Department for Environment, Food and Rural Affairs

Notes for guidance: Export Health Certificate for entry into the European Union or Northern Ireland of semen of porcine animals collected after 20 April 2021 and dispatched from the semen collection centre 8406

August 2024

Contents

No. 8406 NFG

EHC applicable for entry into the EU or NI of semen of domestic animals of the porcine species collected, processed and stored after 20 April 2021, in accordance with Regulation (EU) 2016/429 and delegated Regulation (EU) 2020/692, and dispatched from the semen collection centre where the semen was collected.

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

1. APPLICABLE LEGISLATION

The general animal health requirements governing movement within the EU and entry into the EU of semen, oocytes and embryos of the porcine animals are laid down in Regulation (EU) 2016/429.

Commission Delegated Regulation (EU) 2020/686 and Commission Implementing Regulation (EU) 2020/999 supplement animal health requirements for movement within the Union of semen, oocytes and embryos of porcine animals laid down in Regulation (EU) 2016/429.

Commission Delegated Regulation (EU) 2020/692 supplements animal health requirements for entry into the Union of semen, oocytes and embryos of porcine animals laid down in Regulation (EU) 2016/429.

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

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

Those regulations harmonise:

- The requirements for registration and approval of germinal product establishments
- The requirements for traceability of germinal products
- The animal health requirements for donor animals
- The animal health requirements for germinal products
- The certification and notification requirements

GB is listed for all the relevant commodities. The relevant regulations for germinal material are Implementing Regulation (EU) 2021/404 as amended by Implementing Regulations 2021/634, adding the GB and the Crown Dependencies to the relevant lists.

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 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 EHC set out in Commission Implementing Decision 2020/692 (EU) applicable for entry into the EU or transit through the EU or NI of semen of domestic animals of the porcine species collected, processed and stored after 20 April 2021, in accordance with the above aforementioned Regulations, 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 certificate may be used for entry into the EU or NI of semen of porcine animals, collected, processed, and stored after 20 April 2021, and dispatched from the collection centre where it was collected.

Semen must have been collected processed and stored in accordance with the specific animal health requirements laid down in Part 2 and Chapters I, II, III and IV of Part 5 of Annex II to Delegated Regulation (EU) 2020/686, and the above regulations.

If you are exporting to NI, please make sure you comply with any extra requirement.

https://www.daera-ni.gov.uk/publications/pig-semen-supplementary-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 or NI. The original copy of the required EHC must accompany the consignment to the BCP of entry.

Listing of the EU MS BCPs can be found here: https://ec.europa.eu/food/animals/vet-border-control/bip-contacts_en

The foreign language certificate as received from the APHA Centre for International Trade at Carlisle or via the Export Heath Certificates Online system (EHCO) and bearing the same unique reference number as the English certificate, should be considered an official and accurate translations of the English, as published in EU legislation.

The (sub-) paragraphs / options and how they are numbered and formatted is identical in the English and foreign language editions and to the legislation published by the European Commission. Therefore, the same phrases/sentences in the foreign language versions as in the English version should be struck through and these deletions should be stamped and initialled in both versions. Both versions must also be signed (as opposed to being initialled) and stamped by the OV, the foreign language certificate is deemed to be a genuine and properly authorised translation of the English version.

This also applies to any instructions in the guidance notes to strike out certain paragraphs or to certify statements that the country is free of certain notifiable diseases etc.

Additional information can be found in the APHA Vet Gateway:

http://apha.defra.gov.uk/External_OV_Instructions/Export_Instructions/Certification_Procedures/index.htm

SIGNING AND STAMPING

When signing a certificate, the CO should ensure that the certificate contains no deletions or alterations, other than those which are indicated on the certificate to be permissible and any corrections to permitted entries, subject to such changes being initialled and stamped (in the margin) by the CO. Permissible deletions are normally indicated in the 'Notes' section at the end of the certificate, with the instruction 'Keep as appropriate' or 'delete if not applicable'.

- Where the certificate contains optional or contextual statements, the statements which are not relevant shall be crossed out, individually initialled and stamped by the CO, or completely removed from the certificate.
- Permitted paragraphs and sections may be crossed out by applying a 'Z' across the section or paragraph rather than crossing out line by line.

