

EXPORT OF *BOVINE SERUM OF NON UK ORIGIN AND/OR GOAT SERUM OF NON UK ORIGIN FOR IN-VITRO DIAGNOSTIC USE TO JAPAN- 4372EHC

NOTES FOR GUIDANCE FOR THE CERTIFYING OFFICIAL VETERINARIAN/ EXPORTER

1. **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.

2. 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 processors which export to EU member states are required to be registered under article 4 of Directive 92/118/EEC and are issued with a number. This number must be stated here.

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 below.

All new exporters are advised to contact the British Embassy (BE) in Tokyo, (contact there is Kikuko Okada on telephone number +81 3 5211 1248 and fax number +81 3 5211 1313), if they have not done so already, prior to arranging/ seeking certification for export, for advice on whether other formalities have to be completed.

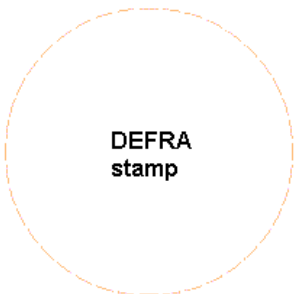
3. Paragraph IV 1-7 may be certified on sight of a suitable declaration from an authorised signatory of the processor.

4. 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.

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

The labels must be held at the local DEFRA office and must be stamped and signed by the Veterinary Officer 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 the exporter, 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.

6. A certified copy of this certificate must be sent to the local Divisional Veterinary Manager on the day of issue.

7. **Disclaimer**

The DEFRA disclaimer (Form 372DMR) will be issued to the exporter with this certificate for his/her information. The 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 International Animal Health Division via the appropriate address in the link given below.

<http://www.defra.gov.uk/animalh/int-trde/general/contacts.htm>