

**Department for Environment, Food and Rural Affairs**

# **Notes for Guidance: Export Health Certificate for entry into the European Union or Northern Ireland of consignments of stocks of *in vitro* produced embryos of bovine animals produced, processed and stored before 21 April 2021 in accordance with Council Directive 89/556/EEC, and dispatched by the embryo production team 8421**

**July 2024**

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**No: 8421 NFG**

**EHC for entry into the EU or NI of consignments of stocks of *in vitro* produced embryos of bovine animals produced, processed and stored before 21 April 2021 in accordance with Council Directive 89/556/EEC, conceived using semen complying with requirements of Council Directive 88/407/EEC, and dispatched by the embryo production team where the embryos were produced.**

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

### **1. APPLICABLE LEGISLATION**

[Commission Implementing Decision 2006/168/EC as amended](#)

[Commission Implementing Decision 2011/630/EU](#)

[Council Directive 89/556/EEC as amended](#)

[Council Directive 88/407/EEC as amended](#)

[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>

Further guidance for completion of the certificate can be found in Chapter 4 of Annex I to Commission Implementing Regulation (EU) 2020/2235.

### **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 export certificate for entry into the EU of**

consignments of stocks of *in vitro* produced embryos of bovine animals produced, processed and stored before 21 April 2021 in accordance with Council Directive 89/556/EEC, conceived using semen complying with requirements of Council Directive 88/407/EEC, and entered into the EU after 20 April 2021, and dispatched by an embryo production team by which the embryos were produced.

The NFG should not be read as a standalone document but in conjunction with the health certificate.

We strongly suggest that exporters obtain full details of the importing country's requirements from the veterinary authorities in the country concerned, or their representatives in the UK, in advance of each consignment.

*[Please note, policies are being reviewed. NFG will be further amended to provide specific guidance. Traders should look at NFGs regularly for any updates]*

## **2. SCOPE OF THE CERTIFICATE**

This EHC may be used for entry into the EU or NI of consignments of stocks of *in vitro* produced embryos of bovine animals produced, processed and stored before 21 April 2021 in accordance with Council Directive 89/556/EEC, conceived using semen complying with requirements of Council Directive 88/407/EEC, and dispatched by an embryo production team by which the embryos were produced. **This includes transits through the EU.**

This certificate is to be completed according to the notes for the completion of certificates provided for in Chapter 4 of Annex I to Implementing Regulation (EU) 2020/2235.

## **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 the Animal and Plant Health Agency (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.

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](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 Health 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 APHA Vet Gateway:

[http://apha.defra.gov.uk/External\\_OV\\_Instructions/Export\\_Instructions/Certification\\_Procedures/index.htm](http://apha.defra.gov.uk/External_OV_Instructions/Export_Instructions/Certification_Procedures/index.htm)

## **SIGNING AND STAMPING**

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

- Where the certificate contains optional or contextual statements, the statements which are not relevant shall be crossed out, individually initialled, and stamped by the CO, or completely removed from the certificate.
- Permitted paragraphs and sections may be crossed out by applying a 'Z' across the section or paragraph rather than crossing out line by line.
- There is no requirement for a date and time to accompany each stamp. The date is only entered at the required entry field in Part I of the certificate, and at the end where the CO signs, stamps and dates that action.
- We are aware of some BCPs demanding that all handwritten information in Part 1 of the EHC is initialled and stamped, including handwritten scoring out of otherwise blank boxes. There is no legal requirement in EU legislation that all the hand-written information entered in the certificate must be signed and stamped. It is only in the

case of correction, in any part of the certificate, or in the case of statements to be crossed out, that the certifier must add signature (or initials) and stamp. This has been confirmed by the European Commission. The Commission noted however, in the case of a hand-written certificate, it is expected that the same one person completes the document. If not, the BCP might suspect that empty boxes were completed by another person after the certificate has been signed by the official.

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

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

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

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

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

## **PART I: DETAILS OF THE CONSIGNMENT**

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

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

Please complete all the boxes in Part I of the certificate in accordance with the guidance laid down in Chapter 4 of Annex I to [Commission Implementing Regulation \(EU\) 2020/2235](#). Amended by [Implementing Regulation \(EU\) 2023/2744](#).

The Harmonised System (HS) Code is a commodity classification system used as a basis for customs tariffs and for international trade statistics.

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

Further information on HS Codes can be found online at:

<https://www.gov.uk/trade-tariff/sections> and <http://madb.europa.eu/madb/euTariffs.htm>

## **PART II: CERTIFICATION**

### **II.1 Health Attestation**

The OV signing the EHC must ensure that the animal 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/team veterinarian due to their knowledge of the operations of the establishment, to facilitate certification of the certificate.

Enter the territory code. GB is listed for all of the relevant commodities. The relevant regulation is [Implementing Regulations \(EU\) 2021/404](#). This regulation have been amended by [Implementing Regulations 2021/634](#), adding the GB and the Crown Dependencies to the relevant lists.

