Department for Environment, Food and Rural Affairs

Notes for Guidance: Export Health Certificate for entry into the European Union or Northern Ireland of oocytes and embryos of bovine animals collected or produced after 20 April 2021, and dispatched from the collection centre 8402

August 2024

Contents

No: 8402NFG

EHC for entry into the EU or NI of oocytes and embryos of bovine animals collected or produced after 20 April 2021, and dispatched from the collection centre where they were collected.

NOTES FOR GUIDANCE (NFG) FOR THE CERTIFYING OFFICERS (COs) AND EXPORTERS

IMPORTANT

These notes provide guidance to COs and exporters. The NFG should have been issued to you together with the relevant export certificate applicable for 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 an embryo collection or production team by which the oocytes or embryos were collected or produced to the EU or NI. The NFG should not be read as a standalone document but in conjunction with the health certificate.

We strongly suggest that exporters obtain full details of the importing country's requirements from the veterinary authorities in the country concerned, or their representatives in the UK, in advance of each consignment.

1. APPLICABLE LEGISLATION

Regulation (EU) No 2016/429

Commission Implementing Regulation (EU) 2020/999

Commission Delegated Regulation (EU) 2020/692

Commission Delegated Regulation (EU) 2020/686

Commission Delegated Regulation (EU) 2020/688

Commission Implementing Regulation (EU) 2021/403

Implementing Regulation (EU) 2024/351 - Model EHC amending Implementing Regulation (EU) 2021/403

Any EU legislation referenced in the EHC must be complied with and EU legislation can be accessed on the following link: https://eur-lex.europa.eu/homepage.html

Consolidated legislation

Consolidated texts, which integrate the basic instruments of EU legislation with their amendments and corrections in a single, non-official document, are available. Each consolidated text contains a list of all legal documents taken into account for its construction.

You can search for consolidated texts by using the 'find results by document number' option on the European Commission website. Once you have selected the relevant legislation, click

'document information', and then scroll down to 'all consolidated versions' and select the most recent version.

https://eur-lex.europa.eu/homepage.html

Please note that the consolidated text may not contain the latest amendment to the legislation, as it takes several weeks for this to be updated.

Texts provided in this section are intended for information only. Please note that these texts have no legal value. For legal purposes please refer to the texts published in the 'Official Journal of the EU'.

2. SCOPE OF THE CERTIFICATE

EHC for entry into the EU or NI of oocytes and embryos of bovine animals collected or produced after 20 April 2021, and dispatched from the collection centre or production centre where they were collected or produced.

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

3. CERTIFICATION BY AN OV

In **England, Scotland and Wales**, this certificate must be signed by a Government Veterinary Officer (e.g. APHA, FSA or FSS employed veterinary officers) or by an OV appointed by the Animal and Plant Health Agency (APHA) on behalf of Ministers in Defra, the Scottish Government or the Welsh Government and who hold the appropriate Official Controls Qualification (Veterinary) (OCQ (V)) authorisation.

OVs must sign and stamp, with the OV stamp, the health certificate in ink of a different colour to that of the printing of the EHC. There is no requirement to sign and stamp in a specific colour.

The OV should keep a copy of the signed certificate and any supporting documents for at least two years after signature or receipt / dispatch of the consignment, whichever is later. These can be electronic copies.

EHC in foreign language/s of the EU Member States (MSs).

EHC should be in English and the foreign language of the Border Control Post (BCP) of entry in the EU. The original copy of the required EHC must accompany the consignment to the BCP of entry.

Listing of the EU MS BCPs can be found here: https://ec.europa.eu/food/animals/vet-border-control/bip-contacts_en

The foreign language certificate as received from the APHA Centre for International Trade at Carlisle or via the Export Heath Certificates Online system (EHCO) and bearing the same unique reference number as the English certificate, should be considered an official and accurate translations of the English, as published in EU legislation.

The (sub-) paragraphs / options and how they are numbered and formatted is identical in the English and foreign language editions and to the legislation published by the European Commission. Therefore, the same phrases / sentences in the foreign language versions as in the English version should be struck through and these deletions should be stamped and initialled in both versions. Both versions must also be signed (as opposed to being initialled) and stamped by the OV, the foreign language certificate is deemed to be a genuine and properly authorised translation of the English version.

This also applies to any instructions in the guidance notes to strike out certain paragraphs or to certify statements that the country is free of certain notifiable diseases etc.

Additional information can be found in APHA Vet Gateway:

http://apha.defra.gov.uk/External_OV_Instructions/Export_Instructions/Certification_Procedures/index.htm

SIGNING AND STAMPING

When signing a certificate, the CO should ensure that the certificate contains no deletions or alterations, other than those which are indicated on the certificate to be permissible and any corrections to permitted entries, subject to such changes being initialled and stamped (in the margin) by the CO. Permissible deletions are normally indicated in the 'Notes' section at the end of the certificate, with the instruction 'Keep as appropriate' or 'delete if not applicable'.

