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, after 20 April 2021, and dispatched from the collection centre 8405

November 2023

Contents

No: 8405 NFG

Export health certificate for dispatch to the European Union or Northern Ireland of consignments of oocytes and embryos of ovine and caprine animals collected or produced, processed and stored in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/692 after 20 April 2021 and dispatched by an embryo collection or production team by which the oocytes or embryos were collected or produced.

NOTES FOR GUIDANCE FOR THE CERTIFYING OFFICERS AND EXPORTERS

1. APPLICABLE LEGISLATION

Regulation (EU) No 2016/429

Commission Delegated Regulation (EU) 2020/692

Commission Delegated Regulation (EU) 2020/688

Commission Implementing Regulation (EU) 2020/999

Commission 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 European 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 European Union'.

IMPORTANT

These notes provide guidance to Certifying Officers and exporters. The NFG should have been issued to you together with the relevant export certificate applicable for oocytes and embryos of ovine and caprine 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.

[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 export health certificate may be used for entry into the European Union or Northern Ireland of oocytes and embryos of ovine and caprine animals collected or produced, processed and stored in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/692 and Delegated Regulation (EU) 2020/686 after 20 April 2021 and dispatched from the collection centre where they were collected or produced.

3. CERTIFICATION BY AN OFFICIAL VETERINARIAN (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 Official Veterinarian (OV) appointed by the Animal and Plant Health Agency 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 Export Health Certificate (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 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 Notes for Guidance 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 Animal and Plant Health Agency'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 lay down on the footnotes of the EHC itself.

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 Official Veterinarian signing the export health certificate must ensure they are aware of the provisions of all the relevant regulations (Please see Part I), and subsequent amendments, detailed in the entirety of the EHC, which lay down the animal health and oocyte/embryo collection, processing and storage requirements, which permit the entry into the European Union of consignments of oocytes/embryos of Ovine and Caprine animals.

The Official Veterinarian 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.1.1 - This can be certified as the UK is authorised for entry into the European Union of oocytes embryos of ovine and caprine animals and listed in Annex X to Implementing Regulation (EU) 2021/404.

II.1.2; II.1.3, II.1.4 - This 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.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:

https://www.gov.uk/government/publications/livestock-and-equine-embryo-collection-approved-premises

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

II.3 to II.5 – This 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.

II.3 - This can be certified based on the disease status as per Section 4 Notifiable Disease Clearance below.

II.4.1 - This can be certified by taking into account the disease status as per Section 4 Notifiable Disease Clearance below and 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.4.2 - The OV must ensure there is available evidence from the team veterinarian (i.e. 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 the appropriate attestation certified.

II.4.5 - 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.4.7 - I**I.4.7.1** can be certified based on the notifiable disease clearance and support certification from the collection team veterinarian.

II.4.7.2 and **II.4.7.3** - shall be deleted as seasonally free disease zone requirements do not apply to GB.

II.4.7.4 - can be certified if the collection team veterinarian can demonstrate vector protection requirements have been met as equivalent to the requirements stipulated in Part F of Annex XII to Regulation 2020/692 for confined establishments. Support certification and evidence from the collection team veterinarian is required.

II.4.7.5 and/or **II.4.7.6 -** can be certified if the donor animals comply with the testing requirements. Support certification and evidence from the 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.4.9 – This section can be certified by the OV, on the basis of the scrapie related controls in place in the UK.

The first attestation in this section may 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 Scrapie Monitoring Scheme (SMS) (see section 7). 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

The second attestation in this section may 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 scrapie. If such restrictions are in place, movement of such sheep, including for trade, will not be allowed (see section UK Animal Health Scheme below).

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 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. ‘OVI’ for ovine or ‘CAP’ for caprine. 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.

8. 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.

9. 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

10. CERTIFIED COPIES OF EXPORT HEALTH CERTIFICATES

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.

11. 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 "retained EU law" under the European Union (Withdrawal) Act 2018. References in our guidance and certification to such EU instruments should be taken to be references to this "retained 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

12. 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 Animal and Plant Health Agency (APHA) in Carlisle.

© Crown copyright 2021

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v.3. To view this licence visit Open Government Licence (nationalarchives.gov.uk) or email PSI@nationalarchives.gsi.gov.uk

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

8405NFG

Version History
NFG

Version 4: Published 27 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 with to align with other NFGs.