Department for Environment, Food and Rural Affairs

Notes for guidance: Export Health Certificate for dispatch to the European Union or Northern Ireland of oocytes and embryos of Equine animals collected, processed and stored after 31 August 2010 and before 1 October 2014, and dispatched by an Embryo collection or production team 8430

July 2024

Contents

No: 8430 NFG

EHC for dispatch to the EU or NI of consignments of stocks of stocks of Oocytes and Embryos of Equine animals collected, processed and stored after 31 August 2010 and before 1 October 2014, and dispatched by an Embryo collection or production team where they were collected or produced.

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

1. APPLICABLE LEGISLATION

Regulation (EU) No 2016/429

Delegated Regulation (EU) 2020/686

Commission Delegated Regulation (EU) 2020/692 which lays down the animal health requirements applicable to trade and dispatch into the EU or NI of equine semen, embryo and Oocytes(germinal products)

Commission Implementing Regulation (EU) 2021/403 provides model animal health certificates for semen, oocytes and embryos of equine animals intended for the movement within the Union and entry into the Union.

Commission Implementing Regulation 2021/404

Implementing Regulation (EU)2021/606 as amending Implementing Regulation (EU)2021/405 which establishes the list of third countries and Parts of the territory of third countries from which the entry into the Union of Equidae and of their semen, ova and embryos are authorised

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

Any EU legislation referenced in the certificate must be complied with and EU legislationcan be accessed on the following link. You should ensure you use the latest version: https://eur-lex.europa.eu/homepage.html

Please note that Official Control Regulations 2017/625 have repealed Regulation (EC)No 854/2004, 882/2004 and Directive No 96/23/EC. Please see link:

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0625&from=EN

Consolidated legislation

Consolidated texts, which integrate the basic instruments of Union 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'

IMPORTANT

These notes provide guidance to COs and exporters. The NFG should have been issued to you together with the relevant export certificate applicable to thedispatch to the EU or NI of consignments of stocks of Oocytes and Embryos of Equine animals collected, processed and stored after 31 ugust 2010 and before 1 October 2014, and entered into the union, and dispatched by an Embryo collection or production team by which the Oocytes or Embryos were collected or produced.

TheNFG 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.

[Please note, policies are being reviewed. NFG will be further amended to provide specific guidance. Traders should look at NFGs regularly for any updates]

2. SCOPE OF THE CERTIFICATE

This certificate may be used for applicable to stocks of oocytes and embryos of Equine animals Collected or Produced, Processed and Stored in accordance with Directive 92/65/EEC after 30 September 2014 and before 21 April 2021, and entered into the union after 20 April 2021, and dispatched by an Embryo collection or production team by which the Oocytes or Embryos were collected or produced.

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 (OV) appointed by 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 or NI. 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 the 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/ehconline.htm

You can also contact 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 fillthe information. See Section 'Addition of Schedules' below.

Box I.11 The place of dispatch shall correspond to the embryo collection team or Embryo production team by which the oocytes/embryos were collected / produced, processed, stored and approved in accordance with Article 17(3)(b) of Council Directive 92/65/EEC and listed on the Commission website:

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

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 https://madb.europa.eu/madb/euTariffs.htm

PART II: CERTIFICATION

II. Health information

The OV signing the EHC must ensure that they are aware of the provisions of Council Directive Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos.

II.1.2, II.1.3, II.1.4 and II.1.5 -
These can be certified on the basis of approval of the collection/production team, personal knowledge of the OV and, if necessary, additional evidence obtained from the team veterinarian of the team described in Box I.11. A list of approved ova/embryo collection teams in GB is available here: https://www.gov.uk/government/publications/livestock-and-equine-embryo-collectionapproved-premises

II.1.6.1 - can be certified based on an owner's declaration that the donor mare resided in the UK for the three months prior to embryo/ova collection or was directly imported from the EU during this three month period and on the basis of notifiable disease clearance guidance (section 4 below).

