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 ovine and caprine animals collected or produced before 21 April 2021, and dispatched from a collection centre 8424

July 2024

Contents

No: 8424NFG

EHC for entry into the EU or NI of oocytes and embryos of ovine and caprine animals collected or produced, processed and stored in accordance with Directive 92/65/EEC before 21 April 2021, and dispatched by an embryo collection or production team by which the oocytes or embryos were collected or produced.

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

1. APPLICABLE LEGISLATION

Commission Decision 2010/472/EU as amended

Council Directive 92/65/EEC as amended

Council Directive 91/68/EEC

Regulation (EC) No 999/2001

Regulation (EU) No 2016/429

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

Implementing Regulation (EU) 2021/404

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

Further guidance for completion of this certificate can be found in Chapter 4 of Annex I to Commission Implementing Regulation (EU) 2020/2235.

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'.

IMPORTANT

These notes provide guidance to COs and exporters. The NFG should have been issued to you together with the relevant export certificate for entry into (and transit through) the EU or NI of consignments of oocytes and embryos of ovine and caprine animals collected or produced, processed and stored in accordance with Directive 92/65/EEC before 21 April 2021 and entered into the EU after 20 April 2021, and dispatched by an embryo collection or production team by which the oocytes or embryos were collected or produced.

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 EHC may be used for dispatch of consignments of ova and embryos of animals of ovine and caprine species collected or produced before 21 April 2021, under Directive 92/65/EEC, to (and including transit through) the EU or NI.

Dispatchments of ovine/caprine ova and embryos to the EU or NI must be collected by approved collection/production teams in accordance with Council Directive 92/65/EEC (as amended). Certifying veterinarians must be familiar with the provisions of this Directive

The ova/embryos MUST be collected from ovine and caprine animals from holdings that meet the requirements of Council Directive 91/68/EEC.

Ovine and caprine embryos dispatched to the EU or NI must meet the requirements in Chapter H of Annex IX of Regulation (EC) No 999/2001.

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 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.

The RCVS Certification principles must be complied with.

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

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 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/ehc-online.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 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

PART II: CERTIFICATION

II.1 Health information

The ova/embryos must meet the conditions in Chapter (I), Chapter (II) and Chapter (III) of Annex D to Directive 92/65/EEC. In the case of embryos, the semen used for conception must have been collected in an EU approved semen collection centre that is located in an EU MS or a listed third country; in the latter case, the semen must also meet the animal health requirements for the dispatch of semen to the EU or NI (see 8209EHC/NFG and 8210EHC/NFG).

The donor animals must comply with the conditions in Directive 91/68/EEC, as amended and have been kept on holdings meeting the requirements for classical scrapie.

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

II.1 – Enter the territory code. The ova/embryos must be obtained from donor animals originating from a third country, territory or zone which is listed in Annex X to Implementing Regulation (EU) 2021/404 (as amended).

II.1.1 – This can be certified on the basis of disease status as per Section 4 Notifiable Disease Clearance below and considering that routine vaccination against rinderpest, peste des petits ruminants, sheep and goat pox, contagious caprine pleuropneumonia and Rift Valley fever are not permitted in the UK in the absence of outbreak of these diseases.

II.1.2 – The first attestation may be certified based on disease notification (as per Section 4 Notifiable Disease Clearance below) for the specific time period, which is 12 months immediately prior to collection and on the basis that routine vaccination against FMD in the absence of FMD occurrence is not permitted in the UK. Where there has been an outbreak of FMD in the specified time period, further evidence should be sought to certify the second attestation of II.1.2.

II.2.1 and II.2.2 – This can be certified based on the disease status as per Section 4 Notifiable Disease Clearance below.

