UNIVERSITY OF CAMBRIDGE

Biological Import and Export Challenges

Biological Safety Officers' Event

16 May 2023

Mark Elsdon - School of the Biological Sciences Safety Officer; University Biomedical Services DSO and BSO

Mark... Help!

- We don’t have all the answers!
- It’s complicated – but let’s learn together!
- Rules constantly changing!
- Tips to facilitate compliant movement of biologicals
- Signpost to key people/guidance
- Don’t gamble! Risk legal non-compliances, prosecution, reputational damage or losing precious samples
- There are no guarantees!
- Thank goodness for the Imports/Exports Hub!

Scenario 1

Mark ... Help! (ABP)

Student doing fieldwork in Borneo and has to fly back to the UK this week as their visa expires.

They have collected hundreds of Orangutan faecal samples (dried and in alcohol) and have been told they need a licence to get them back to the UK.

Scenario 2

Mark ... Help! (Live insects)

My fly stocks are stuck at Stansted.

They say I haven't got the right paperwork

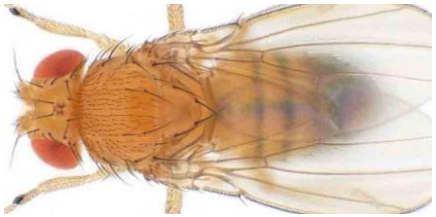
They are confiscating / destroying them

I didn’t know they couldn’t go by DHL/FedEx etc.

Weeks of hard work down the drain

I’ve no back up stocks!

london stansted airport



Scenario 3

Mark ... Help! (Importing Human clinical material & hand/checked luggage rules)

A member of university staff returned from fieldtrip to Africa. Left a box of human blood samples in a box in the corridor.

They are working at an affiliated organisation.

They brought them into the UK on a flight in their personal baggage.

We have opted to send them for autoclaving

Scenario 4

Mark ... Help! (Microorganism)

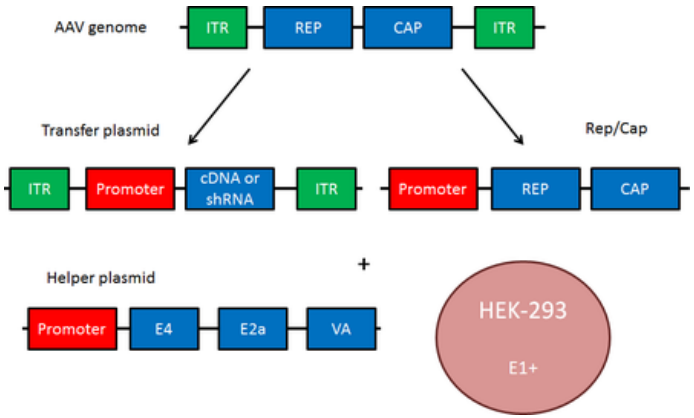
AAV viral vectors stuck in customs.

Urgently need these next week – I have animals bred and ready to use.

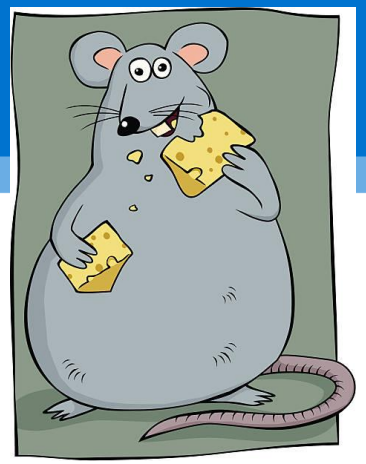
BIP (BCP) say I have a missing licence and won't release.

What paperwork? Commercial paperwork in place.

Did BIP/customs overreact to 'virus'?



Scenario 5



Mark ... Help! (ABP)

My High-Fat animal diet (<50% ABP) held up at Stansted.

It’s temperature sensitive. BIP need paperwork. What?

Bought from commercial supplier in EU (Denmark).

Subsequently sent Facilitation Letter. No joy. Coding issue?

Product destroyed.

Reordered direct from US manufacture with no issue.

Belt & braces – Applied to APHA for Specific Licence for licence for animal feeds with >50% ABP but shouldn't be required?

