# Department for Environment, Food and Rural Affairs

# Notes for Guidance: Export Health Certificate for entry into the European Union or Northern Ireland of porcine animal germinal products, dispatched from a germinal product processing establishment 8413

# July 2024

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No: 8413 NFG

EHC for entry into the EU or NI of semen, embryos and oocytes of porcine animals, dispatched from a germinal product processing establishment.

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

# 1. APPLICABLE LEGISLATION

Regulation (EU) 2016/429

Delegated Regulation (EU) 2020/692 after 20 April 2021

Council Directive 90/429/EEC before 21 April 2021

Delegated Regulation (EU) 2020/686

Delegated Regulation (EU) 2021/403

Implementing Regulation (EU) 2024/351 - Model EHC amending 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 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 applicable for entry into the EU or NI, and transit through the EU of consignments of semen, oocytes and embryos dispatched from a germinal product processing establishment.

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 entry into the EU or NI of porcine animal semen dispatched from an approved processing centre.

The germinal products permitted to be certified on this certificate are:

- Semen of porcine animals collected, processed and stored in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/692 after 20 April 2021;
- Stocks of semen of porcine animals collected, processed and stored in accordance with Council Directive 90/429/EEC before 21 April 2021;
- Oocytes and embryos of porcine animals collected or produced, processed and stored in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/692 after 20 April 2021

It may also be used for these products transiting the EU to another third country.'Porcine animal' means a porcine animal as defined in point (4) of Article 2 of Regulation (EU) 2020/686.

Consignments of germinal products shall only be permitted to enter from approved germinal product establishments that comply with the requirements set out in Annex I to Delegated Regulation (EU) 2020/686.

N.B.: at the time of writing there are no stand-alone porcine processing centres approved in the UK

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. 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 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

  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.
- Internal Movement Certificates that are certified by the centre/team veterinarian and any accompanying schedules must be checked by the OV and stamped and initialled once individually on each page by the OV.

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 <a href="http://apha.defra.gov.uk/official-vets/Guidance/exports/ehconline.htm">http://apha.defra.gov.uk/official-vets/Guidance/exports/ehconline.htm</a>

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</u> (EU) 2020/2235, 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 <a href="http://madb.europa.eu/madb/euTariffs.htm">http://madb.europa.eu/madb/euTariffs.htm</a>

#### PART 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 Council Directive 90/429/EEC before April 2021 applying to imports from third countries and Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/692 after 20 April 2021, applying to collection or production, process and storage of germinal products of porcine animals, and the health certificates that should accompany the consignement.

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

**II.1.1.1 refers** - This may be certified based on GB being listed in <u>Annex IX to</u> <u>Regulation (EU) 2021/404</u> as a third country permitted to export semen, oocytes and embryos to the EU. This has been amended by Regulation (EU) <u>2021/634</u> to include GB and the Crown Dependencies.

#### II.1.1.2., II.1.1.3. and II.1.1.4.-

These health attestations should be certified on the basis of the UK's freedom from these diseases (as applicable to the relevant time) and the prohibition on vaccination against them.

**II.1.1.5** – This can be certified, as vaccination against the diseases listed in II.1.1.5 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. 'Or' option must be deleted.

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

**II.1.2.** - It can be certified on the baiss that the germinal product processing establishment is listed in accordance with Article 233(3) of Regulation (EU) 2016/429 on the EU Commission website: <u>https://ec.europa.eu/food/animals/semen-oocytes-embryos/porcine\_en</u>

Gov.uk website: <u>https://www.gov.uk/government/publications/livestock-and-equine-semen-collection-approved-premises</u>

**II.1.3.** - This may be certified based on the approval of the establishment and support certification of the operation of the processing centre in accordance with the Regulation 2020/686 or certified based on evidence or information from the centre veterinarian responsible for the germinal product processing establishment.

**II.2.1 refers -** The first paragraph may be certified on the basis of the establishment's approval and support certification from the centre veterinarian responsible for the germinal product processing establishment.

The second paragraph, where semen has been introduced the OV must obtain proof of legal importation from listed countries (Annex IX to Regulation 2021/404) or EU member states (i.e. copy of health certificate and other supporting evidence/declaration from the veterinarian responsible).