II.2.3 and II.2.4. – This can be certified on the basis of approval of the embryo collection and/or production teams for trade in embryos and ova of domestic animals (Directive 92/65/EEC) and support certification from the team veterinarian. Please refer to listing of approved establishments of germplasm collection/ production on the Gov.uk website: https://www.gov.uk/government/publications/livestock-and-equine-embryo-collection-approved-premises

or here: https://ec.europa.eu/food/animals/semen/ovine_caprine_en

II.2.5.1 – The first option can be certified where the donor females have been resident in the UK for the time period listed (based on owner's declaration, movement records, declarations

from the veterinary practitioner responsible for the flock/herd, import certification where appropriate, etc.) and where UK freedom has been ascertained by the disease notification process as per section 4. Where this is not the case, further evidence will be required to certify an alternative attestation. Please note there have been no vector-protected collection centres approved in GB prior to 21 April 2021.

II.2.5.2 – The appropriate statement for attestation (d) should be certified and the other option deleted.

In Great Britain, some of these diseases are not officially notifiable at the time of writing. Contagious agalactia is a notifiable disease in GB so premises freedom can be obtained by undertaking the checks as described in Section 4 Notifiable Disease Clearance below. Also, premises freedom for the other non-notifiable diseases can be certified based on the owner's declaration and veterinary certification in the ovine / caprine semen / embryo SUP along with a 618 NDC issued by the Centre for International Trade. The SUP and 618 NDC should be obtained at the time of collection of ova/embryos. NOTE – this 618NDC only confirms that no diagnosis of these diseases has been made by an APHA or SRUC lab, following submission of samples from suspect cases, during the period specified. It does NOT confirm that the disease has not been clinically diagnosed on the premises.

If animals originate from a holding in NI, the attestations (point (a) and (d)) regarding MV/CAE and Contagious agalactia freedom can be certified as NI was free of MV/CAE and Contagious agalactia (Contagious agalactia is a notifiable disease in NI) prior to the date of collection of ova/embryos. The OV may seek further assurances if required.

http://www.daera-ni.gov.uk/articles/maedi-visna-mv

II.2.5.3 - Can be certified on the basis that the ova/ embryos were collected by approved teams/centres. Additional evidence may be sought from the collection team veterinary surgeon.

II.2.5.4 – Where ova/embryos come from donor sheep/goats which originate in the UK the first attestation may be certified on the basis of recognition of official brucellosis free status (Regulation (EU) 206/2010). Otherwise, the appropriate attestation may be selected on the basis of evidence of legal importation to the UK from the Health Certificate which accompanied the sheep/goats.

II.2.5.5 - The OV should ensure there is available evidence and information from the team veterinarian (e.g. owner's declaration, movement records, declarations from the veterinary practitioner responsible of the flock/herd, import certification where appropriate, etc) that confirms the donor complied with one of the two options available and the appropriate attestation certified.

II.2.5.6 – Where the donor female has been kept continuously since birth in the UK, this section can be certified on the basis of the UK's compliance with Regulation 999/2001 and an owner's declaration confirming UK residency. Where the donor female has resided in another country, this section can be certified based on evidence of legal importation. Please refer to the Scrapie Statement in section 7.

If selecting scrapie scheme option, attestation implies the animal must be at least 3 years old, no "or since birth" option is provided. If the animals originate from NI then this can be certified if the animals are at least 3 years old and originate from holdings with Negligible or

Controlled Risk of Classical Scrapie and are listed as such through membership of the DAERA Scrapie Monitored Flock Scheme (SMFS):

https://www.daera-ni.gov.uk/articles/scrapie

II.2.6 – The first attestation can be certified based on UK's disease status as per Section 4 below.

II.2.7 – To certify this, please refer to the list of approved embryo collection teams on the Gov.uk website: https://www.gov.uk/government/publications/livestock-and-equine-embryo-collection-approved-premises

and EU Website here: https://ec.europa.eu/food/animals/semen/ovine_caprine_en

For further clarification, please contact APHA's Centre for International Trace, Carlisle in GB.

II.2.8 - May be certified on the basis of approval of the ova/embryos collection/production teams (https://www.gov.uk/government/publications/livestock-and-equine-embryo-collection-approved-premises) and provided date of collection/production is at least 30 days prior to export.