Scenario 6

Mark ... Help! (ABP)

My collaborator in the US has shipped some human cell lines to Cambridge.

World Couriers have said he needs to have included a licence to enter UK.

These are safe, screened, well characterised established **human** cell lines.

Cells shipped in media containing bovine serum *may* require a licence.

Reduce the risk

PLAN AHEAD

- Do your research on how to move materials compliantly.
  - Import Export Hub, Research Office, Safety Advisors, BSO/DSO etc
  - .Gov, Agencies e.g. APHA Intnl. Trade; Plant Health
  - Consider specialist agents e.g. Biocair
- Share experiences – good / not so good

Compliance ('Biologicals')

- Many 'biologicals' are 'Controlled Goods' for import/export
- Permits, Authorisations, Licences; Health and Phytosanitary Certificates, Commercial docs
- Identify correct paperwork, and in good time!
- In place **BEFORE** import/export – not retrospectively!
- **Must** fully comply with Terms and Conditions
- Exports: Seek advice from country of destination
- Time consuming, esp. where Health Certificates required

Pre-notification/Cut of biological imports

Pre-notified before importing via UK Border Control Post into UK.

- Products of Animal Origin (POAO)
- Animal By-Products (ABP)
- Live animals
- Plants / plant products (regulated & notifiable)
- High Risk Foods and Feed not of Animal Origin (HRFFAO)

IPAFFS and **PEACH** systems. Agents notify some for UK importers?

- ***IF*** you need an account, UBS has master a/c. Can provide access to your own department account.

Export Health Certificates (EHC)

- Export Health Certificate (EHC) may be required when exporting Animals and POAO goods to the EU or and non-EU countries.
- EHCs must be certified by an Official Vet (OV) or Inspector.
- UBS has 2 OVs who can certify EHCs before submitting with your application

Example: A researcher required a OV certified EHC in order to ship their collection of stem cells to China.

What biologicals are you importing/exporting?

Live animals, incl. inverts

- NEW Import Authorisation for *Drosophila melanogaster* from non-EU, NI

POST OFFICE

UK / Intnl. mail rules even if no licence required (EU)

Live creatures, insects and invertebrates

(Including bees, caterpillars, cockroaches, crickets, destroyers of noxious pests, earthworms, leeches and other parasites, lugworms, maggots, mealworms, pupae and chrysalides, rag worms, silkworms, spiders and stick insects.)

- UK & International - Allowed in the mail, see restrictions and packaging guidelines below:
- Live animals and reptiles are prohibited, as are any creatures or insects classified as dangerous within the Dangerous Wild Animals Act 1976 (including certain venomous spiders).
- Must be boxed and packaged to protect the creatures, our staff and our customers from harm.
- Use 1st Class as the minimum service.
- Items must be clearly marked "URGENT - LIVING CREATURES - HANDLE WITH CARE".
- The sender's name and address must be clearly visible on the outer packaging.
- Dead insects, sent as collectables, are allowed.

Authorisation No: IMP/GEN/2023/01

Conditions

1. Each consignment must be accompanied by a copy of this authorisation and a commercial document signed by a veterinarian or natural person responsible for the establishment of origin in the exporting country on the headed paper of the business operating the establishment. The document must include name in block letters, position held and the address of the establishment. The document must be signed and dated no less than 2 months from the date of dispatch of each consignment confirming:

   - The specie and quantity (*) of animals;
   - The name and address of consignor and consignee;
   - The country of origin and the address of the place of origin;
   - That none of the material to which this authorisation relates is intended to be used for human or animal consumption in any circumstances.
   - That the animals are not intended to be released into the wild

prevent any harm to the animals. It must be constructed in such
and scape proof.

port, all specimens must be packaged so that they fully comply
ts of relevant Post Office or International Air Transport
regulations. The packaging must be clearly labelled to indicate
animals.

r its packaging must not be allowed to come into contact with any
swine, poultry or horses.

t for reference purposes, transferred or re-dispatched to the third
vertebrates or products derived from their use and waste shall be

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1141487/Live-insects-drosophila-melanogaster-for-research-and-diagnostic-IMP-GEN-2023-01.pdf

What biologicals are you importing/exporting?