**II.2.2 refers –** This may be certified on receipt of the relevant certificates listed in this EHC and the original health certificates or officially endorsed copies must be attached to this certificate. Otherwise, an Internal Movement Certificate published on <u>gov.uk</u> <u>EHC form finder</u> alongside this NFG/EHC should be certified and attached to this certificate.

However, the European Commission have advised to Defra and EU member states that Internal Movement Certificates may not be required if the Processing Centre is linked to and falls under the same license approval as the Semen Collection Centre where the semen was collected. The centre veterinarian must ensure there are protocols in place describing how the semen is transported for processing within the particular semen collection centre. In order to exercise this advice, it is recommended to contact the EU BCP for agreement before export, to minimise the risk of issues at the EU border. The OV must review the protocols and any further evidence/information from the centre vet that the semen is compliant with the relevant certificate, before certification of this attestation. If germinal products are moved from a Semen Collection Centre or Embryo Collection/Production Team that is not linked to the Processing Centre, then an Internal Movement Certificate is still required.

#### II.2.3, II.2.4 and II.2.5 refer –

These statements may be certified on the basis of evidence or support certification provided by centre veterinarians/collection teams, approval of establishment and statements of compliance with <u>Delegated Regulation (EU) 2020/686</u> and <u>Delegated Regulation (EU) 2020/692</u> for marking.

The ID marking of the straws or other packages must refer to: date of collection or production of semen/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. 'POR' for porcine. There is flexibility in presenting the species information.

**II.2.6. and II.2.7 refer -** May be deleted if not applicable see footnotes (7) and (8). This may be certified on the basis of support certification by the centre veterinarian responsible for the germinal product processing establishment.

#### 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. <u>COLLECTION OF EVIDENCE</u>

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. <u>CONSIGNMENTS OR PARTS OF THE CONSIGNMENT ORIGINATING FROM NI,</u> <u>EU MEMBER STATES OR FROM THIRD COUNTRIES (TRIANGULAR TRADE).</u> [WHEN APPLICABLE]

#### NI origin:

For NI origin raw materials which have then been processed into a final product in GB, or are presented in their original state and bearing a UK(NI) identification mark, the CO can certify certain matters relating to EU compliance at a national level.

Where the EHC refers to EU approval status of the premises of origin or manufacture in NI, this can be certified under the terms of the EU-UK Withdrawal Agreement and the NI Protocol (NIP). The NIP treats NI as if it is in the EU SPS zone (which includes

the EEA/EFTA states). Approved and registered premises in NI continue to implement the full requirements of Regulation (EC) Nos. 852/2004 and 853/2004 and Regulation (EU) No. 2017/625 and all relevant supporting EU legislation as set out in Annex 2 to the Protocol. This compliance is indicated by the presence of the EU oval health and identification marks applied to the products.

Some examples, but not a complete list, of how assurance can be established at national level are listed below.

Compliance with the microbiological criteria set out in Regulation (EC) No. 2073/2005 can be certified if the products originate in an EU approved premises in NI, and bearing the EU oval ID mark.

Public health statements referring to compliance with EU requirements for testing for residues as set out in Regulation (EU) No\_ 2017/625, Directive (EC) Nos 96/22 and 470/2009 can be certified by the CO on the basis of a national residue surveillance programme implemented in NI under The Animals and Animal Products (Examination for residues and maximum Residues Limits) Regulation (NI) 2016. This forms part of the UK national surveillance programme.

With regards to controls for Transmissible Spongiform Encephalopathies, guidance provided in this document relating to statements about the method of slaughter of animals in GB also applies to animals slaughtered in NI and can be certified by the CO on that basis.

Disease clearance for animals or products originating in NI can be completed using auto-clearance NDC found here:

#### https://www.daera-ni.gov.uk/articles/notifiable-diseases-northern-ireland

Where regional or local level disease clearance is required, this can be certified upon request on the basis of information from NI in the form of a declaration or a supporting health attestation.

Animal health statements which refer to the prohibition of certain vaccination programmes e.g. against FMD or CSF or ASF can be certified at a national level by the CO on the basis that NI also enforces a ban on such vaccinations in accordance with EU regulations.

Statements relating to implementation of a national system for identification and registration of bovine animals can be certified on the basis of the requirement to register all bovine animal births, moves and deaths on the DAERA database.

Animal welfare statements can be certified by the CO on the basis that relevant inspections, monitoring and controls are implemented in NI through The Welfare of Animals at the Time of Killing Regulations (NI) 2014 as amended, in compliance with Regulation (EC) No. 1099/2009.

