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NOTES FOR THE GUIDANCE OF THE OFFICIAL VETERINARIAN AND EXPORTER

In relation to 8509EHC titled:
EXPORT OF BOVINE AND PORCINE COLLAGEN TO THE UNITED STATES OF AMERICA FOR MEDICAL, PHARMACEUTICAL OR COSMETIC USE

Associated Documents: 8509EHC

IMPORTANT
These notes provide guidance to Official Veterinarians (OV) and exporters. The NFG should not be read as a standalone document but always in conjunction with certificate 8509EHC.
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**

This certificate may be used for the export of collagen derived from bovine hides, bovine bones, porcine skin and porcine bones to the United States of America for medical, pharmaceutical or cosmetic use.

References in the certificate to the **BSE risk classification** of a region refer to the BSE risk classification as set out under **9 CFR 92.5** of the USA's Code of Federal Regulations.

The Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) publishes a list of those regions (countries or parts of countries) which they officially recognise as having either a negligible or controlled BSE risk under 9 CFR 92.5 on their website at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions

If a country or part of a country does not appear on this list, then it should be considered to have an undetermined BSE risk.

Note that the **BSE risk classifications** recognised by APHIS may not necessarily reflect the BSE risk classifications applied by the World Organisation for Animal Health (still known by its historical acronym, OIE) and published online at:
http://www.oie.int/animal-health-in-the-world/official-disease-status/bse/list-of-bse-risk-status/

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

This **certificate** must be signed by a whole-time salaried Veterinary Officer (VO) of the Department for Environment, Food and Rural Affairs (Defra), or Scottish Government, or Welsh Government or Department of Agriculture, Environment and Rural Affairs Northern Ireland (DAERA). This may be done based on a pre-certificate provided by an Official veterinarian who will undertake the physical inspection of the consignment and validation of the declarations

The VO should keep a copy of the submitted certificate and the final countersigned certificate for his/her own records.

3. **Paragraph I(a) – Description of the products**

This should include the species (bovine and/or porcine) and type of material (hides, skins or bones) used to make the collagen.

4. Paragraph II(a) – UK approval number

This relates to the UK establishment producing/preparing the product to be exported, and not necessarily the establishment which manufactured the collagen from the raw materials of animal origin.

Establishments manufacturing collagen which is not intended for human consumption must be approved in accordance with Regulation (EC) 1069/2009 (as amended). However, registration under this Regulation may be sufficient if the establishment is only handling collagen manufactured elsewhere. In England, this Regulation is enforced by the Animal By-Products (Enforcement) (England) Regulations 2013 (as amended). Similar legislation exists in Scotland, Wales and Northern Ireland.

Certifying Official Veterinarians are advised that, in accordance with Articles 54 and 55 of Regulation (EC) 1069/2009 (as amended), references to Regulation (EC) 1774/2002 (as amended) shall be construed as references to Regulation (EC) 1069/2009 (as amended) and that establishments, plants and users approved or registered in accordance with regulation (EC) 1774/2002 (as amended) before 4 March 2011 shall be deemed to be approved or registered, as required, in accordance with regulation (EC) 1069/2009.

Alternatively, the collagen may be manufactured in a food business premises approved in accordance with the EU Hygiene package which includes Regulations (EC) 852/2004 on the hygiene of foodstuffs, 853/2004 laying down specific hygiene rules for food of animal origin and 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption. In England, the EU Hygiene package is implemented and enforced by the Food Safety and Hygiene (England) Regulations 2013 (as amended). Similar legislation exists in Scotland, Wales and Northern Ireland.

The UK establishment's approved or registered status may be confirmed on sight of a valid approval or registration document, or by reference to the enforcement authority (APHA, DAERA or Local Authority) responsible for the establishment.

5. Paragraph IV – Health information

Paragraph IV may be certified on the basis of a relevant written declaration from an authorised signatory of the manufacturing establishment identified at paragraph II(a) of the certificate, taking into account the following specific guidance and the RCVS Principles of Certification.

The certifying OV must make due enquiry to validate the declarations being made. This may include additional supporting evidence obtained through physical inspection and/or examination of relevant documentation or other records including commercial documentation, veterinary statements and laboratory analysis.

This certificate must be completed depending on the species and type of animal materials used to make the collagen and, in the case of collagen made from bovine bones, the BSE risk status of the country of origin, as recognised by APHIS and published at:

https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions

The certifying OV is therefore advised to verify the relevant BSE risk status as recognised by APHIS at the time of signature rather than relying solely on the manufacturer's declaration.

(a) **Paragraph IV(a) – Presence or absence of bovine collagen**
Either paragraph **IV(a)(i)** or paragraph **IV(a)(ii)** must be certified as appropriate. The paragraph that is not being certified must be struck through in its entirety and the deletion signed and stamped in the usual manner.

(b) **Paragraph IV(a)(ii)1. – Bovine hide collagen**
This paragraph must be certified if the consignment contains any collagen derived from **bovine hides.**

For the purposes of this certificate and the manufacturer's declaration, '*materials ineligible for entry into the United States*' means collagen which cannot satisfy the requirements of this certificate.

