Department for Environment, Food and Rural Affairs

Notes for Guidance: Export Health Certificate for entry into the European Union or Northern Ireland of equine animal semen collected after 20 April 2021, and dispatched from the semen collection centre 8407

August 2024

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8407NFG

EHC for entry into the Union of consignments of semen of equine animals collected, processed and stored in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/692 after 20 April 2021, and dispatched from a semen collection centre where the semen was collected, including when the Union is not the final destination of the semen.

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

1. APPLICABLE LEGISLATION

Regulation (EU) 2016/429 on transmissible animal diseases (the 'Animal Health Law').

<u>Delegated Regulation (EU) 2020/686</u> as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals.

<u>Delegated Regulation (EU) 2020/692</u> supplementing Regulation (EU) 2016/429 as regards the rules for entry into the Union of certain animals, germinal products and products of animal origin.

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

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

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

You should ensure you use the latest version.

Please note that Official Control Regulations 2017/625 have repealed Regulation (EC) No 854/2004, 882/2004 and Directive No 96/23/EC.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

http://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 for entry into the Union or transit through the Union of consignments of semen of equine animals collected, processed and stored in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/692 after 20 April 2021, and dispatched from a semen collection centre where the semen was collected. 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 EHC may be used for dispatch to and transit through the EU or NI of semen of domestic animals of the equine species collected, processed and stored in accordance with the applicable legislation mentioned above. The semen must be collected in accordance with the relevant conditions in Annex I to Delegated Regulation (EU) 2020/686.

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.

The equine animals from which the semen is collected must wholly satisfy the detailed health requirements contained in the Animal Health Certificate.

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.

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 translation 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 <u>signed</u> (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

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

PART II: HEALTH INFORMATION

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

The OV signing the EHC must ensure that they are aware of the relevant regulations (see Part I), and subsequent amendments, which lay down the animal health and semen collection, processing and storage requirements, which permit the entry into the EU or NI of consignments of semen of equine animals.

The OV may also require, where appropriate, support certification and/or evidence from the authorised centre veterinarian due to his/her knowledge of the operations of the establishment and / or written declarations from the owner as appropriate, to facilitate certification of the certificate.

II.1.1.1 - This can be certified based on the knowledge that the semen was obtained from donor animals originating from a third country, territory or zone which is listed in

Annex XII to Commission Implementing Regulation (EU) 2021/404.

Further information on the new reporting requirements can be found here:

http://apha.defra.gov.uk/documents/news/New-disease-reporting-requirements.pdf

II.1.1.2, II.1.1.3, II.1.2.1, II.1.2.2 and II.1.2.3 –

These can be certified based on the Notifiable Disease Clearance as per Section 4 below. The OV may also require, where appropriate, support certification and / or evidence from the authorised centre veterinarian due to their knowledge of the operations of the establishment, to facilitate certification of the certificate.

II.2.

II.2.1, II.2.2, II.2.3 and II.2.4 -

These can be certified based on the Notifiable Disease Clearance as per section 4 below. The OV may also require, where appropriate, support certification and / or

evidence from the authorised centre veterinarian due to their knowledge of the operations of the establishment, to facilitate certification of the certificate.

II.3.

II.3.1. and **II.3.2.** - can be certified based on proof that the Semen Collection Centre is an approved and listed establishment (see section 6 below 'UK approved establishments for export to the EU').

Please refer to listing of approved establishments 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-oocytes-embryos/equine en

1.4

- **II.4.1.** and **II.4.2** may be certified as vaccination against AHS and VEE is prohibited in the UK.
- **II.4.3.** This can be certified based on support certification by the Centre veterinarian, clinical records and official movement records.

II.4.4. , **II.4.5.** , **II.4.6.** , **II.4.7.** -

These can be certified based on notifiable disease clearance and on support certification by the Centre Veterinarian.

- **II.4.8.** can be certified on the basis of the CO witnessing documentary evidence or on the basis of support attestations provided by the centre veterinarian.
- **II.4.9.1**, **II.4.9.2**, **II.4.9.3**. Cross out the programmes that do not apply to the consignment. At least one of the programmes must apply.

A declaration from the semen collection centre veterinarian will be required to certify compliance with the requirements of the relevant test programme(s) and to enable the information relating to the dates samples were collected for the various diseases to be provided in the table at the bottom of the certificate (II.4.8. and II.4.10. refer).

Further detail on the three programmes is provided below:

Programme 1 (II.4.9.1.): For donors which are continuously resident on the centre and no equidae on the semen collection centre come into direct contact with equidae of lower health status than the donor stallion: one set of samples taken at least 14 days after commencement of the minimum 30 days residency required prior to first collection of the season. If the stallions remain on the centre until the next breeding season, they must be tested again before the start of the season. If semen collected under this programme is frozen, it must be held / stored for at least 30 days prior to export.

