NOTES FOR THE GUIDANCE OF THE OFFICIAL VETERINARIAN AND EXPORTER

In relation to 8807EHC titled:
Veterinary certificate for gelatine intended for pharmaceutical use, exported from the United Kingdom into India

Associated Documents: 8807EHC.

IMPORTANT
These notes provide guidance to Official Veterinarians (OVs) and exporters. The NFG should not be read as a standalone document but always in conjunction with certificate 8807EHC. **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.**

1. **SCOPE OF THE CERTIFICATE**

This certificate may be used for the export gelatine to India, including gelatine made from the bones, hides and skins of bovine animals, intended for pharmaceutical use.

2. **Certification by an Official Veterinarian (OV)**

This certificate may be signed by an OV appointed by the Department for Environment, Food and Rural Affairs, the Scottish Government, Welsh Government or the Department of Agriculture, Environment and Rural Affairs (DAERA) Northern Ireland, who is on the appropriate panel for export purposes or who holds the appropriate Official Controls Qualification (Veterinary)(OCQ(V)) authorisation.

OVs must sign and stamp the health certificate with the OV stamp in any ink colour **OTHER THAN BLACK.**

Certified Copy Requirements – England, Wales and Scotland

Guidance concerning return of certified copies of EHCs has changed and only specific certified copies are required to be returned to the APHA. Certifying OVs must return a certified copy of EHCs only for the following EHC types:

• if the exported commodity is cattle, pigs, sheep, goats or camelids;
• if the certificate was applied for manually and the application documents have been emailed to APHA and not applied for via the Exports Health Certificates Online (EHCO) system.

Certified copies should be emailed on the day of signature to the Centre for International Trade Carlisle (CITC) at the following address: certifiedcopies@apha.gov.uk.

For certificates that have been issued to the Certifying OV via the EHCO system, the Certifying OV must complete the certifier portal with the status of the certificate and the date of signature.

A copy of all EHCs and supporting documentation certified must be retained for two years.

Certifying OVs are not required to return certified copies of other EHCs issued, however CITC may request certified copies of EHCs and supporting documentation in order to complete Quality Assurance checks or if an issue arises with the consignment after certification.

DAERA Export Health Certificates: Provision of certified copies

aPVPs (Authorised private veterinary practitioners) certifying DECOL produced Export Health Certificates must return a legible, scanned copy of the final EHC to the relevant DAERA Processing Office within 1 working day of signing.

Good quality photographic copies will be accepted by the department, where obtaining a scanned copy is not feasible - for example, where 'on site' certification is undertaken and scanning facilities are not available.

For record purposes, a copy of the final Export Health Certificate and associated Support documents should be retained by the aPVP for a period of 2 years from the date of certification.

The Department will carry out periodic audits of all aspects of export certification to ensure that a high standard of certification is being maintained.

3. **Paragraph II – Health information**

Paragraph II may be certified on the basis of the following specific guidance in conjunction with the RCVS Principles of Certification. OVs should develop due familiarity with the sourcing, procurement, segregation, processing, handling and storage arrangements in place at the establishment. This should be supported as necessary by physical inspection and by examination of relevant documentation or other records including commercial documentation, veterinary statements, laboratory analysis and valid declarations.

Paragraph II 1 – Negligible BSE risk countries

This paragraph can be certified if all countries where the cattle was born, bred and slaughtered are classified by WOAH as of negligible BSE risk. As of April 2019, in the UK only Northern Ireland is regarded as having a negligible BSE risk.

The BSE risk status of a country or region assigned by WOAH can be seen by clicking on the "*Official Disease Status*" link on the WOAH's website: https://www.woah.org/en/disease/bovine-spongiform-encephalopathy/#ui-id-2

Guarantees are required that the animals from which the material is derived have passed post-mortem inspection. Written confirmation that this is the case, which can be traceable to incoming batches of raw material and also to manufactured gelatine, must be kept for audit purposes.

The paragraph may then be certified on this basis.

Paragraph II 2.(a) – Controlled BSE risk countries

This paragraph should be certified if any countries where the cattle was born, bred and slaughtered are classified by WOAH as of controlled BSE risk. As of April 2019, England, Scotland and Wales are regarded as having a controlled BSE risk.

The status of other countries can be found at; http://www.oie.int/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/

Paragraph II 2.(a) – Post-mortem inspection

Guarantees are required that the animals from which the material is derived have passed post-mortem inspection. Written confirmation that this is the case, which can be traceable to incoming batches of raw material and also to manufactured gelatine, must be kept for audit purposes.

The paragraph may then be certified on this basis.

Paragraph II 2.(b) – Specified risk material

The excluded materials referred to in this paragraph correspond to the definition of specified risk material laid down under Chapter D of Annex IX of Regulation (EC) No 999/2001 (as amended).

Regulation (EC) No 999/2001 (as amended) requires the removal and safe destruction of specified risk material from ruminant animals which are slaughtered in a slaughterhouse approved in accordance with the EU Hygiene package which includes Regulations (EC) 852/2004, 853/2004 and Regulation (EU) 2017/625.

This paragraph may therefore be certified on the basis that the bovine bones were obtained from a slaughterhouse approved in accordance with the abovementioned EU Hygiene package or (if from a country outside the EU) in accordance with equivalent legislation enabling the bovine material or the gelatine to be legally imported into the UK.

Paragraph II 2.(c) – Bone treatments

This paragraph can be certified on the basis that the requirement for such treatments is set out in assimilated regulation 853/2004 Annex III, Section XIV, Chapter III. This should be supported by any evidence or documentation deemed necessary by the OV.

Paragraph II 3. – separation of source material and product from BSE risk materials

The requirement for separation of animal by-products according to category are set out in assimilated Regulation (EC) No 1069/2009 and implementing regulations. This should be supported by any evidence or documentation deemed necessary by the OV.

5. SUPPORTING DECLARATIONS

Where declarations are relied upon to support the completion of this certificate, these must be signed by someone who has knowledge of and responsibility for the relevant parts of the production process and/or declared intended use. The managing director (or equivalent) of the company should provide a letter giving the name(s) and job title(s) of those authorised to give the declaration and the basis on which the declaration is made.

The declaration should include a clause indicating that the signatory is aware that making a false declaration is an offence and that he/she accepts full responsibility if any problems arise with the export should there be any dispute relating to the matters being declared.

Where possible, supporting evidence should be called for and put on file.

6. DISCLAIMER

This certificate is 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 Centre for International Trade, Carlisle or DAERA, via the link or e-mail address below:

https://www.gov.uk/guidance/contact-apha

DAERA – Email: vs.implementation@daera-ni.gov.uk