Department for Environment, Food and Rural Affairs

Notes for Guidance: Export Health Certificate for entry into the European Union or Northern Ireland of bovine animal germinal products from a storage centre 8403

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No: 8403

Export Health Certificate for entry into, and transit through the European Union of, consignments of semen, oocytes and embryos as detailed in heading above, and entered into the European Union or Northern Ireland after April 20th 2021, and dispatched from a germinal product storage centre.

NOTES FOR GUIDANCE FOR THE CERTIFYING OFFICERS AND EXPORTERS

IMPORTANT

These notes provide guidance to Certifying Officers and exporters. The NFG should have been issued to you together with the relevant export certificate applicable for entry into the European Union, and transit through the European Union after 20th April 2021 of consignments of semen, oocytes and embryos subject to the conditions detailed on page 1 of these NFG, and dispatched from a germinal product storage centre.

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]

1. APPLICABLE LEGISLATION

Commission Implementing Regulation (EU) 2021/403

Commission Implementing Regulation (EU) 2020/999

Commission Delegated Regulation (EU) 2020/692

Commission Delegated Regulation (EU) 2020/686

Regulation (EU) No 2016/429

Council Directive 88/407/EEC, as amended by Council Directive 2003/43/EC

Council Directive 88/407/EEC, as amended by Council Directive 93/60/EC

Directive 89/556/EEC

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

Consolidated legislation

Consolidated texts, which integrate the basic instruments of European Union legislation with their amendments and corrections in a single, non-official document, are available. Each consolidated text contains a list of all legal documents, taken into account for its construction.

You can search for consolidated texts by using the 'find results by document number' option on the European Commission website. Once you have selected the relevant legislation, click 'document information', and then scroll down to 'all consolidated versions' and select the most recent version.

https://eur-lex.europa.eu/homepage.html

Please note that the consolidated text may not contain the latest amendment to the legislation, as it takes several weeks for this to be updated.

Texts provided in this section are intended for information only. Please note that these texts have no legal value. For legal purposes please refer to the texts published in the 'Official Journal of the European Union'.

2. SCOPE OF THE CERTIFICATE

This certificate is intended for entry into the European Union or Northern Ireland of semen, oocytes, and embryos of bovine animals, dispatched from a germinal products storage centre.

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

Semen

- semen of bovine 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 bovine animals collected, processed and stored in accordance with Council Directive 88/407/EEC, as amended by Council Directive 2003/43/EC, after 31 December 2004 and before 21 April 2021;
- stocks of semen of bovine animals collected, processed and stored before 1 January 2005 in accordance with Council Directive 88/407/EEC, as amended by Council Directive 93/60/EC;

Oocytes and Embryos

 Oocytes and embryos of bovine animals collected or produced, processed and stored in accordance with Regulation (EU) 2016/429 and Delegated Regulation (EU) 2020/692 after 20 April 2021

Embryos

 stocks of *in vivo* derived embryos of bovine animals collected, processed and stored in accordance with Directive 89/556/EEC before 21 April 2021;

- stocks of *in vitro* produced embryos of bovine animals produced, processed and stored in accordance with Directive 89/556/EEC before 21 April 2021, conceived using semen complying with requirements of Council Directive 88/407/EEC;
- stocks of in vitro produced embryos of bovine animals produced, processed and stored in accordance with Directive 89/556/EEC before 21 April 2021, conceived using semen coming from semen collection or storage centres approved by the competent authority of the exporting country,

It may also be used for these products transiting the European Union to another third country.

(Please note, where the germinal product was collected/produced, processed and stored prior to 01 January 2021, the certificate should follow the relevant format outlined in Chapters 24, 25, 27, 28 and 29 of Annex 1 to Regulation (EU) <u>2021/403</u>, as referred to in Annex IX to Regulation <u>2021/404</u> (as amended).

3. CERTIFICATION BY AN OFFICIAL VETERINARIAN (OV)

In **England, Scotland and Wales**, this certificate must be signed by a Government Veterinary Officer (e.g. APHA, FSA or FSS employed veterinary officers) or by an Official Veterinarian (OV) appointed by the Animal and Plant Health Agency on behalf of Ministers in Defra, the Scottish Government or the Welsh Government and who hold the appropriate Official Controls Qualification (Veterinary) (OCQ (V)) authorisation.

