



## IMPORTS AND EU POLICY TEAM

OVS Note/2015/37

Date: 15 October 2015

### NEW GENERAL LICENCE FOR CERTAIN ANIMAL BY-PRODUCTS FOR IN-VITRO USE WHICH CONTAINS 10% OR LESS ANIMAL BY-PRODUCTS USED AS A CARRIER/STABILISER AGENT

#### Purpose

1. To inform BIPs of the availability of a new general licence for certain processed animal by-products for in-vitro use which contain 10% or less animal by-products as a carrier/stabiliser agent and where the product is imported for the purpose of laboratory or research use or resale for laboratory or resale use.

#### Background

2. Regulations (EC) [No 1069/2009](#) and (EU) [No 142/2011](#) lay down the health rules with regards imports of animal by-products not intended for human consumption. Where there are no harmonised conditions laid down for such a product or its usage, Article 41.3 of Regulation (EC) No 1069/2009 permits Member States to specify those requirements in national measures.
3. The importation of certain processed animal by-products, where any animal by-product used as a stabiliser or carrier is at a concentration of 10% or less, is not subject to harmonised EU rules at the present time. To facilitate trade a general licence is now available ([IMP/GEN/15/06](#)) to import the following products into England:
  - 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;
  - 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 LABORATORY 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 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.

4. Importers must ensure that all conditions laid down in the General licence are adhered to.

**Action for OVSS**

5. To be aware of the new General Licence available for use.

**Contact point for enquiries**

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***Imports and EU Policy Team***