If the consignment **does not** contain any collagen derived from bovine bones then paragraphs **IV(a)(ii)2** and **IV(a)(ii)3** must both be struck-through in their entirety and the deletion signed and stamped in the usual manner.

If the consignment **does** include collagen derived from bovine bones, then paragraph **IV(a)(ii)2** and/or paragraph **IV(a)(ii)3** must also be certified as per the following guidance.

(c) **Paragraphs IV(a)(ii)2. and IV(a)(ii)3. – Bovine bone collagen**
One of these paragraphs must be certified if the consignment contains any collagen derived from **bovine bones.** The paragraph that is not being certified must be struck through in its entirety and the deletion signed and stamped in the usual manner.

The BSE risk status of the area where the premise of dispatch is located (as recognised by APHIS – see **paragraph 1** above) will determine whether paragraph **IV(a)(ii)2.** or **IV(a)(ii)3.** should be certified with respect to the consignment.

Paragraph **IV(a)(ii)2.** should be certified if the premises of dispatch is located in a region of the United Kingdom recognised by APHIS as having a **negligible BSE risk.**

Paragraph **IV(a)(ii)3.** should be certified if the premises of dispatch is located in a region of the United Kingdom recognised by APHIS as having a **controlled BSE risk.**

(d) **Paragraph IV(a)(ii)2. – Export from a negligible BSE risk region**
The **certifying OV** should refer to the APHIS website given in **paragraph 1** above to determine if the consignment is being dispatched from a premises located in a region of the United Kingdom officially recognised by APHIS as having a **negligible BSE risk.**

The space for the **exporting region** should be completed with the name of the specific negligible BSE risk region, for example "United Kingdom, region of Northern Ireland".

(e) **Paragraph IV(a)(ii)3. – Export from a controlled BSE risk region**

The **certifying OV** should refer to the APHIS website given in **paragraph 1** above to determine if the consignment is being dispatched from a premises located in a region of the United Kingdom officially recognised by APHIS as having a **controlled BSE risk**.

The space for the **exporting region** should be completed with the name of the specific controlled BSE risk region. For example "United Kingdom, region of Northern Ireland" or "United Kingdom, region of England".

Paragraph IV(a)(ii)3.A. – Ante- and post-mortem inspection

Confirmation of ante- and post-mortem inspection may be supported by examination of relevant documentation including veterinary import certification, veterinary statements, commercial documentation and valid declarations.

Certifying OVs and exporters are reminded that the above requirement for the bovine animals to have passed post-mortem inspection goes beyond the statutory requirements for the manufacture of collagen that is not intended for human consumption, as set out under Regulation (EC) 142/2011 (as amended).

Therefore the certifying OV should make due enquiry to verify that the bovine bones used satisfy this stricter requirement. For example, documentation simply stating that the raw materials are Category 3 materials 'other than those materials referred to in Article 10(m), (n), (o) and (p) of Regulation (EC) No 1069/2009' does not confirm that the animals had passed post-mortem inspection.

Paragraph IV(a)(ii)3.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 854/2004 (see **paragraph 4** above).

Certification of this paragraph may therefore be supported on the basis that the bovine bones were obtained from a plant approved in accordance with the EU Hygiene package or (if from a country outside the EU) in accordance with equivalent legislation to enable the bovine bones or the collagen to be legally imported into the UK.

Paragraph IV(a)(ii)3.C. – Processing requirements

This paragraph requires the bovine bones to have been processed **either** in accordance with the five bulleted steps **or** to an alternative process "recognised by APHIS as being at least as effective in reducing BSE infectivity".

If the bones have been processed using an alternative process then this paragraph must only be certified if the exporter has obtained written confirmation from APHIS officially recognising the specific alternative process as being at least as effective in reducing BSE infectivity.

In either case, the option which does not apply must be struck through and any blank spaces must be deleted with diagonal lines, and the deletion signed and stamped in the usual manner.

Paragraph IV(a)(ii)3.D. – Comingling with ineligible materials
For the purposes of this certificate and the manufacturer's declaration, '*materials ineligible for entry into the United States*' means collagen which cannot satisfy the requirements of this certificate.

(f) **Paragraph IV(b) – Presence or absence of porcine collagen**
Either paragraph **IV(b)(i)** or paragraph **IV(b)(ii)** must be certified as appropriate. The paragraph which is not being certified must be struck through in its entirety and the deletion signed and stamped in the usual manner.

6. 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.

7. DISCLAIMER
This certificate and these notes 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 Centre for International Trade (CIT) – in Carlisle, via the link below:

https://www.gov.uk/government/organisations/animal-and-plant-health-agency/about/access-and-opening#customer-service-centres-csc

In Northern Ireland, please contact the DAERA trade administration team:

- e-mail - tradeadminpost@daera-ni.gov.uk
- Phone - 02877442146