- There is no requirement for a date and time to accompany each stamp. The date is only entered at the required entry field in Part I of the certificate, and at the end where the CO signs, stamps and dates that action.
- We are aware of some BCPs demanding that all handwritten information in Part 1 of the EHC is initialled and stamped, including handwritten scoring out of otherwise blank boxes. There is no legal requirement in EU legislation that all the hand-written information entered in the certificate must be signed and stamped. It is only in the case of correction, in any part of the certificate, or in the case of statements to be crossed out, that the certifier must add signature (or initials) and stamp. This has been confirmed by the European Commission. The Commission noted however, in the case of a hand-written certificate, it is expected that the same one person completes the document. If not, the BCP might suspect that empty boxes were completed by another person after the certificate has been signed by the official

You should consider checking with the specific BCP regarding their preference when it comes to the stamping and initialling of handwritten scoring out of otherwise blank boxes in Part I of the EHC.

- **Clarification from the European Commission means that all pages (as opposed to sheets of paper) are signed and stamped once individually in place of fan stamping and in addition to any permitted alterations. There is no requirement to fan stamp.**
- COs are reminded to consult the NFG prior to the certification of each EHC. NFG will be updated with this new information in due course.

Further Information COs should make sure they are familiar with all relevant guidance and other documents relating to EHCs and that they discuss requirements with exporters in advance.

See http://apha.defra.gov.uk/official-vets/Guidance/exports/ehconline.htm

You can also contact APHA's Centre for International Trade (CIT) on 03000 200 301.

PART I: DETAILS OF THE CONSIGNMENT

All boxes in Part I of the certificate must be completed. When a box is not applicable/optional, and not filled, please score it through.

Please use schedule to be attached to the certificate if there is not enough space to 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.

- The OV should confirm with the exporter that the HS Code used correctly describes the products 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
- There is information at the bottom of the majority of EHCs with the example commodity codes of 4 or 6 digits. If there is not enough space in Box I.19 to include all the commodity codes, please use a schedule.
- Information on how to create a schedule is available on APHA's Vet Gateway.
- The Commission has confirmed that CN codes (8 digits or more) cannot be required in the official certificate (EHC), as only HS codes (max 6 digits) are required here. In any case, the best accuracy for the classification of the goods is expected in the CHED, not in the certificate.

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. If there is no available guidance, then COs are advised to seek advice from the BCP on what information should be included.

PART II: CERTIFICATION

II. Health Information

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

They must ensure that they are aware of the provisions of the relevant regulations (please 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 of consignments of semen of porcine animals.

II.1.1 - This may be certified based on the knowledge that the semen was obtained from donor animals originating from GB, or resident in GB for a minimum of 3 months if they originated in a third country, territory or zone which is listed in Commission Implementing Regulation (EU) 2021/404 (as amended by Regulation 2021/634);

II.1.2, II.1.3, and II.1.4 - First option may be certified for the time periods specified based on the disease notification clearance in the absence of an outbreak. (Section 4 Notifiable Disease Clearance).

Second option of II.1.2 and II.1.3 may be struck through in the absence of FMD and Classical Swine Fever, respectively, in the UK.

II.1.5 – This can be certified, as vaccination against the diseases listed in II.1.5 is prohibited in the UK, and vaccination against the listed diseases is currently prohibited for imports into GB. There are two sub-options: 'Either' and 'Or'. 'Either' can be certified, as vaccination against FMD is prohibited in the UK, and vaccination against the FMD is currently prohibited for imports into GB. The 'Or' option must be deleted.

GB import requirements can be found on:
https://www.gov.uk/government/collections/health-certificates-for-animal-and-animal-product-imports-to-great-britain

II.2.1 - May be certified based on the disease notification clearance and the prohibition of vaccination. The additional assurance in the third paragraph (after 'or') may be struck through.

II.2.2, II.2.3 and II.2.4. These may be certified based on an attestation from the Semen Collection Centre appointed vet, that the farms of origin of donor animals complied with these conditions prior to being accepted into pre-entry quarantine.

II.3.1 - May be certified on the basis that the Semen Collection Centre is approved/listed by APHA and listed for exports to the EU or NI.

II.3.2 - This paragraph may be certified on the basis that the centre is officially approved by APHA in accordance with Regulation (EU) 2020/686 and a declaration from the Centre Veterinarian confirming (continuity of) compliance with the relevant requirements laid down in Regulation (EU) 2020/686.

II.4 - The assurances below may be certified on the basis of support certification by the Centre Veterinarian that the animals comply with the relevant health attestations, including the requirements for admission into the collection centre, as applicable. The OV and the Centre Veterinarian may support their certification by means of any additional declarations, disease clearances and supporting evidence as they consider necessary.

