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NOTES FOR THE GUIDANCE OF THE OFFICIAL VETERINARIAN AND EXPORTER

In relation to 8088EHC titled:
EXPORT OF COLLAGEN AND GELATINE TO THE REPUBLIC OF KOREA

Associated Documents: 8088EHC

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 8088EHC.
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 of collagen and/or gelatine to the Republic of Korea that is intended for human consumption, animal consumption, pharmaceutical use, medical use, cosmetic use or any other purpose.

However, certifying OVs and exporters are advised of the following information provided by the South Korean authorities via the British Embassy in Seoul:

(a) This certificate **must not** be used for collagen and/or gelatine made from **bones** of any species. **Paragraphs 5 and 7(a)** below refer.

(b) This certificate **must not** be used for collagen and/or gelatine made from **bovine material** derived from **cattle slaughtered outside the UK. Paragraph 7(b)(ii)** refers.

(c) The **only** raw bovine material permitted for making collagen and/or gelatine exported to South Korea is **hide and skin obtained from cattle slaughtered in the UK. Paragraph 7(b)** refers.

(d) This certificate **must not** be used for the export of **collagen casings and films** within the scope of Harmonised System (HS) Code 39 17 10 10 00 for "Artificial guts (sausage casings) of hardened protein". The Harmonised System (HS) Code is a commodity classification system used as a basis for customs tariffs and for international trade statistics. Such products should be exported using the **5838EHC.**

This certificate follows the model certification provided by the South Korean authorities, therefore these guidance notes should be followed if the intention of the English text is not entirely clear.

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 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 I(b) – Species of origin

The species of origin of the raw animal materials used in the manufacture of the products in the consignment must be entered in the space provided.

4. Paragraph I(c) – Origin of the raw materials used

Only one box should be ticked. Note the instruction for mixed origins.

Further to the prohibitions on the use of **bones** outlined under **paragraphs 5** and **7(a)** below, **only the 'Hides and Skins' box or 'Others' box may be ticked** at this time until further notice.

5. Paragraph I(i) – Approval number

Further to **paragraph 1** above and the note appended to this paragraph in the certificate, this paragraph **must only** be completed if the

product is derived from bones obtained from bovine animals and processed in a UK establishment specifically approved by the Korean authorities to manufacture collagen and/or gelatine.

However, at the time of writing, **no UK establishments have been specifically approved by the Korean authorities** for this purpose.

Furthermore, Defra has been advised by the British Embassy in Seoul that the South Korean authorities will not accept collagen and/or gelatine from the UK if it was made from **animal bones**, regardless of the species or country of origin, until they have the necessary legislation in place.

Therefore, this certificate **must not be used to export collagen and/or gelatine made using bones** and the phrase **'not applicable'** should be entered in the space provided at this paragraph.

If there is a significant commercial requirement for the manufacturing establishment's approval number to appear within the certificate, the establishment's statutory approval number, as described in **paragraph 7(b)(i)** below, may be inserted as part of **Paragraph I(h)** of the certificate (as part of the name and address of the manufacturing plant). Please note that entering it under **I(i)** could be misconstrued as indicating the origin being from bones leading to rejection of the consignment.

6. Paragraph I(p) – Intended use

Only one box should be ticked.

'Human consumption' includes pharmaceutical-grade products, which are intended to be consumed by humans, such as empty gelatine capsules or the gelatine used to make such capsules.

'Research' may be considered to be in-vitro laboratory use.

'Other' uses may include animal consumption, other pharmaceutical uses, medical use and cosmetic use.

This may be supported by an exporter's declaration of intended use or the labelling on the product, as appropriate. However, if there is any doubt as to which box should be ticked for the specific consignment, exporters are advised to seek guidance from the Korean authorities via their Korean contacts.

7. Paragraph II – Health information

Note: For the purposes of this certificate, the term '*government officer* of the exporting country' means an Official Veterinarian as described in paragraph 2 above.

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.

Any combination of Paragraphs II 1, II 2 and II 3 may be certified in line with the following guidance in order to reflect the nature and species of origin of the animal materials used to manufacture the collagen and gelatine present in the consignment.

(a) **Paragraph II 1 – Product made from bovine bones**

Defra has been advised by the British Embassy in Seoul that the South Korean authorities will not accept collagen and/or gelatine from the UK if it was made from **animal bones,** regardless of the species.

