Licence No: IMP/GEN/2015/06

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

ANIMAL HEALTH ACT 1981

IMPORTATION OF ANIMAL PRODUCTS AND POULTRY PRODUCTS ORDER 1980 (AS AMENDED)

GENERAL IMPORT LICENCE

The Secretary of State for Environment, Food and Rural Affairs, by this licence issued under the terms of Article 4 of the Importation of Animal Products and Poultry Products Order 1980 licences subject to and in accordance with the conditions set out below, the landing in England of:

 MONOCLONAL AND POLYCLONAL ANTIBODIES, PROTEINS, ENZYMES, PEPTIDES AND POLYPEPTIDES SEPARATED FROM PLASMA OR SERUM AND PURIFIED TO THE EXTENT THAT THEY DO NOT CONTAIN ANY VIABLE PATHOGENIC MICRO-ORGANISMS; Product

- CELLS WHICH DO NOT CONTAIN A PATHOGEN:
- CELL CULTURES MORE THAN ONE GENERATION REMOVED FROM TISSUE HARVESTED FROM AN ANIMAL;
- STEM CELLS DERIVED FROM LABORATORY AND REARED ANIMALS;
- ANIMAL BY-PRODUCTS FOR THE USE IN IN-VITRO L'ABORATORY RESEARCH AND DIAGNOSTIC USE WHICH HAVE UNDERGONE COMPLETE PROCESSING;

WHERE:

- ANY ANIMAL BY-PRODUCT WHICH HAS BEEN USED AS A STABILISER OR CARRIER IS DEEMED AT A CONCENTRATION OF 10% OR LESS. (see note 7) AND
- THE PRODUCT IS IMPORTED FOR THE PURPOSE OF IN VITRO LABORATORY OR RESEARCH AND DIAGNOSTIC USE OR RESALE FOR IN VITRO LABORATORY OR RESEARCH AND DIAGNOSTIC USE ONLY AND
- EACH INDIVIDUAL PRODUCT FOR USE IS OF A UNIT SIZE OF 100ml OR LESS.

from

COUNTRIES THAT ARE MEMBERS OF THE WORLD ORGANISATION FOR ANIMAL HEALTH (OIE)

Countries of origin

at

ANY PORT/ AIRPORT IN ENGLAND

Ports of entry

until further notice or unless revoked by the Secretary of State.

Dated: 12th October 2015

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Officer of the Department for

Environment, Food and Rural Affairs

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Conditions attached to this General licence

- 1. Each consignment must be accompanied by:
 - a copy of this licence and
 - a commercial documentation as per point 3 below.
- 2. All animal based materials used in the products must originate from one or more material or materials as defined in Articles 8, 9 and 10 of Regulation (EC) No 1069/2009.
- 3. Each consignment must be accompanied by a commercial document signed by a senior manager of the facility on company letter headed paper and dated within 3 weeks of the importation date of each consignment confirming:
 - Description and quantity of product to be imported;
 - The name and address of consignor and consignee;
 - The country of origin;
 - That every precaution was taken to prevent contamination of the product;
 - That the final product was packed in new containers;
 - That the product complies with the scope of the General licence;
 - That the product is suitable for its intended use without any further processing.
 - That the products have been processed to make them microbiologically sterile.
 - That the product is only intended for use within a laboratory/ research environment.
 - That any animal by-product used as a carrier/ stabiliser agent is not intended to be and nor should be used as a product in its own right.
- 4. The animal by-products listed in this licence must also comply with the following conditions:
 - The product must be securely packaged in clean, leak proof containers.
 - Each individual product for use is a unit size of 100ml or less.
 - The outer packaging must be clearly labelled "NOT FOR FEED OR FOOD USE FOR TECHNICAL USE ONLY".
 - The product must not be diverted at any stage within the European Union for any use in food, feed material, organic fertilisers or soil improvers.
 - The consignment, or its packaging, must not be allowed to come into contact with any ruminating animals, swine, poultry or horses.
 - The products must remain in the original wrappings at all times until their arrival at the premises of destination. The products are for research and diagnostic testing use only and used solely in the confines of the laboratory of final destination.
 - Any product or products derived from the use of the product must be disposed of as clinical waste in such a way as to render it safe.
 - Any animal by-product used as a carrier/ stabiliser agent cannot be used as a product in its own right.

GENERAL NOTES

- If you wish to import these products through Scottish or Welsh ports, you must obtain a licence from the relevant authority (Scottish Government Rural Directorate, Tel: 0131 2446179; Welsh Assembly Government Rural Affairs Department, Tel: 02920 825111).
- If the material is to be supplied to an organisation in another Member State or reexported, you should ensure that the importing country will permit entry and that you
 have the correct paperwork to accompany the product prior to export. For further
 advice, you should contact the <u>Specialist Service Centre for Exports.</u>

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- 3. Any products and records relating to the product imported under this licence shall be made available if so required for inspection by an Officer of Animal Health Veterinary Laboratory Agency at any place nominated by him/ her for such inspection. The importer or his agent shall afford all assistance necessary to such an officer to enable him/her to carry out the inspection in such a manner as he/ she shall determine and the importer shall be responsible for meeting any costs of carrying out such an inspection.
- 4. This licence is granted under animal health import legislation and gives no exemption from any prohibition, regulation or restriction imposed by any other Government Department or Agency.
- 5. Harmonised EU rules for these products have not been laid down at this time so this licence is issued without prejudice to any future import rules.
- 6. Please note that this licence is current at the time of its issue. Importers should check the <u>website</u> to ensure conditions for import have not changed.
- Please note that this licence only covers the animal by-products used as the stabiliser or carrier referred to above.

CAUTION

- 1. It is the importer's responsibility to ensure that any import covered by this licence complies with the terms and conditions as set out.
- It is the importer's responsibility to ensure that any additional documentation required by any other Government Department or Agency is obtained prior to importation of the said products.
- 3. In addition, it is the importer's responsibility to ensure they are aware of any relevant statutory requirements under the following legislation:
 - The Control of Substances Hazardous to health (2002) (COSHH)
 - Management of Health and Safety at Work Regulations (1999)
 - Health and safety at Work Act (1974)
- It is the importers responsibility to:
 - Provide the required information on the active components/ content of the substance for import and if this is potentially hazardous to health by means of a Material/Chemical Safety Data Sheet to allow adequate risk assessment by the end user.
 - Provide any other relevant information for the end user, including usage of the product and disposal requirements following use of the product as contained in this licence.
 - Measures to be taken if the end user is exposed to the substances contained in the product.
- 5. Any breach of any conditions attached to this licence will constitute an offence against the Animal Health Act 1981.

CONTACT FOR FURTHER INFORMATION

Centre for International Trade – Carlisle Animal and Plant Health Agency (APHA) Hadrian House, Wavell Drive, Rosehill Industrial Estate Carlisle, CA1 2TB

Telephone: 01228 403600 (Option 3)

Fax: 01228 591900

Email: Imports@apha.gsi.gov.uk