II.4.1 – It is a pre-requisite that donor animals to comply with this attestation in order to be admitted into pre-entry quarantine and final admission to the Collection Centre. The Centre veterinarian may be able to provide support certification that they animals complied at the point of entry, and continue to comply with this requirement, especially in regard vaccination status for PRRS (vaccination against Rinderpest and CSF is not currently permitted in the UK).

II.4.2 – Donor animals must be resident in the country where the semen collection and export take place, for a minimum of 3 months prior to collection of the semen.

II.4.3 – Animals must be clinically healthy when admitted to the centre and on the day of collection to the centre.

II.4.4 - Commission Delegated Regulation 2020/692 requires the identification of donors to include the code of the exporting country in accordance with ISO Standard 3166 in the format of two-letter code. This means applying the GB ISO code on the identifiers of the donor animals. Donor boars should be identified with a (an additional) ‘GB’ tag (or tattoo) identifier prior collection of the semen.

II.4.5 – Health status of the Collection Centre, contact with other susceptible animals and use of boars for breeding purposes - this paragraph may be certified, if during the 30 days preceding the semen collection and throughout the collection period:

- if the collection centre has not been included in a restricted zone for the diseases listed in II.4.5.1; and
- in the absence of the diseases named at II.4.5.2 in the collection centre (including the pre-entry quarantine facilities); and

- The donor boars have not been in another collection centre (or pre-entry quarantine facility) or in contact with other animals not complying with the above two conditions; and
- The boars have not been used for natural service during the above required period.

II.4.6 - This paragraph may be certified on the basis of notifiable disease clearances, support attestations by the centre veterinarian and any other evidence that the OV considers necessary, if the following conditions can be attested in relation to the pre-entry quarantine facilities, at the point (date) of admission of the donor animals into the collection centre:

- Not located in a restricted zone due to of FMD, Rinderpest, Classical or African swine fever, or due to an emerging disease relevant for the porcine animals.
- Not located within 10 km where an outbreak of FMD occurred in the previous 30 days;
- No FMD outbreak in the pre-entry quarantine facility for 3 months.
- No occurrence of *Brucella abortus, B. melitensis* and *B. suis*, rabies, anthrax, Aujeszky's disease and PRRS for 30 days at the pre-entry quarantine facility.
- No confirmation of *Brucella abortus, Brucella melitensis* and *Brucella suis* in 3 months at the pre-entry quarantine facility.
- Only animals of the same health status were at the pre-entry quarantine facility during the coterminous quarantine period.

II.4.7 –This paragraph may be certified if the donor boars of the semen for export were resident in a collection centre which:

- Not located in a restricted zone due to of FMD, Rinderpest, Classical or African swine fever, or due to an emerging disease relevant for the porcine animals.
- No occurrence of *Brucella abortus, B. melitensis* and *B. suis*, rabies, anthrax, Aujeszky's disease and PRRS at the centre during the 30 days prior to collection of the semen; and (delete as applicable):
    - 30 days after collection of the (frozen) semen; or
    - despatch for export (fresh/chilled semen):
- Not located within 10 km where an outbreak of FMD occurred in the previous 30 days; and (delete as applicable):
    - No FMD outbreak in the centre for 3 months prior to collection of the semen (frozen semen); or
    - No FMD outbreak in the centre for 3 months prior to collection of the semen and until dispatch of the semen for export, provided that the animals have been resident at the collection centre for a minimum period of 30 days prior to the collection of the semen for export (fresh/chilled semen);
- No clinical, laboratory or pathology evidence of Aujeszky's disease at the centre for the period between 30 days prior to admission of the donors into the centre and 30 days prior to collection of their semen.

II.4.8, II.4.9 and II.4.10 -
These attestations can be certified on the basis of compliance of the donor animals with the requirements for admission into the semen collection centre under Delegated Regulation (EU) 2020/686. Testing must have been carried out at official laboratories using the prescribed testing methods.

Centre veterinarians and OVs should pay attention to three new requirements introduced by the Animal Health Regulation:

- Brucellas: the ELISA testing used by APHA Weybridge covers all the three types of brucella (abortus, melitensis and suis) for which attestation is now needed.
- Classical Swine Fever testing is now required as follows:
    - during pre-isolation (4.8.3) – if CSF has been reported or vaccination has been practised for this disease in the country for the preceding 12 months.
    - The semen collection cnetre (4.10.3) - if CSF has been reported and vaccination has been practised for this disease in the country for the preceding 12 months;
- PRRS testing – serological testing during pre-isolation; and both serological and antigen tests during pre-entry quarantine

Vaccination against Aujeszky's disease is not permitted in the UK (free without vaccination). The testing/attestations for non-vaccinated animals should be certified and the other one for vaccinated animals deleted.

