Department for Environment, Food and Rural Affairs

Notes for Guidance: Export Health Certificate for entry into the European Union or Northern Ireland of collagen intended for human consumption 8396

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No: 8396

Export health certificate for entry into the European Union or Northern Ireland of collagen intended for human consumption.

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

1. APPLICABLE LEGISLATION

Regulation (EC) No 999/2001

Regulations (EC) No. 178/2002

Regulation (EC) No. 853/2004

Regulation (EC) No. 852/2004

Regulation (EC) No 2073/2005

Commission Decision 2007/453/EC

Regulation (EU) 2016/759

Regulation (EU) No 2017/625

Please note that Official Control Regulations 2017/625 repeal Regulation (EC) No 854/2004 and Directive No 96/23/EC.

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 European Union'.

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 dispatch of collagen into European Union or Northern Ireland intended for human

consumption. The NFG should not be read as a standalone document but in conjunction with the veterinary 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 the European Union or Northern Ireland of collagen intended for human consumption.

It can only be used for definitive imports into the European Union or Northern Ireland of these goods, it cannot be used for these products transiting the European Union or Northern Ireland to another third country.

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.

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

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.

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 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' for further information.

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 that can be accessed via this link:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020R2235

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

II.27: Please insert HS Code and Combined Nomenclature (CN) title

I.27 Insert the appropriate Harmonised System (HS) code(s) using headings such as 3504 or 3917.

It is the exporter's responsibility to ensure that the HS code and CN title is entered correctly and accurately reflects the product(s) being consigned, as defined by the World Customs Organisation as referred to in Council Regulation (EEC) No 2658/87, please see link:

https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A31987R2658

Further information on HS Codes for customs tariffs can be found online at:

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

I.27- Type of packaging: identify the type of packaging according to the definition given in Recommendation No 21 (10) of UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business). Please see link:

https://www.unece.org/fileadmin/DAM/cefact/recommendations/rec21/rec21_Rev10e_Annex-V-VI_2019.xls

PART II: CERTIFICATION

II.1 Public Health Attestation

The Official Veterinarian signing the export veterinary certificate must ensure that the public health attestations set out in Part II of the veterinary certificate have been complied with.

They must ensure that they are aware of the provisions of Regulations (EC) No 178/2002 of the European Parliament and of the Council, laying down the general principles and requirements of food law, and procedures in the matters of food safety.

853/2004 and Regulation (EC) 2017/625 which lay out the requirements surrounding the establishment the collagen was produced in according to the HACCP principles, and the requirements surrounding the hygienic preparation processes respectively.

They must ensure that they are aware of the provisions of Regulation (EC) No 999/2001, which lays out specified risk materials which the collagen must not contain and must not be derived from.

They must ensure that they are aware of the provisions of Regulation (EC) No 2073/2005, which lays out microbiological criteria for foodstuffs. **II.1.1; II.1.2; II.1.3 and II.1.4** - may be certified on the basis of the oval mark, own knowledge of the operations, certifying officers' own verification checks and/or any required support health attestations.

II.1.5 [Either/Or]

Select appropriate option for the consignment described in Part I.

Note: You may only certify one option. If the consignment contains material from one of more one of option, e.g. land animals and fishery products you will require two EHCs.

II.1.6 - BSE attestations [Excluding collagen derived from hides and skin]

If collagen is of bovine, ovine and caprine animal origin (except for hides and skins) the correct sub-category must be selected depending on the BSE risk category of the country of origin.

In accordance with the OIE Terrestrial Code, England, Scotland and Wales are controlled BSE risk in UK. All specified risk material (SRM) as described in the certificate must be removed from the meat intended for dispatch to the EU or NI as required by EU legislation and UK TSE legislation.

BSE status of Member States or third countries or regions thereof according to their BSE risk:

http://data.europa.eu/eli/dec/2007/453/2021-01-01

For collagen produced in GB from raw materials derived from GB animals there are 3 'either/or' sections relating to BSE risk of the country/region of dispatch. There are 3 options:

 The first option may be certified if the country of origin is classified as a country or region posing a negligible BSE risk. This option cannot currently be certified.