Animal by-products

Examples

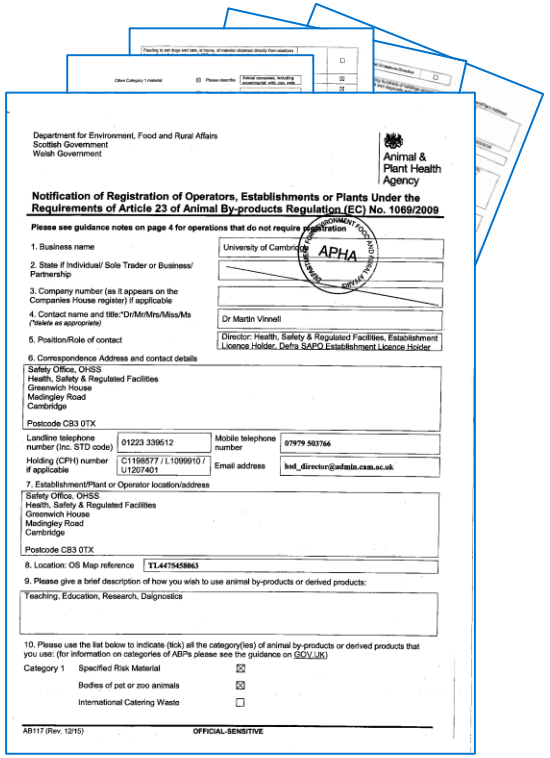
- Tissue / blood samples
- cell cultures, stem cells, DNA, proteins, antibodies
- Hides, skins
- Formalin fixed animal/bird tissues
- Human cell cultures in media containing bovine serum
- Rodent sperm carried in skimmed powdered milk

https://www.gov.uk/guidance/importing-live-animals-or-animal-products-from-non-eu-countries-general-licences-and-authorisations

What biologicals are you importing/exporting?

Animal by-products from Non-EU countries

- Check for & download ‘General Licence’
- Read with any separate amendment note.
- No suitable GL? IV58 app to APHA. I can assist with wording.
- We are ABP registered. See Safety Office web for details. ABP Registration U1207401/ABP/OTHER
- YOU MUST adhere to ALL licence T&Cs



Department for Environment, Food and Rural Affairs
Scottish Government
Welsh Government

Animal & Plant Health Agency

Notification of Registration of Operators, Establishments or Plants Under the Requirements of Article 23 of Animal By-products Regulation (EC) No. 1069/2009

Please see guidance notes on page 4 for operations that do not require registration

1. Business name: University of Cambridge
2. State if Individual/ Sole Trader or Business/ Partnership:
3. Company number (as it appears on the Companies House register) if applicable:
4. Contact name and title:*Dr/Mr/Mrs/Miss/Ms (*delete as appropriate)*: Dr Martin Vinnell
5. Position/Role of contact: Director: Health, Safety & Regulated Facilities, Establishment Licence Holder, Defra SAPO Establishment Licence Holder
6. Correspondence Address and contact details:

Safety Office, OHSS
Health, Safety & Regulated Facilities
Greenwich House
Madingley Road
Cambridge

Postcode CB3 0TX

Landline telephone number (inc. STD code): 01223 339512
Mobile telephone number: 07979 583766
Holding (CPH) number if applicable: C1198577 / L1099107 / U1207401
Email address: hsd_director@admin.cam.ac.uk

7. Establishment/Plant or Operator location/address:

Safety Office, OHSS
Health, Safety & Regulated Facilities
Greenwich House
Madingley Road
Cambridge

Postcode CB3 0TX

8. Location: OS Map reference: TL4475458863

9. Please give a brief description of how you wish to use animal by-products or derived products:

Teaching, Education, Research, Daignostics

10. Please use the list below to indicate (tick) all the category(ies) of animal by-products or derived products that you use: (for information on categories of ABPs please see the guidance on GOV.UK)

Category 1 — Specified Risk Material ☒
Bodies of pet or zoo animals ☒
International Catering Waste ☐

AB117 (Rev. 12/15) OFFICIAL-SENSITIVE

https://www.gov.uk/guidance/importing-live-animals-or-animal-products-from-non-eu-countries-general-licences-and-authorisations

Examples General Licences and T&Cs (IAPPPO)

