Department for Environment, Food and Rural Affairs

Notes for Guidance: Health certificate for dispatch to the EU or NI of consignments of stocks of semen of equine animals collected, processed and stored after 31 August 2010 and before 1 October 2014, and dispatched from a semen collection centre. 8428

July 2024

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No: 8428 NFG

EHC for dispatch to the EU or NI of consignments of stocks of semen of Equine animals collected, processed and stored after 31 August 2010 and before 1 October 2014, and dispatched from a semen collection centre where the semen was collected.

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

### 1. APPLICABLE LEGISLATION

Regulation (EU) No 2016/429

Commission Implementing Regulation (EU) 2018/659

Delegated Regulation (EU) 2020/686

Commission Delegated Regulation (EU) 2020/692

Implementing Regulation (EU)2021/606 as amending Implementing Regulation (EU)2021/405

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

#### Commission Implementing Regulation (EU) 2021/404

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

Please note that Official Control Regulations 2017/625 have repealed Regulation (EC) No 854/2004, 882/2004 and Directive No 96/23/EC.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 for dispatch to the EU or NI of consignments of stocks of semen of Equine animals collected, processed and stored after 31 August 2010 and before 1 October 2014, and entered into the union 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

EHC for dispatch to the EU or NI of consignments of stocks of semen of Equine animals collected, processed and stored in accordance with <u>Regulation (EU) No 2016/429</u> after 31 August 2010 and before 1 October 2014, and entered into the union after 20 April 2021, and dispatched from a semen collection centre where the semen was collected.

#### 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: <u>https://ec.europa.eu/food/animals/vet-border-control/bip-contacts\_en</u>

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 <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\_Procedur es/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 handwritten 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 <u>Commission Implementing Regulation (EU) 2020/2235</u>, Amended by <u>Implementing Regulation (EU) 2023/2744</u>.

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. 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 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** - This can be certified based on the Approval of semen collection Centre in which the Semen described in Part 1 was collected, processed and stored for export to the Union was approved and supervised by the competent authority in accordance with the conditions of Article 230,233 and 234 of Regulation (EU) 2016/429 which repealed Directive 92/65/EEC. Approved semen collection centres listed in accordance with Regulation (EU) 2016/429 (Reapled Directive 92/65/EEC,) on the Commission website: https://ec.europa.eu/food/animals/semen/equine\_en.

GB Approved premises: <u>https://www.gov.uk/government/publications/livestock-and-equine-embryo-collectionapproved-premises/equine-embryo-collection-and-production-teams</u>

### II.2 and II.2.1 -

These paragraphs can be certified on the basis of UK notifiable disease clearances that African horse sickness, Venezuelan equine encephalomyelitis and dourine have never been present in the UK, and glanders has not been present since 1928.

#### II.2.2 and II.2.2.1 -

These can be certified on the basis of UK notifiable disease clearances that the semen collection centre, the holdings of origin in the UK, would not maintain E U approval, unless the stated requirements laid down in Article 4(5) of <u>Directive 2009/156/EC</u> and in particular the listed diseases are all notifiable and not present in the UK for the last 6 months. In the case of animals which have not been in the UK for the last 6 months a written declaration from the owner, supported by a copy of the import certificate, will be needed to check where the animals have come from and the disease status of those regions. The first attestation should be certified as the control measures adopted should any of the diseases be confirmed will reflect what is in this attestation. The attestation essentially means that the holding of origin must not be under any official prohibitions because of the diseases in question. Prohibitions may last for as long as 6 months after the last case has been recorded or slaughtered, depending on the disease, so if in doubt, the centre veterinarian or certifying OV should contact CSC in Carlisle if necessary, to confirm the position.

**II.2.3** - can be certified as written as the diseases are notifiable in the UK and freedom is required for the centre to maintain EU approval. equine viral arteritis and contagious equine metritis.

**II.3.1** - can be certified based on an owner's declaration that the animal has resided in the UK for the last three months. If this is not the case a written declaration will be needed by the owner, supported by a copy of the import health certificate, to check where the animals have come from and disease status of these holdings.