- The second option should be certified if the country of origin is classified as a country
 or region posing a controlled BSE risk. This option applies to exports of collagen from
 GB. If this is the case, the following attestations must be certified:
 - The first point (a) may be certified for meat derived from animals slaughtered in GB as this method of slaughter is not carried out in the UK in accordance with Retained EU Regulation 999/2001 and TSE Regulations (England) 2018 and parallel legislation in Wales and Scotland.
 - If the meat is derived from animals slaughtered in other countries, please refer to Section 6 regarding triangular trade.
 - The second point (b) has two sub-sections (i) and (ii) both of which must be certified:
 - The first can be certified when all the SRM was removed at the slaughterhouse or a cutting plant (in the case of bovine vertebral column of animals over 30 months old, which is classed as SRM and/or sheep spinal cord from animals over 12 months old which is also SRM) as required by Annex V to Retained EU Regulation 999/2001 and Schedule 7 to TSE Regulations (England) 2018 and parallel legislation in Wales and Scotland. The presence of the ID mark denotes the SRM was removed.
 - The second may be certified for export on the basis that production of MSM from bones of bovine, ovine and caprine animals is not permitted by Retained Regulation (EU) 999/2001.
 - There are two options for the third point (c) only one of which must be selected:
 - The first either can be certified for POAO obtained from animals of GB origin or a country with controlled or negligible risk.
 - The second option can only be certified if the animals from which the POAO was derived from are from an undetermined BSE risk country.

For collagen produced in GB from raw materials imported from other countries, or collagen produced in other countries and imported into the UK, the relevant statements can be certified by reference to import documentation that includes attestations of compliance with the relevant EU export requirements. Please refer to Section 6 on Triangular Trade.

For a mixed load containing products originating from differing BSE risk regions, the OV is advised to contact the BCP of entry to make sure they will accept a mixed load and advice on how they would prefer the consignments certified.

4. COLLECTION OF EVIDENCE

In GB, the Certification Support Officer (CSO) role has been developed by APHA. CSOs can collect evidence, directed by an OV, which may be used to support OV_certification of matters which do not require a clinical assessment or judgement e.g. for POAO and ABPs.

In **England, Scotland and Wales,** CSOs can be utilised by OVs for gathering evidence relating to this certificate. The CSOs must be authorised by APHA and they must hold the appropriate Official Controls Qualification (Animal Health Professional) (OCQ (AHP)-CSO) qualification.

The OV must direct the CSO as to how and where any necessary evidence relevant to the requirements of the Export Health Certificate (EHC) should be obtained. CSOs may not carry out any functions that require the exercise of veterinary judgement, and are restricted to the execution of administrative checks.

They may only carry out such inspections, factual verification and evidence collection as specified by the directing OV, who remains responsible for the certification of the product. CSOs are not authorised to sign an EHC in their own right or on behalf of an OV.

Any documentary evidence collected by the CSO must be stamped, signed and dated by the CSO, before being submitted by them as supporting evidence to the OV. It is required that the OV is familiar with the product process and evidence required to start with, before directing the CSO to provide future evidence on an ongoing basis.

Additional guidance and principles of implementation are provided in the <u>OV Instructions</u> <u>Exports section</u> of the APHA Vet Gateway.

Groupage Export Facilitation Scheme (GEFS)

For groupage exports from Great Britain, where certain types of products are produced from a stable supply chain and are fully packaged for the final consumer, exporters who are GEFS members may use 30 day support attestations to provide information to OVs to facilitate completion of this certificate.

For further information including the definition of groupage exports, the template 30 day support attestation which must be used and requirements for exporters, suppliers and vets to use the scheme see:

http://apha.defra.gov.uk/External_OV_Instructions/Export_Instructions/Certification_Procedures/Products_Exports.html

You can check that exporters are GEFS members by emailing the exporter's name, GEFS membership number and the address of the exporting premises to GEFS@defra.gov.uk

5. <u>CONSIGNMENTS OR PARTS OF THE CONSIGNMENT ORIGINATING FROM NI, EU</u> MEMBER STATES OR FROM A THIRD COUNTRY (TRIANGULAR TRADE)

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:

For imported goods that need to be certified for export from GB, these are normally subject to import certification, or the availability of a Common Health Entry Document (CHED) issued by the Border Control Post (BCP) of entry to verify that they are compliant with GB import requirements and for placing on the GB market. Certifying Officers including Official Veterinarians may use these official documents to provide supporting evidence of compliance with relevant requirements for the re-export of products. In this context OVs may rely on the CHED issued by an Official Fish Inspector (a non-veterinarian) for Fishery Products and live bivalve molluscs, live echinoderms, live tunicates or live marine gastropods for human consumption, cleared via a GB BCP.