Licence No: IMP/GEN/2008/03

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 (as amended) authorises subject to and in accordance with the conditions set out below, the landing in England of:

• DNA, plasmid DNA or RNA other than sequences which could be used to reconstitute a pathogen. • Stem cells derived from laboratory born and reared animals. • Proteins, antibodies (monoclonal and polyclonal), peptides and polypeptides separated from plasma or serum and purified to the extent that any pathogenic micro-organisms likely to be present would have been removed or inactivated. • Cell cultures more than one generation removed from tissue harvested from an animal.	Product

from

All non EU countries	Countries of origin

at

All ports and airports in England with BIP facilities	Ports of entry

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

Dated: 18 July 2008

Officer of the Department for Environment, Food and Rural Affairs

Licence No: IMP/GEN/2008/03

Conditions attached to this licence

1. Each consignment must be accompanied by commercial/shipping documents describing the product, quantity and the name and address of consignor and consignee;

2. The packaging must be clearly labelled to indicate the nature and use as medical products or *in vitro* laboratory products for research;

3. None of the material to which this licence relates shall be used for human consumption under any circumstances.

NOTES

1. Nothing in this licence gives exemption from any prohibition or restriction imposed by the Imported Food Regulations 1997, the provisions of the Food Safety Act 1990 and Regulations made under it, the Animal By-Products (Identification) Regulations 1995, the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 or by any regulation superseding or amending the same.

2. This is not a Department of Trade and Industry licence and gives no exemption from any prohibition, regulation or restriction imposed by the Department of Trade and Industry.

3. Please note that while this licence is current at the time of its issue, conditions can be subject to frequent change and importers are advised to check the latest position with the Animal Health Import Team (see below).

4. Any products imported under this licence shall be made available if so required for inspection by an Officer of Animal Health 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.

CAUTION

It is the importer's responsibility to ensure that any import covered by this licence complies with the terms and conditions as set out.

Any breach of any conditions attached to this licence will constitute an offence against the Animal Health Act 1981.

CONTACT FOR FURTHER INFORMATION

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; • 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. (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.	Product

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

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS
12 OCT 2015

Officer of the Department for Environment, Food and Rural Affairs

Licence No: IMP/GEN/2015/06

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

1. 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).
2. If the material is to be supplied to an organisation in another Member State or re-exported, 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 Specialist Service Centre for Exports.

Example General Licence and T&Cs (POAO)

Authorisation No: IMP/GEN/2011/03

DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

EUROPEAN COMMUNITIES ACT 1972

THE PRODUCTS OF ANIMAL ORIGIN (THIRD COUNTRY IMPORTS) (EN REGULATIONS 2006 (AS AMENDED)

GENERAL IMPORT AUTHORISATION

The Secretary of State for Environment, Food and Rural Affairs, by this author issued under the terms of Regulation 4 of the Products of Animal Origin (Third Imports) (England) Regulations 2006 (as amended) authorises subject to and accordance with the conditions set out below, the landing in England of:

Animal tissue derived from mammals and birds fixed in formalin intended for research use (as defined in Regulation (EU) No 142/2011) (see note p)	Produc

from

Third countries or parts of third countries, from which Member States authorise imports of fresh meat of domestic bovine animals, which are listed in Part I of Annex II to Regulation (EU) No 206/2010 (as amended) (see note p)	Countri origin

at

All ports and airports in England (but see note o)	Ports of entry

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

General Licence IMP/GEN/2010/02 is hereby revoked.

NOTES

a) Please see the guidance for the declaration template.

