

EXPORT OF SHEEP AND BOVINE SERUM OF NON-UK ORIGIN FOR IN-VITRO DIAGNOSTIC
USE TO JAPAN- 4837EHC

NOTES FOR GUIDANCE FOR THE CERTIFYING OFFICIAL VETERINARIAN / EXPORTER

IMPORTANT

These notes provide guidance to Official Veterinarians (OV) and exporters. The Notes for Guidance (NFG) should have been issued to you together with export certificate 4837EHC. The NFG should not be read as a standalone document but in conjunction with certificate 4837EHC. 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. 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 or the Welsh Government, who is on the appropriate panel for export purposes or who holds the appropriate Official Controls Qualification (Veterinary)(OCQ(V)) authorisation, or an Authorised Veterinary Inspector (AVI) appointed by, or an OV of, the Department of Agriculture, Environment and Rural Affairs in Northern Ireland (DAERA).

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

In GB a certified copy of the completed certificate must be sent to the Centre for International Trade, Carlisle within seven days of signing. In the case an AVI in Northern Ireland, a certified copy must be sent to DAERA, Dundonald House, Belfast.

The OV/AVI should keep a copy for his/her own records.

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 in accordance with Regulation (EC) 1069/2009 (as amended). In England, this is enforced by the Animal By-Products (Enforcement) (England) Regulations 2013 (as amended). Similar legislation exists in Scotland, Wales and Northern Ireland. The establishment's registration number must be stated here.

All new exporters are advised to contact the British Embassy (BE) 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.

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. **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>