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: AUSTRALIA — **Animal health certificate to the EU**

Part I: Description of the consignment

I.1. Consignor/ Exporter
Name:
Address:
Country:

~~I.2. Certificate reference~~
~~**RME-00**~~

I.2.a. IMSOC reference

I.3. Central competent authority
Department of Agriculture, Water and the Environment

I.4. Local competent authority
Department of Agriculture, Water and the Environment

QR CODE

I.5. Consignee/ Importer
Name:
Address:
Country ISO country code

1.6. Operator responsible for the consignment
Name:
Address:
Country ISO country code

I.7. Country of origin	ISO code	I.8. Region of Origin	Code
AUSTRALIA	**AU**	**VICTORIA**	**VIC**

I.9. Country of destination	ISO Code	I.10. Region of destination	Code

I.11. Place of dispatch
Name:
Address:
Country ISO country code
Registration/Approval Number: XXXXXXX

I.12. Place of destination
Name:
Address:
Country ISO country code
Registration/Approval Number: XXXXXXX

I.13. Place of loading **MELBOURNE, AUSTRALIA**

I.14. Date and time of departure

I.15. Means of transport
☒Aeroplane ☐ Vessel
☐ Road vehicle ☐ Railway
Identification: Flights: XXX

I.16. Entry Border Control Post

I.17.

I.18	Transport conditions	□ Ambient	□ Chilled	☒ Frozen

I.19 Container number/Seal number
Container No XXXXXXXX Seal No XXXXXXXXXX

I.20 Certified as or for ☒ Germinal products

I.21. For transit ☐
Third Country ISO code

I.22. For internal market ☒

I.23.

I.24 Total number of packages # cryogenic tanks	I.25 Total quantity # embryos	I.26

I.27 Description of consignment

CN Code: **HS code 05 11 99 85** Species: **Bovine**

Subspecies/Category:	Identification number	Quantity	Type	Approval or registration number of plant/establishment centre	Identification mark	Date of collection/ production	Test

See attachment 1

II. Health Information	~~II.a. Certificate reference No~~ **~~RME-00~~**	II.b. IMSOC reference No

Part II: Certification

I, the undersigned embryo transfer veterinarian, hereby declare that:

II.1. The ~~oocytes~~(1)/ in vivo derived embryos(1)/ ~~in vitro 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

~~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;~~

~~(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;]~~

(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;]~~

~~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;~~

~~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.~~

(1)[II.2. The *in vivo* derived embryos described in Part I have been collected, processed and stored, and dispatched by the embryo collection team(3) which

II.2.1. is approved and listed by the competent authority of the third country or territory;

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.]

(1)[~~II.2. The oocytes(1)/ in vitro produced embryos(1) described in Part I have been collected or produced, processed and stored, and dispatched by the embryo production team(3) which~~

~~II.2.1. is approved and listed by the competent authority of the third country or territory;~~

~~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.]~~

II.3. The ~~oocytes~~(1)/ embryos(1) described in Part I were obtained from the donor animals which originate from establishments

II.3.1. free from infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), and they have never been kept previously in any establishment of a lower health status;

II.3.2. free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* and they have never been kept previously in any establishment of a lower health status;

(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 *(Trypanosoma evansi*) 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~~

~~– the infected animals have been removed from the establishment, and~~

~~– the remaining animals on the establishment have been subjected to a test for surra (*Trypanosoma evansi*) 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 *Brucella abortus*, *B. melitensis* and *B. suis*, infection with *Mycobacterium tuberculosis* complex (*M. bovis*, *M. caprae* and *M. tuberculosis*), rabies, anthrax, surra (*Trypanosoma evansi*), 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

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)(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~~

~~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;~~

~~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;~~

~~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);~~

~~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;]~~

(1)(6)[II.4.7. comply with at least one of the following conditions as regards infection with bluetongue virus (serotypes 1-24):

(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~~(1)/ embryos(1) 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;]

(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(1)/ embryos(1), in a third country, territory or zone thereof with an approved eradication programme against infection with bluetongue virus (serotypes 1-24);]~~

(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(1)/ embryos(1), in a third country, territory or zone thereof where the competent authority of the place of origin of the consignment of oocytes(1)/ in vitro produced embryos(1) 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(1)/ in vitro produced embryos(1);~~]

(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(1)/ embryos(1);~~]

(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~~(1)/ embryos(1);]

(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);]]

(1)(6)[II.4.8. comply with at least one of the following conditions as regards infection with epizootic haemorrhagic disease virus (serotypes 1-8) (EHDV 1-8):

(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~~(1)/ embryos(1) in a third country, territory or zone thereof where EHDV 1-8 has not been reported for a period of at least the preceding 2 years within a radius of 150 km of the establishment;]

(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)/ embryos(1);~~]

(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: **1, 2, 4, 5, 6, 7 & 8** 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 1-8, with negative results, on blood sample taken between 28 and 60 days from the date of the collection of the ~~oocytes~~(1)/ embryos(1)]]

(1)*and/or* [II.4.8.3.2. an agent identification test for EHDV 1-8, with negative results, on blood sample taken on the day of collection of the ~~oocytes~~(1)/ embryos(1).]]]

(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 have not 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 Regulation (EU) 2016/429 on the Commission website: http://ec.europa.eu/food/animal/semen_ova/bovine/ova_embryos_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:	*"Species"*: Select amongst "*Bos taurus*", "*Bison bison*" or "*Bubalus bubalis*" as appropriate. *"Type"*: Specify if oocytes, in vivo derived embryos, *in vitro* produced embryos or micromanipulated embryos. *"Identification number"*: Indicate identification number of each donor animal. *"Identification mark"*: Indicate 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 was 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 number of straws or other packages with the same mark.

Part II:

(1) Delete if not applicable.

(2) Only for a third country, territory or zone thereof with opening date in accordance with column 9 in part 1 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/bovine/ova_embryos_en.htm.

(4) Option available only for the consignment of in vivo derived embryos.

(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/).

(6) Applicable for the consignment of oocytes and in vitro produced embryos.

(7) Applicable for frozen oocytes or embryos.

(8) Applicable for the consignment where in one container oocytes, in vivo derived embryos, in vitro produced embryos and micromanipulated embryos of bovine animals are placed and transported.

(9) Does not apply to oocytes.

(10) Mandatory attestation in case antibiotics were added.

(11) Insert the name(s) of the antibiotic(s) added and its(their) concentration

Embryo transfer veterinarian

Name (in capital letters):

Date: Qualification and title:

Stamp:

Signature: .. **(PDF only)**

ATTACHMENT 1

I.27 Description of consignment					
CN Code: **HS code 05 11 99 85** Subspecies/ Category: Species: **Bovine** Approval or registration number of plant/establishment centre					
Identification number	Quantity	Type	Identification mark	Date of collection/production	Test

Document information

Document Details			
Country	Commodity	Protocol	Verified against MICOR
European Union	BOVINE EMBRYOS	Not agreed. Importing country template. https://ec.europa.eu/food/animals/semen-oocytes-embryos_en	Not applicable

Version history

Version	Date	Amendment details
1.0	2021 12 10	Not agreed certificate. Obtained from EU website and advice sought from ABB.