**II.1.1 and II.1.2** – See Notifiable Disease Clearance, see [Section 4](#) to certify freedom of diseases. Ensure you are aware of the provisions of Council Directive 89/556/EEC which set out the animal health conditions for trade with and dispatch into the EU or NI of bovine embryos. This can be certified on the basis that the embryo production team is approved and listed on the European Commission website, and if applicable, the embryos were produced after the date of approval of the team as mentioned on the website. EU website:

[https://ec.europa.eu/food/animals/semn/bovine\\_en](https://ec.europa.eu/food/animals/semn/bovine_en)

**II.2, II.3 and II.4** – Certify based on Notifiable Disease Clearance, see [Section 4](#).

**II.4.3** – The production team veterinarian should be asked for evidence (movement records, declarations from the veterinary practitioner responsible for the herd etc.) that the donor was only resident in a maximum of two herds during the 6 months prior to collection, and that these herds met the health status indicated (TB/Br/EBL/IBR).

**II.5** – They must ensure that they are aware of the provisions of Council Directive 88/407/EEC, which set out the animal health conditions for the collection, processing and storing of bovine semen. The semen used must be fully compliant with the requirements of the Directive, especially in relation to IBR/IPV (i.e. originate from donor bulls and semen collection centres which are seronegative). This is because the risk of IBR/IPV transmission through in-vitro produced (as opposed to in-vivo collected) embryos cannot be mitigated through processing/washing in accordance with IETS standards.

Commission Implementing Decision lists the competent authorities of countries approved to collect, process and/or store semen in approved semen collection or storage centres that is used to conceive the embryos by artificial insemination.

## **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 [Exports > Certification Procedures](#) page of the APHA Vet Gateway.

## **For Great Britain:**

**In the absence of a specific Notifiable Disease Clearance (618NDC) from CITC:** COs may certify that GB has disease free status or region free status for those diseases mentioned in the health certificate, once they have checked the disease list(s) for the last occurrence of the disease and have ensured it complies with the time frames in the certificate.

In the event of a disease outbreak that affects a CO being able to obtain their own disease clearance, CITC will notify COs to make it clear which disease freedom statements should not be certified and where necessary, will issue a 618NDC notifiable disease clearance if the EHC can continue to be issued for certain regions that retain free status.

In the event of a disease outbreak after the EHC has been issued that affects the disease clearance, COs must not certify the EHC and must contact CITC immediately for advice on whether certification can still take place. If a disease outbreak affects the disease clearance procedures for this EHC, a 618NDC will be reinstated by CITC which will be issued with the EHC until a time when disease clearance can be reinstated.

**NOTE:** This does not apply to Transmissible Spongiform Encephalopathies (TSEs) or Bovine Tuberculosis (TB) freedom statements.

## **5. COLLECTION OF EVIDENCE**

Certification Support Officers may not be utilised for gathering evidence relating to this certificate.

## **6. UK APPROVED ESTABLISHMENTS ELIGIBLE TO EXPORT TO THE EU**

The exporting establishment must be listed as a 'UK approved establishment' and a list of UK approved establishments for import of germinal products to the EU, can be found on the European Commission's list of approved establishments' link below:

[https://ec.europa.eu/food/animals/semen-oocytes-embryos\\_en](https://ec.europa.eu/food/animals/semen-oocytes-embryos_en)

Please note that the list is updated regularly and ONLY establishments on the list are approved to export to the EU, and this does not include establishments with pending applications for approval.

If the final product contains germinal products from other establishments, then these establishments should also be listed as UK and/or EU approved establishments.

## **7. ADDITION OF SCHEDULES**

When the space in Part I or Part II of the certificate is insufficient to accommodate full details of the consignment a schedule may be used. In the relevant section of the certificate the CO should annotate the certificate 'see attached schedule'. A new schedule should be created (typed or clearly written) containing the same information as that required in the certificate. The schedule must include the certificate reference number on each page and must be signed, dated and stamped by the CO in a colour other than the printed text on each page and under the last entry. The schedule forms part of the certificate. All pages of the certificate, including the schedule, must be sequentially numbered. Any blank spaces in the schedule or the certificate should be struck through with diagonal lines.

Further guidance is available here:

[http://apha.defra.gov.uk/External\\_OV\\_Instructions/Export\\_Instructions/Certification\\_Procedures/index.htm](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.



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## Version History:

### EHC

**Notes –**

**Part I -**

**Box I.6:** Guidance removed

**Box I.11:** Guidance expanded

**Box I.12:** Guidance added

**Box I.21 and I.22:** Guidance removed

**Box I.27:** Guidance added

### NFG:

#### **Version 3: Published 31 July 2024**

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

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

#### **Version 2 Published November 2023**

**Notifiable Disease Clearance:** This paragraph is updated to align with other NFGs.