II.1.6.2 - can be certified based on notifiable disease clearance guidance (section 4 below). Vesicular stomatitis has never been identified in the UK.

II.1.6.3 - can be certified on the based on notifiable disease clearance guidance (section 4 below) and written declaration from the owner or agent stating that the donor animals were resident on holdings that met the conditions of Article 4(5) of Directive 2009/156/EC during the time period specified on the certificate. This declaration should be retained by the OV for record purposes.

II.1.6.4 and II.1.6.8 –
These can be certified on the basis of a written declaration from the owner or agent stating the holdings on which the donor was resident during the 60 days, in the case of contagious equine metritis (II.1.6.4) and 15 days, in the case of any infectious or contagious disease (II.1.6.8), prior to the collection of ova/embryos and statements as necessary from the veterinary surgeons responsible for these premises stating that the donor animal and other contact equidae comply with the requirements of these attestations. This declaration should be retained by the OV for record purposes.

II.1.6.5 - can be certified on the basis of a written declaration from the owner or agent that donor animals were not used for natural breeding at least 30 days prior to collection of embryos and during the time period between testing and collection specified on the certificate. The validity of this declaration should be checked against available breeding records. This declaration should be retained by the OV for record purposes.

II.1.6.6 and II.1.6.7 -
These require specific disease testing for CEM and EIA to be carried out. These tests must be carried out a UK accredited laboratory that meets relevant ISO standards for such tests (currently APHA lab in Weybridge). This may be certified based on written declaration from the team veterinarian responsible for collection of the ova/embryo. This declaration should be retained by the OV for record purposes.

II.1.6.9 - can be certified on the basis that approved collection teams must comply with this requirement. If necessary, veterinary records can be sought from the ova/embryo collection team.

II.1.7 and II.1.8 - can be certified on the basis of approval of the collection/production team, personal knowledge of the OV and, if necessary, additional evidence obtained from the team veterinarian of the team described in Box I.11. A list of approved ova/embryo collection teams in GB is available here: https://www.gov.uk/government/publications/livestock-and-equine-embryo-collectionapproved-premises

II.2 - does not apply to ova. Embryos must be conceived by artificial insemination or in vitro fertilisation only. The list of approved semen collection centres in Great Britain is available here: https://www.gov.uk/government/publications/livestock-and-equine-semen-collection-approved-premises

II.3 - delete if none of the embryos in the consignment was produced by in vitro fertilisation of ova or if the consignment contains ova only.

4. NOTIFIABLE DISEASE CLEARANCE

For guidance on certifying paragraphs relating to Avian Influenza (AI) see APHA guidance for "COs Obtaining Clearance for AI" available here:

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

COs (OVs and Environmental Health Officers (EHO)) can certify certain disease clearances paragraphs within this EHC, on behalf of the Department, provided written authority to do so has been provided/obtained on form 618NDC from APHA's Centre for International Trade – Carlisle (CITC).

The clearance will be provided by CITC on form 618NDC. It will specify the statements on the certificate that it covers and is only in relation to the official GB disease status specified in the relevant paragraphs. All other matters such as residency, vaccination status, status of premises in respect of other diseases not covered by the 618NDC and disease status of countries, areas, premises outside the UK, are for the CO to check and verify, obtaining support certification where necessary including support certification for products of animal origin that have originated in NI.

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 informationas 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 black 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 EHCs

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 already complies with will be 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 bereferences to this “assimilated EU law”. Under the Withdrawal Act we will ensure that current EU standards remain in force, without amendment, in the immediate months after our EU exit as part of UK domestic law (apart from corrections to make the EU legislation fully operable).

10. DISCLAIMER

This certificate is 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 APHA in Carlisle.

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

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Version History:

EHC

Notes -
I.11: guidance on 'place of dispatch' expanded
I.12: guidance on 'place of destination' added
I.27: expanded to explain: 'type', 'identification number', 'identification mark', 'date of collection/production', 'approval or registration number' and 'quantity'

NFG

Version 2: 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