Importing NIBSC influenza reagents (pdf)

Please read Importing NIBSC reagents before reading this document.

A number of specific requirements have been included in recent import permits for influenza reagents. The following notes clarify what can and cannot be confirmed for the two categories of influenza materials available.

Obtaining an import permit can take several weeks so we advise that you apply as early as possible for a RESEARCH/ Non-Commercial permit. The reagent 'Instructions for Use' (IFU), which will accompany the shipment and which is also available on the NIBSC website, should be consulted for product specific information.

For current and future seasonal influenza reagents NIBSC is using its best efforts to obtain more information about the processes and materials used and this information will be included as it becomes available. It is also looking to modify its processes to more closely match the requirements of importing countries.

For reagents which have been made in previous years, as indicated by the first two digits of the product code eg 07/nnn (2007), the reagents cannot be remanufactured and the information may no longer be obtainable.

NIBSC influenza antigen reagents

The antigens are donated by a range of companies and have been manufactured as commercial influenza vaccines for human use under the terms of EU product licences, in accordance with GMP.

They are freeze dried whole virus preparations grown in hens' eggs or cells and inactivated by the manufacturer using either ß-propiolactone or Formalin. The reagent 'Instructions for Use' (IFU), which will accompany the shipment and which is also available on our website will indicate the inactivation method used.

The details of the inactivation processes and confirmation testing are commercially confidential and NIBSC does not receive any of the data. NIBSC accepts confirmation from the vaccine manufacturer of the inactivation step, prior to freeze drying the product.

Consequently NIBSC cannot confirm that the products have been inactivated according to any particular procedure specified in an import permit.

NIBSC does not perform any inactivation testing of these materials as they are certified as inactive by the manufacturer. Consequently NIBSC cannot confirm that the products have been tested for inactivation according to any particular procedure specified in an import permit.

The viruses from which the antigens have been derived were grown in cells or in hen's eggs of EU or US origin. However we cannot confirm the area of the EU/USA from which they were obtained.

As NIBSC does not have details of the manufacturing processes used, we cannot confirm that any animal derived nutrients or similar materials have been sourced only from specified countries. However, as the reagents have been manufactured under GMP for human medical use, they will have complied with the normal conditions applied to these types of pharmaceutical products to minimise risk of contamination with TSE's and other animal derived diseases.

Gamma irradiation will destroy these products and should not be used.

It is not possible to label each reagent ampoule or vial with a statement similar to 'For in vitro use or use in laboratory animals only'. However, where required and appropriate, such a statement can be applied to the shipping container and invoice.

NIBSC influenza antiserum reagents

All of our seasonal influenza antibodies are currently raised in sheep in the UK in controlled animal facilities under close veterinary supervision. However we can make no statement concerning the region of the UK from which the sheep were obtained. All sheep have an individual health certificate, confirming their disease free status, signed by a veterinary surgeon, which is attached to the IFU.

Antibody to Haemagglutinin (HA) is prepared by first cleaving off the HA antigen from live influenza virus using bromelain. This serves to inactivate the virus although no tests for effective inactivation are done.

The HA antigen inoculation schedule for the sheep is described in the IFU for the reagent.Details of processing of the resultant sheep serum is described in the IFU.

At times when there were foot and mouth disease (FMD) outbreaks in the UK, the serum was treated to inactivate the FMD virus using an APHIS approved method of holding at less than pH 5.5 for at least 30 minutes. This is described in the IFU and will apply to products with codes 01/nnn and 07/nnn. NIBSC cannot confirm that the product has been treated to inactivate FMD virus according to any other procedure specified in an import permit.

At times when there has been no prevailing outbreak of FMD in the UK, the serum has not been treated in this manner and the IFU will not refer to this inactivation process. Again, NIBSC cannot confirm that these products have been treated to inactivate FMD virus according to any procedure specified in an import permit.

Gamma irradiation will destroy these products and should not be used.

It is not possible to label each reagent ampoule or vial with a statement similar to 'For in vitro use or use in laboratory animals only'. However, where required and appropriate, such a statement can be applied to the shipping container.