II.2.9 - Council Directive 92/65/EEC requires the ova/embryos to be transported in containers which have been cleaned and disinfected or sterilised before use and which have been sealed and numbered before dispatch. The number marked on the straws, ampoules or other packages must coincide with the number on the container in which they are transported and the number on the health certificate.

II.2.10 – This applies to embryos only, delete entire section if ova being certified. Delete non applicable method of production. The OV must ascertain the source of the semen and confirm whether the semen collection centre is approved. UK approved semen collection centres should be checked on the Gov.uk website: https://www.gov.uk/government/publications/livestock-and-equine-semen-collection-approved-premises

and EU website:

https://ec.europa.eu/food/animals/semen/ovine_caprine_en

If the semen is from a collection centre outside of the UK, evidence such as import health certification must be sought to confirm eligibility for certification of this.

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 FOR 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. ANIMAL HEALTH SCHEME

Scrapie Statement

Relevant scrapie text can be certified on the basis that the UK implements a Scrapie Monitoring Scheme (SMS), provided by the SAC Consulting: Premium Sheep and Goat Health Schemes (part of Scotland's Rural College (SRUC). Scrapie is a notifiable disease in the UK and Scrapie control is enforced under the TSE Regulation 2018 (England and Wales) and TSE Regulation 2010 (Scotland).

Holdings with Controlled or Negligible Risk of Classical Scrapie are listed on the SAC and along with a valid certificate of membership, provides robust evidence that the holding complies with the requirements at point 1.2 of Section A of Chapter A of Annex VIII to Regulation (EC) No 999/2001.

ARR/ARR genotype sheep, can be certified if the sheep are of the ARR/ARR prion protein genotype as defined in Annex I to Commission Decision 2002/1003/EC and their holding of origin is not subject to any official – e.g. CSFS - restrictions for classical scrapie. If such restrictions are in place, certification of ARR/ARR sheep for trade is not allowed. If unsure as to whether the holding is under such restrictions, the OV may contact the local APHA office or CIT Carlisle.

The genotyping must be either carried out at an APHA laboratory or SAC / SRUC OR the individual sheep must have a genotyping certificate issued under the National Scrapie Plan (NSP) or the Compulsory Scrapie Flocks Scheme (CSFS) by a laboratory which is / was authorised by the government to carry out genotyping under the plan/scheme.

Any such genotyping certificates issued under the scheme/plan before it/they closed remain valid, but the OV must ensure that the identification of the animal as recorded on the genotyping certificate correlates with the official ear tag on the animal as recorded on the EHC; if only the electronic identification number is recorded on the genotyping certificate, then the OV must scan and check the electronic identification of the sheep to confirm correlation between the certificate, the sheep and the official ear tag number on the Certificate. Unless genotyping was carried out officially under the NSP or CSFS, all blood samples for genotyping must be taken by a veterinary surgeon.

8. 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

9. 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.

10. 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.

11. 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 APHA in Carlisle.

This publication is available at Search - GOV.UK (www.gov.uk) Any enquiries regarding this publication should be sent to us at farmandgermcarlisle@apha.gov.uk

PB 8424 NFG

Version History:

EHC

Notes -
Box I.6, I.21 and **I.22** removed
Reference I.11: further detail added
Reference I.27: further detail added
Part II - (8): legislative reference amended to Implementing Regulation (EU) 2021/404

NFG

Version 4: Published 31 July 2024
Applicable Legislation: Implementing Regulation (EU) 2024/351 and Implementing Regulation (EU) 2021/404 added
Part I: Commission Implementing Regulation (EU) 2020/2235, amended by Implementing Regulation (EU) 2023/2744 added
Part II – **II.1** Guidance expanded
Part II – II.2.5.1: expanded

Version 3 Published November 2023
Notifiable Disease Clearance: This paragraph is updated to align with other NFGs.