Programme 2 (II.4.9.2.): For donors stallions which are resident (have complied with the 30 days residency prior to first collection) but which may leave the centre under the responsibility of the centre veterinarian for a continuous period of less than 14 days during the collection period or if other equine animals in the semen collectin centre came into direct contact with equine animals of a lower health status: two or more sets of samples taken; the first set taken as per programme 1 above, the second / further sets in such a way as to ensure that the donor stallion has been sampled and tested prior to semen collection as follows (depending on the disease): within 90 days for EIA, within 30 days (if a SNT is carried out on blood, with negative results) or within 6 months (provided the SNT carried out on blood is positive AND the VI/PCR carried out on semen is negative) for EVA and within 60 days for CEM. In essence, if the donors are not being collected from on a continuous basis, they no longer have to be sampled / tested regularly at the above intervals. If semen collected under this programme is frozen, it must be held / stored for at least 30 days prior to export.

Programme 3 (II.4.9.3.): Two or more sets of samples, the first taken prior to the first collection of the season, the second / further sets between 14 and 90 days after last collection of semen intended for export. In essence, donors will need to be sampled / tested within a maximum of 90 days after semen intended for export has been collected. The donors do not have to be resident on the centre for 30 days prior to the first collection of the season, and although they can be sampled at the home stables by a private veterinarian, the samples MUST be submitted to an official laboratory (see below) for testing. The test results (which should fully identify the horse/s in question) should be provided to the centre veterinarian as evidence that this particular requirement has been complied with. Frozen semen must have been stored in approved conditions for at least 30 days prior to certification and the results of these tests must be available and satisfactory.

IMPORTANT - Mix of Programmes/ Other Equidae at the Centre

It should be borne in mind that if a centre chooses to follow a mix of programmes and / or have other equidae on the centre (e.g. resident or walk-on mares), then the protocol to be adopted must address any attendant risks. Generally speaking, compliance with the EU requirements for trade in breeding equidae and pre-breeding season sampling / testing, as recommended by the HBLB code, will be necessary. Travelling donor stallions from which semen is intended for trade must comply with one of the three programmes, although only programme 3 is likely to be practical. The following are examples (not exhaustive) of how risks may be mitigated: If a centre chooses to collect fresh semen in accordance with programme 1 from some stallions and frozen semen in accordance with programme 3 from the others with which there is or likely to be direct (nose-to-nose or skin) contact, then the donors for the latter will need to undergo a 30 days' residency in isolation and sampled 14 days after commencement of residency / isolation, or the donors for the former should follow programme 2. This assumes that the centre or any horses resident on or entering the centre are not subject to restrictions for notifiable diseases – see paragraph 4 below - especially those which could be transmitted by vectors (eg EIA, equine encephalomyelitis). If other equidae (e.g. resident or walk-on mares) are present within the curtilage of the centre AND the donor stallions are likely to come into direct contact with them (donor stallions cannot be used for natural breeding in any case while on the centre), the other equidae could undergo the protocol set out in programme 1 and

be considered of equal health status. This will require isolation for 30 days (resident mares only), collection of a set of samples as per programme 1 (although sampling sites for CEM in mares will be different and the HBLB code should be followed for this) and testing with satisfactory results (for EVA in mares, where serology is the only option available, positive results are considered satisfactory as long as they are stable or declining in two sequential blood tests taken at an interval of at least 14 days). The tests could be performed at any laboratory approved under the HBLB code. These equidae could be deemed to be of equal health status i.e. the second / further set of samples is not required (in effect meaning that programme 1 can be followed).

II.4.10. - This can be completed by filling in the table of information for the health tests performed. The instructions for the completion of the table in Part II of the EHC should be followed.

II.5. and II.6. - These may be certified on the basis of support certification from the centre veterinarian. The ID marking of the straws must refer to: date of collection or production of semen, 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 maybe referred to by species code, e.g. 'EQUI' for equine. There is flexibility in presenting the species information.

II.6. - Can be deleted if not applicable. If applicable, OV needs to insert the name(s) of the antibiotic(s) added and its concentration or the commercial name of the semen diluent containing antibiotic(s), as required per footnote (8).

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

When completing export certification the CO 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 <u>APHA Vet</u> <u>Gateway</u>.

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 APHA in Carlisle, via the link below:

https://www.gov.uk/government/organisations/animal-and-plant-health-agency

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Any enquiries regarding this publication should be sent to us at: equineexportscarlisle@apha.gov.uk

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Version History:

EHC

II.27: 'Test' added

II.1.1.2: removal of notifiable diseases

II.1.1.2: replaces previous II.1.1.3

II.1.1.3: replaces previous **II.1.1.4** and is expanded to include date of collection of the semen

II.1.2.2: replaces previous II.2.2

II.1.2.3: replaces previous II.2.3; now refers to Surra

II.2.1: amended to clarify timeframe for disease testing

II.2.3: sentence on reporting of equine infectious anaemia in preceding 90 days removed

II.6: worded amended and listing of specific antibiotics removed

NFG

Version 4: Published 16 August 2024

Part I: Guidance added for addition of 'Test' to I.27

Version 3: 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 - Guidance on II.1.1.2 and II.1.1.3 moved to following paragraph on II.1.2.1,

II.1.2.2 and II.1.2.3

II.6: added