Where the CHED or accompanying import certificate are not available or do not provide sufficient supporting information, the Certifying Officer should seek a supporting attestation from an 'authorised veterinarian' who has personal knowledge of the matters in question. This may be further supported by relevant commercial information or records. It is the responsibility of the GB exporter to obtain the necessary supporting information to enable the Certifying Officer to verify compliance with export requirements.

For goods sourced in the EU and EFTA countries, especially those that are not accompanied by a veterinary certificate or CHED issued by a BCP - Certifying Officers may rely on the oval ID mark applied at approved food establishments in the EU as evidence that the goods were produced compliant with EU food production requirements for placing on the EU market - but care must be taken not to extrapolate this to animal health requirements not covered by the obligations of a food approved establishment, i.e. matters that extend beyond the scope of Regulations 852/2004 and 853/2004.

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.

6. <u>UK APPROVED ESTABLISHMENTS ELIGIBLE TO EXPORT TO</u> THE EU

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

https://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_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 POAO from other establishments, or products were previously processed in different establishments in the production chain, then these establishments should also be listed as UK and/or EU approved establishments.

There are lists of approved establishments for other commodities, e.g. germinal products on the link above.

For approved establishments in Northern Ireland the "EC" suffix which is present in the health/ID mark, and appears on the label, is not part of the approval number should not be included when referring to establishment approval numbers in the certificate.

7. OVAL MARK ON PRODUCTS OF ANIMAL ORIGIN - POAOs

EU hygiene regulations require that food of animal origin carries and oval health or identification mark and that official controls are carried out by enforcement authorities to ensure the appropriate marking has been applied. Domestic legislation has been introduced to ensure these requirements continue to apply in GB as retained legislation.

The health marks indicate that meat is fit for human consumption and the identification marks show when foods of animal origin have been produced in officially approved establishments which are compliant with retained EU food hygiene Regulations (EC) No 852/2004, (EC) No 853/2004 and (EU) No 2017/625. Also, the primary food legislation in England, Wales and Scotland is The Food Safety Act 1990 (as amended).

https://www.food.gov.uk/business-guidance/guidance-on-health-and-identification-marks-that-applies-from-1-january-2021

Relevant text on the EHC can be certified on the basis that carcases, half carcases or quarters, or half carcases cuts into three pieces, of domestic ungulates, farmed game mammals (other than lagomorphs) and large wild game bear the official health mark or that the primary, secondary and/or shipping packaging on food products of animal origin show the identification mark.

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. ANIMAL HEALTH SCHEME

BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) ATTESTATION BSE control is enforced under the:

- The Transmissible Spongiform Encephalopathies (England) Regulations 2018;
- The Transmissible Spongiform Encephalopathies (Wales) Regulations 2018;
- The Transmissible Spongiform Encephalopathies (Scotland) Regulations 2010 (Scotland);
- The Bovines and Bovine Products (Trade) Regulation 1999.

Animals born or reared in the UK before the 1st August 1996 must not be certified for export. In addition, the following bovine animals cannot be certified for export if they are, under the UK TSE Regulations, subject to restrictions/slaughter at the time of consignment for trade:

- Offspring born within 24 months of clinical suspicion or confirmation of BSE in the dam;
- Cohort of a BSE case.

Defra IT systems would identify and trace these (offspring and cohort) animals as soon as a suspect BSE case is identified <u>or a bovine tested under the BSE active surveillance programme receives a positive result from a rapid test,</u> and therefore for all practical purposes, if an animal is not subject to a BSE related restriction at the time of certification, it can be certified for trade.

11. 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 "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

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

PB 8396 NFG

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NFG_

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- Triangular trade section EU paragraph:
 - <u>Amended to standardise the advice we provide on documentary evidence across</u> POAO NFGs.