**II.3.2** - can be certified based on the fact that the vesicular stomatitis has never been present in the UK.

**II.3.3** - can be certified based on an owner's declaration that the animal originated from holdings in the UK and have been in the UK for the last 6 months as these diseases are all notifiable and not present in the UK. In the case of animals which have not been in the UK for the last 6 months prior to admission into the centre, a written declaration from the owner, supported by a copy of the import health certificate, will be needed to check where the animals have come from and the disease status of these regions. The centre veterinarian should be asked to verify the evidence presented if in doubt.

**II.4.1** - can be certified on the basis that an EU approved semen collection centre needs to comply with this requirement. If necessary, veterinary records can be sought from the semen collection centre.

**II.4.2** - can be certified on basis that an EU approved semen collection centre needs to comply with this requirement and that EVA and CEM are notifiable in the UK.

**II.4.3** - can be certified based on a declaration from the semen collection centre where the stallions were not used for natural mating during a period of at least 30 days prior to the date of first semen collection and between the dates of the first sample referred to in points II.4.5.1., II.4.5.2. and/or II.4.5.3. and until the end of the collection period.

**II4.4** - can be certified based on personal knowledge of the OV and supporting evidence from the centre Veterinarian that the donor animals underwent the following tests, which meet at least the requirements of the relevant Chapter of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of WOAH, carried out in a laboratory which is recognised by the competent authority and has the tests referred to hereinafter included in its accreditation equivalent to that provided for in Article 12 of Regulation (EC) No 882/2004. As set out on the paragraphs II.4.4.1., II.4.4.2., II.4.4.3.

#### II.4.5.1, II.4.5.2 and II.4.5.3 -

Cross out the programmes that do not apply to the consignment. At least one of the test 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.4.4 and II.4.6 refer).

Further detail on the three programmes is provided below:

*Programme 1 (II.4.5.1):* 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.4.5.2):* For donors stallions which are resident (have complied with the 30 days residency prior to first collection) but which may leave the centre for less than 14 days at a time and/or if other Equidae of a lesser health status are allowed onto the centre and come into direct contact with donors stallions: two or more sets of samples, 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.4.5.3):* 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/testingas 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 donorsfor 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 above - especially those which could be transmitted by vectors (e.g. 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 andbe considered of equal health status. This will require isolation for 30 days (resident maresonly), 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 withsatisfactory 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 sequentialblood tests taken at an interval of at least 14 days). The tests could be performed at anylaboratory 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 meaningthat programme 1 can be followed).

**II.4.6** - can be completed by deleting the VS column and filling in the table of information for the health tests performed. The test programme column refers to which of II.4.5.1/ II.4.5.2/ II.4.5.3 applies. There are two rows per semen sample for EIA, EVA, and CEM columns. The upper of the two rows should be used for dates when samples were taken for laboratory testing prior to first collection of semen. The lower of the two rows should be used for dates when samples were taken for dates when samples were taken for repeat laboratory testing as required in accordance with II.4.5.2 or II.4.5.3, where either of these apply.

**II.5** - can be certified / filled in on the basis of a declaration from the semen collection centre veterinarian whether they used antibiotics or not

**II.6.1 and II.6.2 -** can be certified on the basis of the approval of the semen collection centre. The main requirements of the approval is to collect and produce the semen described in Part I.

### 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 information as that required in the certificate. The schedule must include the certificate reference number on each pageand must be signed, dated and stamped by the CO in a colour other than blackon each page and under the last entry. Any blank spaces in the schedule or the certificateshould be struck through with diagonal lines.

 Further
 guidance
 is
 available
 here:

 http://apha.defra.gov.uk/External\_OV\_Instructions/Export\_Instructions/Certification\_Proce
 dures/index.htm

# 8. <u>CERTIFIED COPIES OF EHCs</u>

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-professionalconduct-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 Gateway</u>.

# 9. <u>LEGAL STATEMENT</u>

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.

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PB 8428

# Version History:

EHC

Notes -

I.12 added for guidance on 'place of destination'

**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