Where the certificate contains optional or contextual statements, the statements which are not relevant shall be crossed out, individually initialled and stamped by the CO, or completely removed from the certificate.

- Permitted paragraphs and sections may be crossed out by applying a 'Z' across the section or paragraph rather than crossing out line by line.

- There is no requirement for a date and time to accompany each stamp. The date is only entered at the required entry field in Part I of the certificate, and at the end where the CO signs, stamps and dates that action.

- We are aware of some BCPs demanding that all handwritten information in Part 1 of the EHC is initialled and stamped, including handwritten scoring out of otherwise blank boxes. There is no legal requirement in EU legislation that all the hand-written information entered in the certificate must be signed and stamped. It is only in the case of correction, in any part of the certificate, or in the case of statements to be crossed out, that the certifier must add signature (or initials) and stamp. This has been confirmed by the European Commission. The Commission noted however, in the case of a hand-written certificate, it is expected that the same one person completes the document. If not, the BCP might suspect that empty boxes were completed by another person after the certificate has been signed by the official

You should consider checking with the specific BCP regarding their preference when it comes to the stamping and initialling of handwritten scoring out of otherwise blank boxes in Part I of the EHC.

- **Clarification from the European Commission means that all pages (as opposed to sheets of paper) are signed and stamped once individually in place of fan**

stamping and in addition to any permitted alterations. There is no requirement to fan stamp.

- **COs are reminded to consult the NFG prior to the certification of each EHC. NFG will be updated with this new information in due course.**

Further Information COs should make sure they are familiar with all relevant guidance and other documents relating to EHCs and that they discuss requirements with exporters in advance.

See http://apha.defra.gov.uk/official-vets/Guidance/exports/ehc-online.htm

You can also contact the APHA's Centre for International Trade (CIT) on 03000 200 301.

PART I: DETAILS OF THE CONSIGNMENT

All boxes in Part I of the certificate must be completed. When a box is not applicable / optional, and not filled, please score it through.

Please use schedule to be attached to the certificate if there is not enough space to fill the information. See Section 'Addition of Schedules' below.

Please complete all the boxes in Part I of the certificate in accordance with the guidance laid down in Chapter 4 of Annex I to Commission Implementing Regulation (EU) 2020/2235, Amended by Implementing Regulation (EU) 2023/2744.

The Harmonised System (HS) Code is a commodity classification system used as a basis for customs tariffs and for international trade statistics.

It is the exporter's responsibility to ensure that the HS code is entered correctly and accurately reflects the product(s) being consigned.

Further information on HS Codes can be found online at:

https://www.gov.uk/trade-tariff/sections and http://madb.europa.eu/madb/euTariffs.htm

https://www.unece.org/fileadmin/DAM/cefact/recommendations/rec21/rec21_Rev10e_Annex-V-VI_2019.xls

'Test' has been added to I.27. Refer to the guidance within the Notes section for information on how to complete.

PART II: CERTIFICATION

II.1 Animal Health Attestation

The OV signing the EHC must ensure that the animal health information set out in Part II of the health certificate have been complied with.

They must ensure that they are aware of the provisions of Commission Delegated Regulation (EU) 2020/692 and Commission Delegated Regulation (EU) 2020/686 which set out the animal health conditions for trade with and dispatch into the EU or NI of bovine embryos and oocytes. Commission implementing decision (EU) 2020/2215 amending

Annex I to Implementing Decision 2011/630/EU lists the competent authorities of countries approved to collect, process and or store semen in approved semen collection or storage centres that is used to conceive the embryos by artificial insemination.

The OV may also require, where appropriate, support certification and / or evidence from the authorised team veterinarian due to their knowledge of the operations of the establishment, to facilitate certification of the certificate.

II.1.1 - This can be certified based on UK is authorised for entry into the EU of oocytes embryos of bovine animals and listed in Annex IX to Implementing Regulation (EU) 2021/404, repealing Decision 2006/168/EC. This should be checked by the OV.

II.1.2, II.1.3 and II.1.4 –

These can be certified based on the notifiable disease clearance and the fact that vaccination against these diseases is prohibited in the UK (as per section 4 below).

II.1.4 – This can be certified, as vaccination against the diseases listed in II.1.1.4 is prohibited in the UK, and vaccination against the listed diseases is currently prohibited for imports into GB. There are two sub-options: 'Either' and 'or'. 'Either' can be certified, as vaccination against FMD is prohibited in the UK, and vaccination against the FMD is currently prohibited for imports into GB. 'Or' option must be deleted.