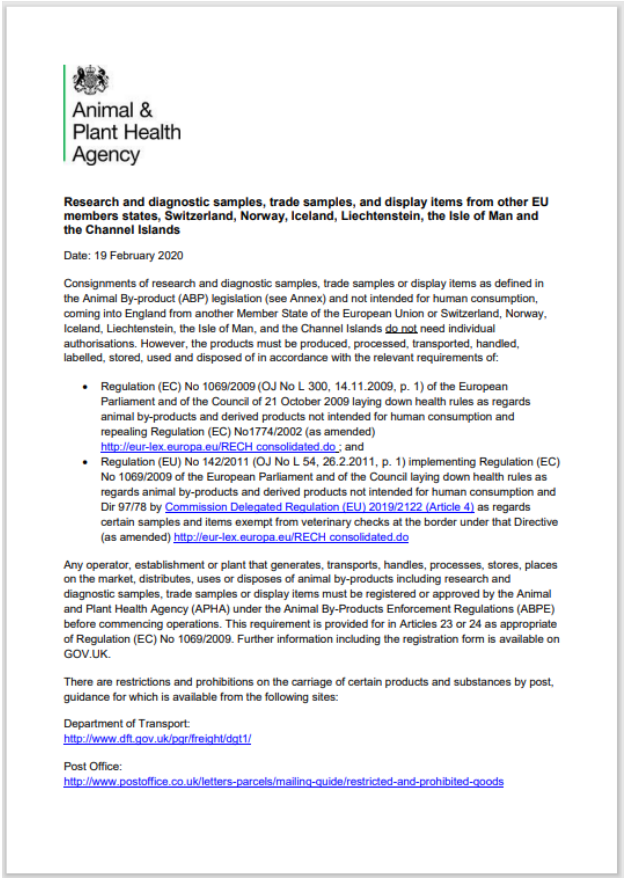
b) It is the responsibility or the importer to ensure that the exporter provides the necessary declaration referred to above.

c) **Formalin:** Aqueous solutions of formaldehyde are referred to as formalin. *100%* formalin consists of a saturated solution of formaldehyde (this is about 40% by volume or 37% by mass) in water. Importers should note that the time taken to fix the tissue varies with factors such as the thickness of the tissue. **When tissues are initially fixed in formalin it is normal to use about 10 volumes of fixative to one volume of tissue.** Formalin fixed specimens for research must be cut so that one dimension is no greater than one centimetre and must be placed in not less than 9 times its own volume of 10% formalin for at least 48 hours before being imported. Larger specimens for example for museum and educational purposes must be placed in not less than 9 times its own volume of 10% formalin for at least **two weeks** before being imported. When the tissue is imported into the UK, providing the tissue has been thoroughly fixed throughout, the same volume of fixative is not required.

d) **Safety:** Importers are responsible for ensuring that the health and safety requirements relating to the specimens, any infectious agents and the fixative are

What biologicals are you importing/exporting?

- Animal by-products from **EU Member States**
- Research & diagnostic samples, trade and display do NOT need to be licenced or authorised
- Must still comply with rules on ABP
- Include copy of **'Facilitation Letter'**



Animal & Plant Health Agency

Research and diagnostic samples, trade samples, and display items from other EU members states, Switzerland, Norway, Iceland, Liechtenstein, the Isle of Man and the Channel Islands

Date: 19 February 2020

Consignments of research and diagnostic samples, trade samples or display items as defined in the Animal By-product (ABP) legislation (see Annex) and not intended for human consumption, coming into England from another Member State of the European Union or Switzerland, Norway, Iceland, Liechtenstein, the Isle of Man, and the Channel Islands do not need individual authorisations. However, the products must be produced, processed, transported, handled, labelled, stored, used and disposed of in accordance with the relevant requirements of:

- Regulation (EC) No 1069/2009 (OJ No L 300, 14.11.2009, p. 1) of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No1774/2002 (as amended) http://eur-lex.europa.eu/RECH consolidated.do ; and
- Regulation (EU) No 142/2011 (OJ No L 54, 26.2.2011, p. 1) implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and Dir 97/78 by Commission Delegated Regulation (EU) 2019/2122 (Article 4) as regards certain samples and items exempt from veterinary checks at the border under that Directive (as amended) http://eur-lex.europa.eu/RECH consolidated.do

Any operator, establishment or plant that generates, transports, handles, processes, stores, places on the market, distributes, uses or disposes of animal by-products including research and diagnostic samples, trade samples or display items must be registered or approved by the Animal and Plant Health Agency (APHA) under the Animal By-Products Enforcement Regulations (ABPE) before commencing operations. This requirement is provided for in Articles 23 or 24 as appropriate of Regulation (EC) No 1069/2009. Further information including the registration form is available on GOV.UK.

