No: .....

NOTES FOR THE GUIDANCE OF THE OFFICIAL VETERINARIAN AND EXPORTER

In relation to 5901EHC titled:
EXPORT TO THE REPUBLIC OF SOUTH AFRICA OF BOVINE SERUM INTENDED FOR LABORATORY USE ONLY

Associated Documents: 5901EHC

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 5901EHC.**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 irradiated bovine serum or products containing irradiated bovine serum to South Africa in accordance with the requirements of a valid veterinary import permit issued by the competent South African authority.

The number of the relevant import permit must be entered into the appropriate space on the first page of the certificate.

Note that in the case of the re-export of products imported into the UK, copies of the veterinary import certification issued by the competent authority of the country of origin may need to accompany the consignment to South Africa.

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

Certified Copy Requirements
Certifiers are only required to return a certified copy of EHCs for the following EHC types:

If the commodity is cattle, pigs, sheep, goats or camelids EHC's where the certifier cannot submit certifier feedback

If you are required to return a certified copy to CITC, email a scanned copy to certifiedcopies@apha.gov.uk.

Retain a copy of all EHCs and supporting documentation certified for two years.

Certifiers 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 II(a) – Origin of products (Country of origin)**
In the case of bovine serum imported into the UK, a copy of a veterinary certificate confirming the country of birth and residence of the donor animals must be attached to this certificate.

The certifying OV should make due enquiry to ensure that the veterinary health certification being attached relates to the serum used in the consignment to be exported by, for example, cross-referencing the batch or lot numbers.

4. **Paragraph II(b) – Bottling premises**
This should be completed for both imported and UK-origin bovine serum.

In the case of bovine serum imported into the UK, a copy of a veterinary certificate confirming the bottling premises and accompanying the material into the UK must be attached to this certificate.

The certifying OV should make due enquiry to ensure that the veterinary health certification being attached relates to the serum used in the consignment to be exported by, for example, cross-referencing the batch/ or lot/catalogue numbers.

5. **Paragraph II(c) – Approved irradiation facility**
It is expected that the irradiation facility will be ISO accredited with respect to its irradiation capabilities.

The facility's accredited status may be confirmed by reference to a relevant ISO accreditation document.

6. **Paragraph IV – Health Information**
Paragraph IV 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.

(a) **Paragraph IV 1 – Irradiation**

This may be certified on the basis that the serum was irradiated as described at a facility which is ISO accredited with respect to its irradiation capabilities.

The facility's accredited status may be confirmed by reference to a relevant ISO accreditation document. Confirmation of the irradiation process applied may be obtained by reference to a statement or certificate issued by the accredited irradiation facility or to veterinary certification relating to the batches/lots of the serum being exported.

(b) **Paragraph IV 2 – Serum collected from slaughtered cattle**

If the consignment contains bovine serum collected only from live donor animals, this paragraph should be entirely struck through in the usual manner.

If the consignment contains bovine serum collected from slaughtered animals, this entire paragraph must be certified.

(i) **Paragraph IV 2.1 – Approved slaughtering establishment**

For imported bovine serum, this may be certified on the basis of relevant assurances provided by the veterinary certification accompanying the bovine serum into the UK.

For UK-origin bovine serum, this may be certified on the basis that the blood was obtained from animals slaughtered in a slaughterhouse approved in accordance with The Food Safety and Hygiene (England) Regulations 2013 (as amended) or equivalent legislation in force in Scotland, Wales and Northern Ireland.

These statutory instruments continue to enforce and implement the principles and controls laid down in the retained EU Food 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 Regulation 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and protection products.

Approval of a UK slaughterhouse may be confirmed on sight of a valid approval document.

(ii) **Paragraph IV 2.2 – Not intended for human consumption**

This may be supported by confirmation that the product was derived from blood classed as Category 3 material as defined in Article 10 of the retained Regulation (EC) 1069/2009. This regulation continues to be enforced and implemented by the Animal By-Products (Enforcement) (England) Regulations 2013 (as amended) and by equivalent legislation in force in Scotland, Wales, and Northern Ireland.

This may also be supported by reference to the usage instructions, data sheets and marketing information relating to the products in the consignment.

(iii) **Paragraph IV 2.3 –BSE risk status**

The option to be certified will depend on the BSE risk status of the country or zone in which the cattle were slaughtered.

