen oocytes or embryos.</p> <p>(8) 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 bovine animals are placed and transported.</p> <p>(9) Does not apply to oocytes.</p> <p>(10) Mandatory attestation in case antibiotics were added.</p> <p>(11) Insert the name(s) of the antibiotic(s) added and its(their) concentration.</p>	<p>Regulation (EU) 2016/429 on the Commission website: http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_en.htm.</p> <p>“<i>Place of destination</i>”: Indicate the address and unique registration or approval number of the establishment of destination of the consignment of oocytes or embryos.</p> <p>Seal number shall be indicated.</p> <p>Total number of packages shall correspond to the number of containers.</p> <p>“<i>Species</i>”: Select amongst “<i>Bos taurus</i>”, “<i>Bison bison</i>” or “<i>Bubalus bubalis</i>” as appropriate.</p> <p>“<i>Type</i>”: Specify if oocytes, <i>in vivo</i> derived embryos, <i>in vitro</i> produced embryos or micromanipulated embryos.</p> <p>“<i>Identification number</i>”: Indicate the identification number of each donor animal.</p> <p>“<i>Identification mark</i>”: Indicate the mark on the straw or other packages where oocytes or embryos of the consignment are placed.</p> <p>“<i>Date of collection/production</i>”: Indicate the date on which oocytes or embryos of the consignment were collected or produced.</p> <p>“<i>Approval or registration number of plant/establishment/centre</i>”: Indicate the unique approval number of the embryo collection or production team by which the oocytes or embryos were collected or produced.</p> <p>“<i>Quantity</i>”: Indicate the number of straws or other packages with the same mark.</p> <p>“<i>Test</i>”: 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.</p>	
<p>Official veterinarian</p> <p>Name (in capital letters)</p> <p>Date</p> <p>Stamp</p>		<p>Qualification and title</p> <p>Signature</p>