OVs must sign and stamp, with the OV stamp, the health certificate in ink of a different colour to that of the printing of the Export Health Certificate (EHC). There is no requirement to sign and stamp in a specific colour.

The OV should keep a copy of the signed certificate and any supporting documents for at least two years after signature or receipt/dispatch of the consignment, whichever is later. These can be electronic copies.

The RCVS Certification principles must be complied with.

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

EHC in foreign language/s of the EU Member States (MSs).

EHC should be in English and the foreign language of the Border Control Post (BCP) of entry in the EU. The original copy of the required EHC must accompany the consignment to the BCP of entry.

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

The foreign language certificate as received from the APHA Centre for International Trade at Carlisle or via the Export Heath Certificates Online system (EHCO) and bearing the same

unique reference number as the English certificate, should be considered an official and accurate translations of the English, as published in EU legislation.

The (sub-) paragraphs / options and how they are numbered and formatted is identical in the English and foreign language editions and to the legislation published by the European Commission. Therefore, the same phrases/sentences in the foreign language versions as in the English version should be struck through and these deletions should be stamped and initialled in both versions. Both versions must also be <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 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.
- Internal Movement Certificates that are certified by the centre/team veterinarian (or other official certificates/documents) and any accompanying schedules must be

checked by the Official Veterinarian and stamped and initialled once individually on each page by the Official Veterinarian.

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

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

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

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

You can also contact the Animal and Plant Health Agency's Centre for International Trade (CIT) on 03000 200 301.

PART I: DETAILS OF THE CONSIGNMENT

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

Please use schedule to be attached to the certificate if there is not enough space to fill the information. See Section 'Addition of Schedules' below.

Please complete all the boxes in Part I of the certificate in accordance with the guidance/footnotes detailed at the end of the EHC.

- Box I.17 refers: The official document(s) or certificate(s) accompanying the germinal product from the approved centre/team of collection or production to the storage establishment should be the certificate(s) which provide(s) the same or equivalent conditions to the relevant EU model certificate(s) referenced in II.2.2 of the 8403EHC.
- The European Commission have confirmed that this box is mandatory, even where
 the storage centre and collection centre or embryo team at which the germinal
 products was collected/produced are both in Great Britain.
- Exporters should make arrangements, to enable this information to be provided. These individual official document(s) or certificate(s) or officially endorsed copies thereof must be attached to the 8403EHC.
- The Harmonised System (HS) Code is a commodity classification system used as a basis for customs tariffs and for international trade statistics.

It is the exporter's responsibility to ensure that the HS code is entered correctly and accurately reflects the product(s) being consigned.

Further information on HS Codes can be found online at:

https://www.gov.uk/trade-tariff/sections and

http://madb.europa.eu/madb/euTariffs.htm

PART II: CERTIFICATION

II.1 Animal Health Attestation

The Official Veterinarian signing the export health certificate must ensure that they are aware of the provisions of the regulations detailed in this Official Certificate.

The Official Veterinarian 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.1.1.1.** This may be certified based on GB being listed in Annex IX to Implementing Regulation (EU) 2021/404 (as amended) as a third country permitted to export semen, oocytes and embryos to the European Union.
- **II.1.1.3** This can be certified based on Notifiable Disease Clearance. See section below. Care should be taken when certifying older stocks of germinal products as regards Foot and Mouth Disease.
- **II.1.1.4** This can be certified, as vaccination against the diseases listed in II.1.1.4 is prohibited in the UK. Vaccination against the listed diseases is currently prohibited for imports into GB. GB import requirements can be found on gov.uk: https://www.gov.uk/government/collections/health-certificates-for-animal-and-animal-product-imports-to-great-britain
- **II.1.2** The establishment should be listed on gov.uk and also listed as an Approved Germinal Product Storage centre in accordance with Article 233(3) of Regulation (EU) 2016/429 on the European Commission website.

EU website: https://food.ec.europa.eu/animals/semen-oocytes-embryos_en

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

- **II.1.3** This may be certified based on the approval of the establishment and support certification from the centre/team veterinarian.
- **II.2.1 -** The first paragraph may be certified, on the basis of the establishment's approval and support certification by the centre/team veterinarian.