There are restrictions and prohibitions on the carriage of certain products and substances by post, guidance for which is available from the following sites:

Department of Transport:
http://www.dft.gov.uk/pgr/freight/dgt1/

Post Office:
http://www.postoffice.co.uk/letters-parcels/mailing-guide/restricted-and-prohibited-goods

https://www.gov.uk/guidance/importing-live-animals-or-animal-products-from-non-eu-countries-general-licences-and-authorisations

What biologicals are you importing/exporting?

Plant, seeds, timber, pathogens, pests, soils/sediments

Imports: Use **Phytosanitary** route if available.

- **Plant Health Inspector (PHI)** can advise.
- If none, **Licences** may be required and separate **Letter of Authority** (LoA) to be sent to supplier.

Exports: Receiving country reqmts - National Plant Protection Orgn.

- Use phyo routes where possible
- If not - speak to PHI - complex

What biologicals are you importing/exporting?

Human Pathogens (WT/Non-GMM)

- Cultures
- ‘Clinical samples’ that may contain pathogens?

- Risk assessment
- Approvals and notified (where applicable) before importing?

What biologicals are you importing/exporting?

Specified Animal Pathogens (and carriers of)

- SAPO licence (SO administered)
- An offence to have a SAPO agents on unlicensed site.
- Risk assessment


HSE

Health and Safety Executive

Guidance for licence holders on the containment and control of specified animal pathogens

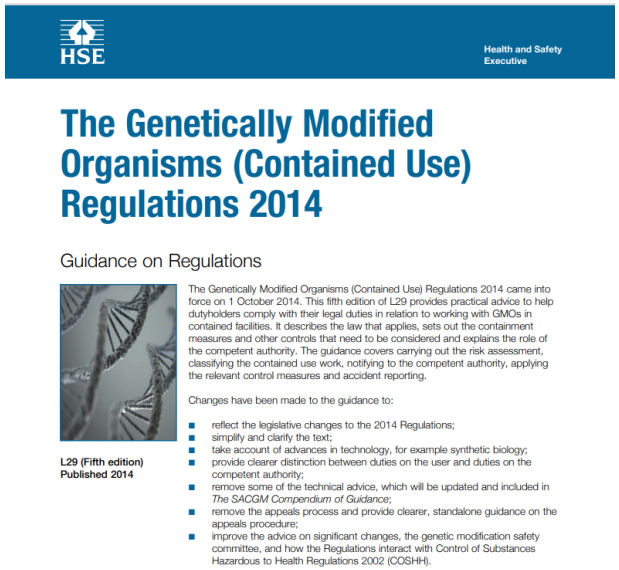
This guidance is aimed at Specified Animal Pathogen Order (SAPO) licence holders, users and biosafety professionals, but managers and health and safety representatives may also find it useful. It describes the containment and control measures and related management arrangements which must be applied when working with specified animal pathogens.

HSG280
Published 04/15

What biologicals are you importing/exporting?

GMOs/GMMs (Human/Animal/Plant)

- GM Risk Assessment
- GMSC/BSO approval
- HSE notification
- Includes commercial or donated sources even if you didn't make them e.g. GM viral vectors



HSE Health and Safety Executive

The Genetically Modified Organisms (Contained Use) Regulations 2014

Guidance on Regulations

L29 (Fifth edition)
Published 2014

The Genetically Modified Organisms (Contained Use) Regulations 2014 came into force on 1 October 2014. This fifth edition of L29 provides practical advice to help dutyholders comply with their legal duties in relation to working with GMOs in contained facilities. It describes the law that applies, sets out the containment measures and other controls that need to be considered and explains the role of the competent authority. The guidance covers carrying out the risk assessment, classifying the contained use work, notifying to the competent authority, applying the relevant control measures and accident reporting.

Changes have been made to the guidance to:

- reflect the legislative changes to the 2014 Regulations;
- simplify and clarify the text;
- take account of advances in technology, for example synthetic biology;
- provide clearer distinction between duties on the user and duties on the competent authority;
- remove some of the technical advice, which will be updated and included in *The SACGM Compendium of Guidance*;
- remove the appeals process and provide clearer, standalone guidance on the appeals procedure;
- improve the advice on significant changes, the genetic modification safety committee, and how the Regulations interact with Control of Substances Hazardous to Health Regulations 2002 (COSHH).