II.4.10 & II.4.11 -
These attestations can be certified based on the semen collection centre's compliance with Delegated Regulation (EU) 2020/686.

II.4.11 can be certified on basis of animal subjected to tests referred as per II.4.10 (applicable option that are certified).

Routine testing of all animals (not only donor boars) resident in porcine semen collection centres can be achieved in three ways:

- 10% of animals monthly
- 25% of animals quarterly.
- 100% animals annually - All donor boars must be tested at least annually and/or at the point or exiting the collection centre.

Laboratory test reports or a written declaration regarding AD, Brucellosis, CSF, porcine reproductive and respiratory syndrome virus may be requested from the centre veterinarian to determine which attestation is appropriate to certify. It is very likely that some of the animals would have had non-negative results to the tests following admission at some point since the approval of the semen collection centre and certification may be needed according to the methods used and the results of the (negative) testing required at II.4.10.and II.4.11.

II.5 & II.6 –
In general, these paragraphs may be certified based on compliance of the standards of operation of the Collection Centre with Delegated Regulations (EU) 2020/686 and 2020/692 and their approval by APHA in accordance with Regulation (EU) 2020/686.

More specifically, these paragraphs may be certified on the basis of supporting attestations/declarations by the Centre Veterinarian for the collection and processing of semen (including expanders, diluents and antibiotic cocktail additions) and/or based on personal observations/supervision by the certifying OV in relation to storage, sealing and despatch of semen for export, and any other enquiries and checks that the OV considers necessary.

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 (7).

Important *– marking of germinal products for export to the EU and NI must be done in such a manner that the following information can be readily established:*

(i) the date of collection or production of those germinal products.

(ii) the unique approval number of the Collection Centre (as published in the listing of GB establishments by the EU Commission, which still contains UK identifiers in the approval codes)

(iii) the species of the donor animal(s): Regulation (EU) 2020/692 does not specify the format of information on species of donor animals to be printed or written on the straw. Therefore, there is a flexibility in presenting that information.

The approval code of the Collection Centre used for listing for export to the EU or NI may be suitable to determine the species concerned; However, operators are advised to include explicit references for the species concerned such as: 'POR' for porcine, 'BOV' for bovine, 'EQUI' for equine etc

(iv) the identification of the donor animal(s): Donor animals must be identified with a GB identification tag/identifier prior to the collection of their semen, and the straws, ampoules or other semen containers marked with the individual identification of the animals accordingly;

(v) any other relevant information.

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 or NI, 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 or NI, 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 and, if applicable, FCCO must make photocopies of, or scan and save all documents they certify. OVs must retain copies of certification documents in accordance with RCVS Certification principles.

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

COs must retain copies of all export documentation for a period of two years. A certified copy of this EHC does not need to be returned to the APHA CITC. For the purposes of completing routine Quality Assurance checks on export certification, CITC may request certified copies of certification from COs.

Further details on Post Certifying Procedures, ‘certified copies’ of certification and the types of documents that should be retained by COs can be found on the APHA Vet Gateway.

9. LEGAL STATEMENT

The existing EU legislation that the UK 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 the APHA in Carlisle.

This publication is available at www.gov.uk/government/publications

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

8406 NFG

Version History:

EHC

Part I
I.27: 'Test' added
Part II -
II.1.5: 'either/or' options added for vaccination status against foot and mouth disease
II.4.7.2: 'either/or' options added for timeframes on disease reporting
II.4.7.3: 'either/or' options added for timeframes on disease reporting
II.4.8: 'either/or' options added for vaccination status against Aujeszky's disease
II.4.9.2: 'either/or' options added for vaccination status against Aujeszky's disease
II.4.9.4: replaced by **II.4.9.3**
II.4.10.2: 'either/or' options added for vaccination status against Aujeszky's disease
II.4.10.3: expanded for reporting status of third country for classical swine fever
II.6: worded amended and listing of specific antibiotics removed
Notes - (2): removal of opening date in accordance with Implementing Regulation (EU) 2021/404

NFG

Version 3: Published 16 August 2024
Part I: I.27 Guidance for addition of 'test' included
Part II: II.4.8-11 Guidance amended

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
II.1.5: Guidance added
II.6: Guidance added