

**EXPORT OF \*BOVINE/HORSE SERUM OF NON UK ORIGIN \*AND/OR UK ORIGIN NON-BIUNGULATE SERUM FOR IN-VITRO DIAGNOSTIC USE TO JAPAN**

**NOTES FOR THE GUIDANCE OF THE OFFICIAL VETERINARIAN AND THE EXPORTER**

1. **SCOPE OF THE CERTIFICATE**

Export health certificate 4340EHC may be used for the export of bovine/horse serum of non UK origin and/or UK origin non-biungulate serum for in-vitro diagnostic use from Great Britain to Japan.

2. **CERTIFICATION BY AN OFFICIAL VETERINARIAN (OV)**

This certificate may be signed by a Local Veterinary Inspector appointed by the Department for Environment, Food and Rural Affairs, Scottish Executive Environment and Rural Affairs Department or National Assembly for Wales who is an Official Veterinarian (OV) on the appropriate panel for export purposes. OVs should affix the OV stamp to the certificate in the normal manner.

The health certificate must be signed and stamped with OV stamp in any ink colour **OTHER THAN BLACK**.

A certified copy of the completed certificate must be sent to the local Divisional Veterinary Manager within seven days for his/her own record keeping purposes.

3. Paragraph II (b): Japan has not asked for a specific approval of establishments for the export of in-vitro products covered by the certificate. However, the establishment must only handle sera obtained from the countries authorised by Japan- see footnote on the certificate. In addition, processors who intend to export to Japan must be registered and inspected under article 4 of Directive 92/118/EEC (Balai Directive) and are issued with a number. This number must be stated here.

Veterinary inspections must be carried out (under the Directive) at least annually during which the veracity of the declaration of paragraph IV must be ascertained. As a minimum the inspection should cover the points at paragraph 3 and address the sealing requirement at paragraph 4 below. After the first inspection for this purpose, a report confirming that the inspection was satisfactory, and enclosing photographs of the seal (as per paragraph 4) to be used, should be sent to International Animal Health Service Delivery Unit (IAHSDU). The list of countries of origin of the sera used/ handled in the establishment must also be included in the report. IAHSDU will then confirm official registration of the establishment to the Japanese authorities via the British Embassy in Tokyo. IAHSDU will inform the Animal Health Divisional Office that this has been done to enable shipment to be certified.

**All new exporters are advised to contact the Commercial Section of the British Embassy in Tokyo, if they have not done so already, prior to arranging/ seeking certification for export, for advice on whether other formalities have to be completed.**

4. Paragraph IV 1-7 (except 2 (a)) may be certified on sight of a suitable declaration from an authorised signatory of the processor

and any necessary support documents. The RCVS Guide to Professional Conduct 2004 Part 2, G - Certification, Certainty paragraphs 3 & 4 states that veterinary surgeons "must not recklessly confirm what other people have stated." "They may attest to what another veterinary surgeon has certified or confirm that a statement has been made by another person without stating that it is correct."

5. Paragraph IV 2 (a) may be certified on sight of a veterinary certificate issued by the government of the country of origin of the serum/raw material.
6. Paragraph V may be signed on the basis of the official inspection which should cover the following with satisfactory results.
  - a conducted tour of the establishment;
  - inspection of standard operating procedures (SOPs); any changes/ upgrades / additions, especially to the countries and species from which the serum is sourced, have to be discussed and agreed beforehand;
  - traceability checks- consisting of selecting, at random, a specific batch of incoming serum and following through the Lot/Batch/Production Numbers to final packaged product ready for despatch to ensure a valid audit trail;
  - inspection of any relevant additional documentation;
  - inspection of randomly selected export certification and related incoming certification/documentation, including packaging where appropriate; copies of incoming certificates/ documentation for the serum used in each consignment intended for export are made available to the certifying official veterinarian prior to certification;
  - discussion of export health certification issues to ensure that liaison between manufacturing establishments and DEFRA is working satisfactorily.
7. **IMPORTANT:** The exporter must ensure that the outer packaging (i.e. the boxes containing the reagent and calibrator packs) is sealed with a label, (The format of which is pre-agreed with Japan. The BE in Tokyo will provide assistance with this, but as far as we are aware the following format has been acceptable:

<p><b>Name of company</b> <b>BALAI Registration number: BALAI / xx / x</b></p> <p style="text-align: center;"><b>DEFRA stamp</b></p> <p style="text-align: right;"><b>OV signature and date</b></p>
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(the text, signature and stamp must be in a colour other than black)

The labels must be stamped and signed by the Official Veterinarian and the number of the health certificate accompanying the consignment stated on the label. The required number of labels may then be sent with the signed certificate to OCD, who should then apply the labels to the boxes (prior to despatch) in such a way that they will be destroyed when the boxes are opened.

8. **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 Centre for International Trade - Carlisle, via the link below:

<http://www.gov.uk/government/organisations/animal-and-plant-health-agency/about/access-and-opening>