What biologicals are you importing/exporting?

‘Schedule 5’ Pathogen or Toxins

- Pathogens & toxins notifiable to National Counter Terrorism Security Office under the Anti-Terrorism, Crime and Security Act
  - Intact pathogens, including GM.
  - Nucleic acid derived from these - synthetic or natural, that can encode infectious / replication competent forms
  - Nucleic acid encoding for listed toxin; GMO containing sequence
- Do not import unless approvals are in place
- University **Export Control Policy** for Controlled Goods (see ROO)

What biologicals are you importing/exporting?

Human Tissue

- No specific HTA import licences
- Compliance with principles required by HTA - ethics, consent etc

What biologicals are you importing/exporting?

CITES - Endangered animals and plants (and products of)

- Permits may be required. APHA.
- Exemptions can be applied for purposes of

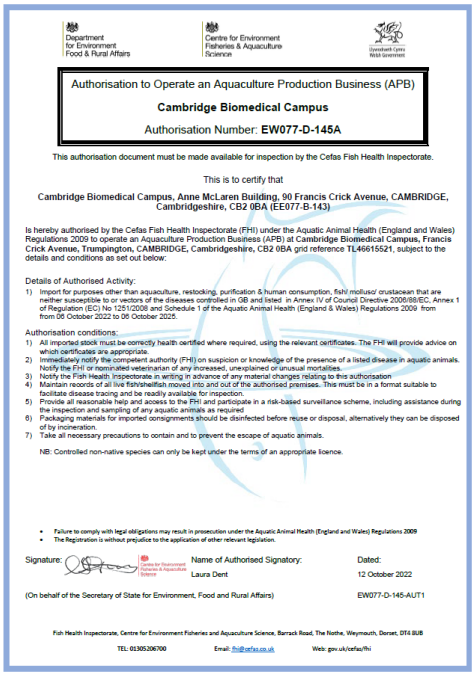
*non-commercial loan, donation or exchange between scientists or scientific institutions **(registered)** of museum, herbarium, diagnostic and forensic research specimens*

- Registered departments
  - Dept. Zoology
  - Dept. Plant Sciences - Herbarium SLCU

What biologicals are you importing/exporting?

CEFAS

- Importing or moving live fish and shellfish
- Authorisation for Aquaculture



Department for Environment Food & Rural Affairs | Centre for Environment Fisheries & Aquaculture Science

Authorisation to Operate an Aquaculture Production Business (APB)

Cambridge Biomedical Campus

Authorisation Number: **EW077-D-145A**

This authorisation document must be made available for inspection by the Cefas Fish Health Inspectorate.

This is to certify that

Cambridge Biomedical Campus, Anne McLaren Building, 90 Francis Crick Avenue, CAMBRIDGE, Cambridgeshire, CB2 0BA (EE077-B-143)

Is hereby authorised by the Cefas Fish Health Inspectorate (FHI) under the Aquatic Animal Health (England and Wales) Regulations 2009 to operate an Aquaculture Production Business (APB) at **Cambridge Biomedical Campus, Francis Crick Avenue, Trumpington, CAMBRIDGE, Cambridgeshire, CB2 0BA** grid reference **TL46615521**, subject to the details and conditions as set out below:

Details of Authorised Activity:

1) Import for purposes other than aquaculture, restocking, purification & human consumption, fish/ mollusc/ crustacean that are neither susceptible to or vectors of the diseases controlled in GB and listed in Annex IV of Council Directive 2006/88/EC, Annex 1 of Regulation (EC) No 1251/2008 and Schedule 1 of the Aquatic Animal Health (England & Wales) Regulations 2009 from from 06 October 2022 to 06 October 2025.

Authorisation conditions:

1) All imported stock must be correctly health certified where required, using the relevant certificates. The FHI will provide advice on which certificates are appropriate.
2) Immediately notify the competent authority (FHI) on suspicion or knowledge of the presence of a listed disease in aquatic animals. Notify the FHI or nominated veterinarian of any increased, unexplained or unusual mortalities.
3) Notify the Fish Health Inspectorate in writing in advance of any material changes relating to this authorisation
4) Maintain records of all live fish/shellfish moved into and out of the authorised premises. This must be in a format suitable to facilitate disease tracing and be readily available for inspection.
5) Provide all reasonable help and access to the FHI and participate in a risk-based surveillance scheme, including assistance during the inspection and sampling of any aquatic animals as required
6) Packaging materials for imported consignments should be disinfected before reuse or disposal, alternatively they can be disposed of by incineration.
7) Take all necessary precautions to contain and to prevent the escape of aquatic animals.