Animal By-Products are handled in accordance with EU Regulation 1069/2009, which is implemented by the EU Implementing Regulation 142/2011, and ABP statements for materials originating in NI, can be certified on that basis.

When the certificate requires specific information to be included, such as the date of slaughter or the date of introduction into NI, the GB exporter / CO must request this information from the NI exporter. This NI exporter may forward the request to the relevant NI CO to provide this information. This supporting information must be in writing and kept by the GB CO. The GB CO is not required to attach it as a supporting document to the EHC, unless requested by the EU BCP or told otherwise.

# EU origin:

It is possible that some consignments may contain animal products that are of EU origin and were imported into to the GB on a Commercial Document or EU Intra-Trade Animal Health Certificate (ITAHC). The Commercial Document may not contain enough information to allow the CO to sign an EHC.

In such cases, the CO will need further information from the EU member state regarding particular attestations on the EHC that cannot be signed by the CO without support documentation. Thus, the GB exporter must request from the EU exporter an attestation or written declaration from an EU registered vet. The GB exporter may wish to obtain these directly from the EU vet who has inspected the animal products before export from the EU.

When the certificate requires specific information to be included, such as the date of slaughter or the date of introduction into the EU, the GB exporter / CO must request this information from the EU exporter. This EU exporter may forward the request to the relevant EU vet to provide this information. This supporting information must be in writing and kept by the GB CO. The GB CO is not required to attach it as a supporting document to the EHC, unless requested by the EU BCP or told otherwise.

# Third country origin:

It is also possible that some consignments may contain POAO that have been imported to GB form non-EU countries and further processed in GB, which GB exporters intend to export to EU (known as Triangular Trade). In these cases, COs may obtain a copy of the EHC for the import of such commodity from the Third Country to the GB.

GB COs are not required to attach a copy of the Third Country EHC as a supporting document to the EHC, unless requested by the EU BCP or specifically instructed in the NFG.

It is the GB exporter's ultimate responsibility to obtain any necessary support documents (from the EU member state exporter / Third Country exporter), to enable GB COs to be able to certify the products in good time before the export to the EU.

# 8. ADDITION OF SCHEDULES

When the space in Part I or Part II of the certificate is insufficient to accommodate full details of the consignment a schedule may be used. In the relevant section of the certificate the CO should annotate the certificate 'see attached schedule'. A new schedule should be created (typed or clearly written) containing the same information

as that required in the certificate. The schedule must include the certificate reference number on each page and must be signed, dated and stamped by the CO in a colour other than the printed text on each page and under the last entry. <u>The schedule forms part of the certificate</u>. 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.

Furtherguidanceisavailablehere:http://apha.defra.gov.uk/ExternalOVInstructions/ExportInstructions/CertificationProcedures/index.htm

# 9. CERTIFIED COPIES OF EHCs

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

https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-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</u> <u>Gateway</u>.

# 10. LEGAL STATEMENT

The existing EU legislation that the UK complied with prior to the end of the Transition Period has been incorporated into our domestic law as "assimilated EU law" under the EU (Withdrawal) Act 2018. References in our guidance and certification to such EU instruments should be taken to be references to this "assimilated EU law". The EU standards that this legislation includes continue to remain in force, without substantive amendment, as part of UK domestic law (apart from corrections to make the EU legislation fully operable.

# 11. DISCLAIMER

This certificate and NFG are provided on the basis of information available at the time and may not necessarily comply fully with the requirements of the importing country. It is the exporter's responsibility to check the certificate against any relevant import permit or any advice provided by the competent authority in the importing country. If these do not match, the exporter should contact APHA in Carlisle.

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# Version History:

# EHC

Part II –

**II.1.1.5**: 'either/or' options added for vaccination status against foot and mouth disease

II.2.1: Wording of 'imported to' amended to 'introduced into'

Notes -

(6): Legislation reference to Regulation (EU) 2021/404 amended

# NFG

# Version 4: Published 31 July 2024

**Applicable Legislation**: Implementing Regulation (EU) 2024/351 and Implementing Regulation (EU) 2021/404 added

**Part I:** Commission Implementing Regulation (EU) 2020/2235, amended by Implementing Regulation (EU) 2023/2744 added

**II.1.1.5**: Guidance added