GB import requirements can be found on:
https://www.gov.uk/government/collections/health-certificates-for-animal-and-animal-product-imports-to-great-britain

II.2 - This attestation can be signed provided that the embryo collection team complies with requirements as regards to responsibilities, operational procedures, facilities and equipment set out in Part 2 of Annex I to Delegated Regulation (EU) 2020/686 and teams listed in accordance with Article 233(3) of Regulation (EU) 2016/429 on the Commission website:

Semen, Oocytes & Embryos (europa.eu)

II.3, II.4, II.5 and II.6 –

These can be certified by the OV based on support certification from a veterinarian with relevant knowledge of the herd(s) and premises, clinical status and disease status of the animal(s) and operating procedures of the collection team (e.g. certificate from a vet on the approved embryo collection team which collected the embryos). The OV will also base certification on the disease status as per section 4 Notifiable Disease Clearance below.

Only the collecting donor animals must be identified with a 'GB' ISO code as per requirements in Article 21(1) to Regulation 2020/692.

II.3.3 – Can be certified providing there has been no clinical case of enzootic bovine leukosis for at least 3 years prior to the date of collection or production of the oocytes or embryos and during the collection period.

II.4.2 – Donor animals **must be resident in Great Britain for at least 6 months** prior to the date of collection or production of oocytes/embryos.

II.4.7 - II.4.7.1 can be certified based on the notifiable disease clearance as regards bluetongue virus (serotypes 1-24) and support certification from the collection team veterinarian.

II.4.7.2 - shall be deleted as seasonally free disease zone requirements do not apply to GB.

II.4.7.3 - can be certified subject to APHA approval of the vector protected establishment and their verification that measures have been applied effectively throughout the time period required. Vector protection establishment requirements are stipulated in Article 44 and Chapter 3 of Part II of Annex V to Regulation (EU) 2020/686.

II.4.7.4 and **II.4.7.5** - can be certified if the donor animals comply with these testing requirements, against all serotypes (1-24). Support certification and evidence from collection team veterinarian is required.

II.4.8 - Regarding Epizootic Haemorrhagic Disease, the first paragraph of this section may be certified for the time periods specified based on the notifiable disease clearance. All the other paragraphs can be struck out.

II.5, II.6 and II. 7 - The relevant attestations can be certified and, for II.6 the other option deleted. Support certification will be required from the collection team veterinarian.

The ID marking of the straws or other packages must refer to: date of collection or production of oocytes / embryos; species and ID number of donor animals; unique approval number of the establishment as listed on the EU website; and any other relevant information.

Note, the species reference on the straws or other packages maybe referred to by species code, e.g. 'BOV' for bovine. There is flexibility in presenting the species information.

4. NOTIFIABLE DISEASE CLEARANCE

Some export certificates for animals and animal products will include statements that will require the OV to certify that specified zones or the entire country of origin are free from certain diseases.

COs must check the following sources of disease information for the United Kingdom immediately prior to certification, to ensure disease freedom statements can be certified:

- the Notifiable Disease Occurrence List for Great Britain (ET171) available on the Exports > Certification Procedures page of the APHA Vet Gateway

- the UK Status for Non-Notifiable Diseases Relevant to Export Certification (ET152) available on the Exports > Certification Procedures page of the APHA Vet Gateway.

For Great Britain:

In the absence of a specific Notifiable Disease Clearance (618NDC) from CITC: COs may certify that GB has disease free status or region free status for those diseases mentioned in the health certificate, once they have checked the disease list(s) for the last

occurrence of the disease and have ensured it complies with the time frames in the certificate.

In the event of a disease outbreak that affects a CO being able to obtain their own disease clearance, CITC will notify COs to make it clear which disease freedom statements should not be certified and where necessary, will issue a 618NDC notifiable disease clearance if the EHC can continue to be issued for certain regions that retain free status.

In the event of a disease outbreak after the EHC has been issued that affects the disease clearance, COs must not certify the EHC and must contact CITC immediately for advice on whether certification can still take place. If a disease outbreak affects the disease clearance procedures for this EHC, a 618NDC will be reinstated by CITC which will be issued with the EHC until a time when disease clearance can be reinstated.

NOTE: This does not apply to Transmissible Spongiform Encephalopathies (TSEs) or Bovine Tuberculosis (TB) freedom statements.

5. COLLECTION OF EVIDENCE

Certification Support Officers may not be utilised for gathering evidence relating to this certificate.

6. UK APPROVED ESTABLISHMENTS ELIGIBLE TO EXPORT TO THE EU

The exporting establishment must be listed as a 'UK approved establishment' and a list of UK approved establishments for import of germinal products to the EU, can be found on the European Commission's list of approved establishments' link below:

https://ec.europa.eu/food/animals/semen-oocytes-embryos_en

Please note that the list is updated regularly and ONLY establishments on the list are approved to export to the EU, and this does not include establishments with pending applications for approval.

If the final product contains germinal products from other establishments, then these establishments should also be listed as UK and/or EU approved establishments.