NB: Controlled non-native species can only be kept under the terms of an appropriate licence.

- Failure to comply with legal obligations may result in prosecution under the Aquatic Animal Health (England and Wales) Regulations 2009
- The Registration is without prejudice to the application of other relevant legislation.

Signature: | Name of Authorised Signatory: Laura Dent | Dated: 12 October 2022

(On behalf of the Secretary of State for Environment, Food and Rural Affairs) | EW077-D-145-AUT1

Fish Health Inspectorate, Centre for Environment Fisheries and Aquaculture Science, Barrack Road, The Nothe, Weymouth, Dorset, DT4 8UB

TEL: 01305206700 Email: fhi@cefas.co.uk Web: gov.uk/cefas/fhi

Other areas of Compliance

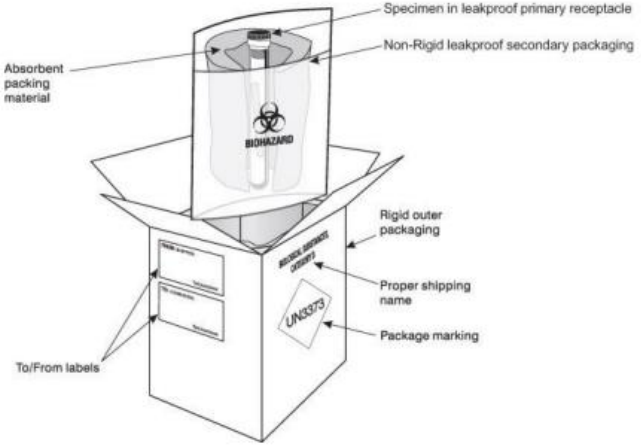
Material Transfer Agreement (MTA)

- Required for transfer of research materials.
- Commercial sources may not have terms. Some do - Jackson Labs for mouse lines; Addgene for plasmids; ATCC cell lines etc.
- If provider says MTA not required - as long as correct people confirm in writing, e.g. *"There are no terms and conditions attached to the use of these materials",* then it may be possible to accept
- Caution where transferring regulated/controlled materials
- MTAs may *try* to transfer liability to Cambridge – e.g. Transport of infectious agents, packed by donor.

Other areas of Compliance

Transport of Dangerous Goods by Road, Air

- **Category A** Infectious (human/animal) ('Indicative list')
  - High Consequence Dangerous Goods (HCDG)
  - Dept. of Transport Security Plan?
  - Specialist approved Class 6 Courier
- **Biological Substance, Category B**
- Packed, marked, labelled correctly?
- Dangerous Goods by Air trained?



Other areas of Compliance

Nagoya Protocol

Convention on Biological Diversity

International agreement for sharing of the benefits arising from the utilisation of genetic resources in a fair and equitable way.

Legal obligations on researchers to comply

Planning fieldwork and sample collection or obtaining genetic material originating overseas - must consider.

Research Operations Office

https://www.research-operations.admin.cam.ac.uk/nagoya-protocol

Other areas of Compliance

Balai Directive – Imports/Exports live animals and germinal products – registered/approved premises

Natural England - Wildlife Licensing

Non-Native Species Secretariat

Wildlife and Countryside Act

Wildlife and Countryside Act 1981

International 'laws' Fieldworkers: local permits to collect samples?

Transferring Controlled Materials - Due Diligence

Will you need to move the material to

- another room/building in your department?
- another department/facility at the UoC?
- an external collaborator, service provider (in the UK, overseas)?

BEFORE transferring check:

- T&Cs of your licences; Consent/licence updates required?
- Consignee is authorised to receive the material
- MTAs etc are signed off


FAILURE
TO PLAN
ON YOUR PART
DOES NOT CONSTITUTE
AN EMERGENCY
ON MY
PART