

Importing NIBSC Reagents (pdf)

Obtaining an import permit can take several weeks so we advise that you apply as early as possible. Some countries make a distinction between import permits for commercial purposes where the material will be distributed commercially and for research purposes where the material will be consumed within the importing organisation. We advise applying for a research permit as the conditions applied will usually be less strict and thus help to avoid delays. If import conditions are required, please check with the product Instructions For Use or staff at NIBSC that the conditions are appropriate for the materials being ordered before finalising the import permit.

Unfortunately, NIBSC cannot negotiate the terms of the import permit with the national authorities, this has to be done by you, the customer. NIBSC provides all the available information applying to the products you wish to import in the specific Instructions for Use (IFU).

NIBSC is taking steps to improve the information available regarding future batches of its products but it is unlikely to be able to provide more information on existing batches.

For influenza reagents, further information is available based on our experience of import licence requirements for these products, [Importing NIBSC influenza reagents](#).

Before submitting your order to NIBSC, please obtain any licences required to allow the importation of products as described in the statements below and in the IFU.

Where appropriate we recommend that you request the permit using phrases such as:

- reference material for use only in research or internal Quality Control procedures under controlled laboratory conditions.
- material will be consumed in use and all waste will be disposed of as biological waste.
- not to be administered to humans or animals.
- not to be sold, resold, or commercially distributed.

We also recommend that you avoid using phrases such as:

- diagnostic reagent
- in-vitro

Please do not refer to the product number in the licence application as we may on occasion have to supply an alternative or replacement product.

Where you are unable to obtain an import licence which matches the product description provided, we cannot provide any different information. You will have to negotiate with your national authorities.

For the USA, staff at the port of entry may request that our reagents are classified under the FDA National Drug Code system. The Food and Drug Administration (FDA) has confirmed that this system only applies to prescription drugs and insulin products for commercial distribution. Therefore these regulations do not apply to NIBSC products. NIBSC recommend that US customers obtain a statement of exemption from their local FDA office to accompany any import permit.

If you cannot obtain a suitable licence, then we do not recommend shipping the product as it is likely to be detained at the port of entry and destroyed or returned.