The BSE risk status of a country or zone, as recognised by the World Organisation for Animal Health (WOAH, formerly the OIE), can be confirmed by clicking on the "Official Disease Status" link on the WOAH's website at:

https://www.woah.org/en/disease/bovine-spongiform-encephalopathy/#ui-id-2

First Option – Controlled BSE risk status

The first option must be certified for countries or zones with a controlled BSE risk status, and the second option must be struck through in the usual manner.

For imported material, compliance with the stunning requirements may be certified on the basis of a suitably worded veterinary import certificate relating to the batches/lots of the serum being exported.

For UK origin material, compliance with the stunning requirements may be certified on the basis that these practices are prohibited in zones of the UK with a controlled BSE risk by the Transmissible Spongiform Encephalopathies (England) Regulations 2018 (as amended) and by equivalent legislation in force in Scotland, Wales and Northern Ireland.

Second Option – Negligible BSE risk status

The second option must be certified for countries or zones with a negligible BSE risk, and the first option must be struck through in the usual manner.

(c) **Paragraph IV 3 – Specified Risk Material**

For the purposes of this paragraph, the term "**specified risk material**" may be interpreted to mean the tissues described under points 1 and 2 of Annex V of **retained Regulation (EC) 999/2001, as s**ummarised below:

- the skull excluding the mandible and including the brain and eyes, and the spinal cord of bovine animals aged over 12 months from any country;
- the vertebral column excluding the vertebrae of the tail, the spinous and transverse processes of the cervical, thoracic and lumbar vertebrae and the median sacral crest and wings of the sacrum, but including the dorsal root ganglia, of bovine animals aged over 30 months from a country or region with an undetermined or controlled BSE risk status in accordance with the OIE (now WOAH);
- the tonsils, the last four meters of the small intestine, the caecum and the mesentery of bovine animals of all ages from a country or region with an undetermined or controlled BSE risk status in accordance with the OIE (now WOAH);

- the skull including the brain and eyes, and the spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum from any country;

The principles and controls laid down in the **retained Regulation (EC) No 999/2001** continue to be enforced and implemented by the Transmissible Spongiform Encephalopathies (England) Regulations 2018 (as amended) and by equivalent legislation in force in Scotland, Wales and Northern Ireland.

For UK-origin bovine serum, this paragraph may be certified on the basis that the material used in the manufacture of the consignment was derived from Category 3 material as defined under Article 10 of the **retained Regulation (EC) No. 1069/2009**. This regulation continues to be enforced and implemented by the Animal By-Products (Enforcement) (England) Regulations 2013 (as amended) and by equivalent legislation in force in Scotland, Wales, and Northern Ireland.

For imported bovine serum, this may be certified on the basis of relevant assurances provided by the veterinary certification accompanying the material into the UK.

(d) **Paragraph IV 4 – Legally imported**

For UK-origin bovine serum, this paragraph must be entirely struck through in the usual manner.

For imported bovine serum, this paragraph must be certified. This may be certified on the basis of the veterinary certification accompanying the material into the UK.

Either option (a) or (b) must be certified. The option which is not to be certified must be struck through in the usual manner.

Option (c) must be certified in all cases.

For imported serum which remained sealed whilst in the UK, option (c) may be supported by reference to relevant assurances provided by the veterinary certification accompanying the material into the UK.

For imported serum which did not remain sealed whilst in the UK, the serum containers must be re-sealed using appropriate tamper-evident seals.

(e) **Paragraph IV 5 – BSE risk status**

The BSE risk status of a country or zone, as recognised by the World Organisation for Animal Health (WOAH, formerly the OIE), can be confirmed by clicking on the "Official Disease Status" link on the WOAH's website at: https://www.woah.org/en/disease/bovine-spongiform-encephalopathy/#ui-id-2

(f) **Paragraph IV 6 – Sealed under official supervision**

This refers to the packaging and sealing of the final consignment for export. This paragraph requires the consignment to be sealed under official supervision.

This means that appropriate uniquely numbered tamper-evident seals must be applied in the direct presence of either the certifying OV or the Certification Support Officer (CSO), and the unique seal numbers entered in the space provided.

7. 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.

8. 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) – 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