7. ADDITION OF SCHEDULES

When the space in Part I or Part II of the certificate is insufficient to accommodate full details of the consignment a schedule may be used. In the relevant section of the certificate the CO should annotate the certificate 'see attached schedule'. A new schedule should be created (typed or clearly written) containing the same information as that required in the certificate. The schedule must include the certificate reference number on each page and must be signed, dated and stamped by the CO in a colour other than the printed text on each page and under the last entry. The schedule forms part of the certificate. All pages of the certificate, including the schedule, must be sequentially numbered. Any blank spaces in the schedule or the certificate should be struck through with diagonal lines.

Further guidance is available here: http://apha.defra.gov.uk/External_OV_Instructions/Export_Instructions/Certification_Procedures/index.htm

8. CERTIFIED COPIES OF EHC

When completing export certification the CO and, if applicable, FCCO must make photocopies of, or scan and save all documents they certify. OVs must retain copies of certification documents in accordance with RCVS Certification principles.

https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/certification/

COs must retain copies of all export documentation for a period of two years. A certified copy of this EHC does not need to be returned to the APHA CITC. For the purposes of completing routine Quality Assurance checks on export certification, CITC may request certified copies of certification from COs.

Further details on Post Certifying Procedures, 'certified copies' of certification and the types of documents that should be retained by COs can be found on the APHA Vet Gateway.

9. LEGAL STATEMENT

The existing EU legislation that the UK complied with prior to the end of the Transition Period has been incorporated into our domestic law as "assimilated EU law" under the EU (Withdrawal) Act 2018. References in our guidance and certification to such EU instruments should be taken to be references to this "assimilated EU law". The EU standards that this legislation includes continue to remain in force, without substantive amendment, as part of UK domestic law (apart from corrections to make the EU legislation fully operable.

10. DISCLAIMER

This certificate and NFG are provided on the basis of information available at the time and may not necessarily comply fully with the requirements of the importing country. It is the exporter's responsibility to check the certificate against any relevant import permit or any advice provided by the competent authority in the importing country. If these do not match, the exporter should contact the APHA in Carlisle.

This publication is available at: https://www.gov.uk/search/all Any enquiries regarding this publication should be sent to us at: farmandgermcarlisle@apha.gov.uk

8402NFG

Version History:

EHC

Part I
I.27: 'Test' added
Part II -
II.1.4: 'either'/'or' options added for vaccination status against foot and mouth disease
II.3.3, **II.3.4** and **II.3.5**: amended to clarify timeframe for disease testing
II.4.7.2: now "*or" option.* Statement is amended and third country zone/territory with approved eradication programme against bluetongue is removed. However, footnote 12 is added which refers to Implementing Regulation 2021/404 for the zone with an entry "SF-BTV".
II.4.7.3: statement is amended by adding "vector-protected establishment". The statement about written consent of the competent authority of the Member States of destination to accept the consignment of oocytes *in vitro* produced embryos, is removed.
II.4.7.4: now "*or"* option. Statement about Vector-protected establishment is removed, which is now covered in the II.4.7.3. II.4.7.5 attestation about serological test to detect antibodies of bluetongue is now II.4.7.4.
II.4.7.6 is now **II.4.7.5.**
II.4.8.2: is now an "or" option. "Vector-protected establishment" is changed to "seasonally disease-free zone"
II.4.8.3: replaces previous **II.4.8.2.**
II.4.8.4: replaces previous **II.4.8.3**.
II.6: Addition of requirements for collection, processing and storage and legislative reference to **Commission Delegated Regulation (EU) 2020/686**
Notes –
Part II- (12) and **(13)**: added to clarify the zones

NFG

Version 5: Published 16 August 2024
Part I: Guidance added for addition of 'Test' to I.27

Version 4: Published 31 July 2024
Applicable Legislation: Implementing Regulation (EU) 2024/351 added

Part I –
Commission Implementing Regulation (EU) 2020/2235, amended by Implementing Regulation (EU) 2023/2744 added
Part II –
II.1.4: added
II.4.7.4: This requirement can be certified subject to APHA approval. This paragraph is amended to reflect that

Version 3: Published November 2023:

II.4.2: Information is added about the donor animal residency for 6 months in the Great Britian prior to the date of collection or production of oocytes/embryos.

II.4.7: Further information is added for **II.4.7.1** about the Bluetongue disease.

I**I.4.7.2 and II.4.7.3**: Clarification is added that seasonally disease-free zone requirements do not apply.

II.4.7.4: This requirement can be certified if the collection team veterinarian can demonstrate that the conditions set out in this point can be met.

II.4.7.5 and/ or II.4.7.6: Further clarity is added about the documentary evidence required by the collection team Veterinarian.

Notifiable Disease Clearance: This paragraph is updated to align with other NFGs.