The second option, where the germinal product has been imported the OV must obtain proof of legal importation from approved third countries or EU member states (i.e. copy of the health certificate and other supporting evidence from the centre/team veterinarian).

II.2.2 – This may be certified on receipt of the relevant model certificates listed in II.2.2 (or equivalent certificates with conditions at least as strict as the relevant model certificates). The original documents or the health certificates or officially endorsed copies must be attached to this certificate. For movement of germinal products within Great Britain, an

Internal Movement Certificate published on gov.uk EHC form finder should be certified and attached to 8403EHC.

Please note, germinal products must be moved to the storage centre under conditions at least as strict as described in the relevant EU model certificate. Article 20 to Regulation (EU) 2021/403 provides a list of EU model certificates, which can be used to determine which model certificate is relevant for the germinal product to be exported, as this depends on the export date, collection/production date and what EU legislation was in force at the time of collection/production/storage. For example, for bovine semen collected after 20 April 2021 an official certificate/document with conditions at least as strict as the EU Model BOV-SEM-A-ENTRY EHC must be certified to enable certification of II.2.2.

'Model 1 in Section A of Part 1 of Annex II to Decision 2011/630/EU' EHC (or equivalent version) may be certified for bovine semen collected, processed and stored after 31 December 2004 and before 20 April 2021 when the Decision was in force in the EU. Please see Commission Implementing Decision 2011/630(EU), which provides an explanation of the scope of the model certificates contained in the Decision.

II.2.3, II.2.4, II.2.5, II.2.6, II.2.7 - These statements may be certified based on evidence provided by the centre/team veterinarian with statements of compliance to Delegated Regulation (EU) 2020/686 and Delegated Regulation (EU) 2020/692 for ID 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. 'BOV' for bovine. There is flexibility in presenting the species information.

4. NOTIFIABLE DISEASE CLEARANCE

Some export certificates for animals and animal products will include statements that will require the OV to certify that specified zones or the entire country of origin are free from certain diseases.

COs must check the following sources of disease information for the United Kingdom immediately prior to certification, to ensure disease freedom statements can be certified:

- the Notifiable Disease Occurrence List for Great Britain (ET171) available on the Exports > Certification Procedures page of the APHA Vet Gateway
- the UK Status for Non-Notifiable Diseases Relevant to Export Certification (ET152) available on the <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.

FMD was reported in the UK in February 2001 and then again in August 2007. Its freedom was restored in January 2002 and December 2007, respectively, by the WOAH.

Bluetongue was reported in Great Britain on 3 August 2007. Great Britain was declared free again on 5 July 2011 until 10 November 2023.

Bluetongue serotype 3 was reported in Great Britain on 11 November 2023 and Great Britain is currently no longer recognised as Bluetongue free.

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

NI origin:

For Northern Ireland 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 Northern Ireland 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 autoclearance 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 Border Control Post or told otherwise.

EU origin:

It is possible that some consignments may contain animal products that are of EU origin and were imported into 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 a 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 Border Control Post 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 Border Control Post 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. 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

9. CERTIFIED COPIES OF EXPORT HEALTH CERTIFICATES

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

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

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

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

10. <u>LEGAL STATEMENT</u>

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

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

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8403 NFG

Version History: NFG

Version 3 published 27 Nov 2023

Notifiable Disease Clearance: Information about Bluetongue serotype 3, reported in Great Britain on 11 November 2023 is added. Great Britain is currently no longer recognised as Bluetongue free.

<u>Scope of the certificate:</u> Paragraph with the information about the relevant format to be used, when germinal product was collected/produced, processed and stored prior to 01 January 2021 is moved under this section.

Part detail of Consignment: I.17 further information about accompanying documents/certificates to have same or equivalent conditions as per II.2.2 of the EHC 8304.

Part II Certification: II.1.1.4: Further information is added about the GB requirements for vaccination against diseases for imports of the product.

- **II.1.2**: Websites links are added for the establishments on Gov.uk and approved establishments on the EU commission website.
- **II.2.2** Certificates should be listed as per II.2.2 (or equivalent certificates with conditions at least as strict as the relevant model certificates). Further information is added about which model certificate to be used, as this depends on the export date, collection/production date and what EU legislation was in force at the time of collection/production/storage.