Therefore, **this certificate must not be used to export collagen and/or gelatine made using bovine bones** and this section of the certificate has been struck through in its entirety to reflect this.

(b) **Paragraph II 2 – Product made from bovine hides and skins from animals in countries with reported cases of BSE**
Despite the reference to the use of "hides and skin of cattle from countries with reported cases of BSE", this paragraph goes on to require the cattle to have been slaughtered in the UK.

This paragraph must therefore be interpreted as reading "**For collagen and gelatin derived from hides and skin of cattle from the United Kingdom**".

Note also that the South Korean authorities have, via the British Embassy in Seoul, specifically confirmed that **bovine tendons cannot be used** to make the collagen and/or gelatine and that **the only permitted bovine raw material is hide and skin.**

If the collagen and/or gelatine is made exclusively from raw materials derived from **animals other than bovines**, this paragraph is not applicable and must be struck through in its entirety in the usual manner. In such cases, the certifying OV should consider whether **paragraph II 3** can be certified for the consignment (see **paragraph 7(c)** below).

(i) **Paragraph II 2(a) – Prevention of contamination**
This may be certified on the basis that the UK manufacturing establishment is, and has been, operating within the terms of its statutory approval, as follows:

- For collagen and gelatine **intended for human consumption:**
  Approval in accordance with the Food Safety and Hygiene (England) Regulations 2013 (as amended) or with parallel legislation in force in Scotland, Wales and Northern Ireland.

  These statutory instruments currently enforce and implement the principles and controls laid down under 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.

- For collagen and gelatine **NOT intended for human consumption:**
  Approval in accordance with the Animal By-Products (Enforcement) (England) Regulations 2013 (as amended) or with parallel legislation in force in Scotland, Wales and Northern Ireland.

  These statutory instruments currently enforce and implement the principles and controls laid down

under Regulations (EC) 1069/2009 (as amended).

Certifying OVs 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.

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

(ii) **Paragraph II 2(b) – Ante- and post-mortem inspection**
This paragraph requires that the bovine hides and skins used must have come from cattle that "passed ante-mortem and post-mortem inspections **conducted by the government of exporting country**" (SIC).

Therefore, the cattle must have been slaughtered in a UK slaughterhouse approved in accordance with the Food Safety and Hygiene (England) Regulations 2013 (as amended) or with parallel legislation in force in Scotland, Wales and Northern Ireland.

These statutory instruments currently enforce and implement the principles and controls laid down under 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.

Certifying OVs and exporters should be aware that the above requirement for the bovine animals to have passed ante- and post-mortem inspection goes beyond the statutory UK requirements for the manufacture of collagen and/or gelatine which is **not intended for human consumption**.

Therefore, the certifying OV should make due enquiry to verify that the bovine hides and skins used satisfy this stricter requirement if the product is **not intended for human consumption**.

(c) **Paragraph II 3. – Product made from other raw animal materials**
This paragraph must be certified for consignments containing any collagen and/or gelatine made from raw materials obtained from animals other than bovines, as explained at **paragraph 7(b)** above.

Although this paragraph does not set out any specific requirement in relation to the nature, species or country of origin of the raw materials used, exporters are strongly advised to obtain confirmation from the South Korean authorities, for example via their importer, that their specific product will be permitted entry and under what

conditions.

(i) **Paragraph II 3(a). – Prevention of contamination**
This may be certified for collagen and gelatine produced in the UK on the basis that the manufacturing establishment is, and has been, operating within the terms of its statutory approval, as follows:

- For collagen and gelatine **intended for human consumption:**
  Approval in accordance with the Food Safety and Hygiene (England) Regulations 2013 (as amended) or with parallel legislation in force in Scotland, Wales and Northern Ireland.

  These statutory instruments currently enforce and implement the principles and controls laid down under 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.

- For collagen and gelatine **NOT intended for human consumption:**
  Approval in accordance with the Animal By-Products (Enforcement) (England) Regulations 2013 (as amended) or with parallel legislation in force in Scotland, Wales and Northern Ireland.

  These statutory instruments currently enforce and implement the principles and controls laid down under Regulations (EC) 1069/2009 (as amended).

  Certifying OVs 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.

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

8. 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.

9. 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