

Don't bury your head in the sand

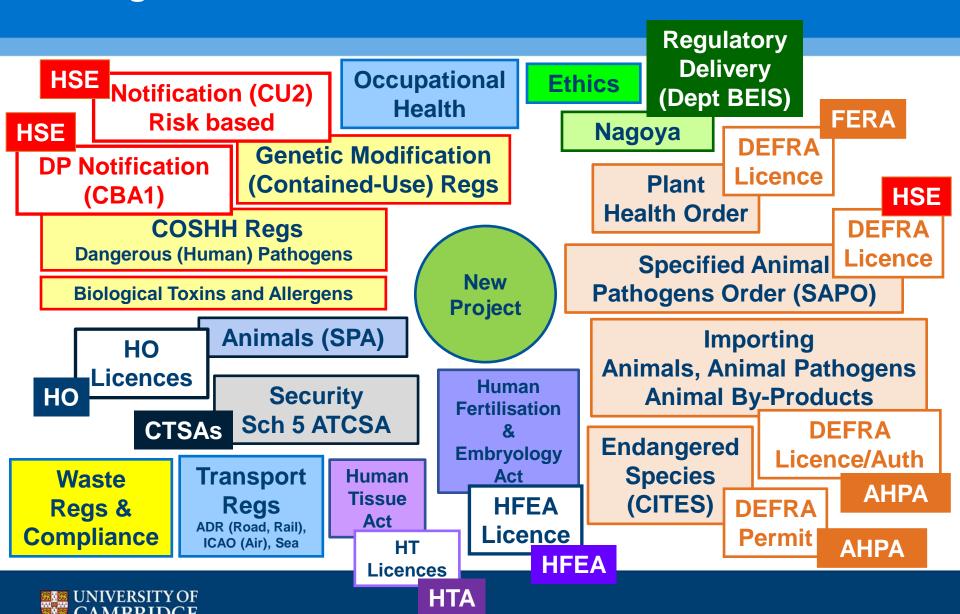
A closer look at some biological considerations other than GM

Biological Safety Officers' Event 16 May 2017



Mark Elsdon – School of the Biological Sciences Safety Officer

Biologicals: There's a lot to think about!



What do all these things all have in common?

- Live animals, incl. insects Welfare, Import/Export, Records
- Animal By-Products (ABP) Import, Export, Storage, Disposal, Records
- Specified Animal Pathogens Storage, Disposal, Security, Records,
- Transport Security
- Human Tissue Ethics, Consent, Storage, Disposal
- Plants, Seeds, Soils Importation, Storage, Disposal, Records,
- Import & Export Plants, Human Tissue, ABP, Animals
- Security Sch 5, Transport, Storage
- Ethics
- Nagoya Storage, ABP, Plant Health, Records
- Endangered Species Records
- **Polio** Importation, Storage, Records
- Waste ABP, HTA, Sch5, Records
- Storage ABP, HTA, Sch5, Records
- Fieldwork Import/Export



Licences/Authorisations/Permits





Nagoya Protocol

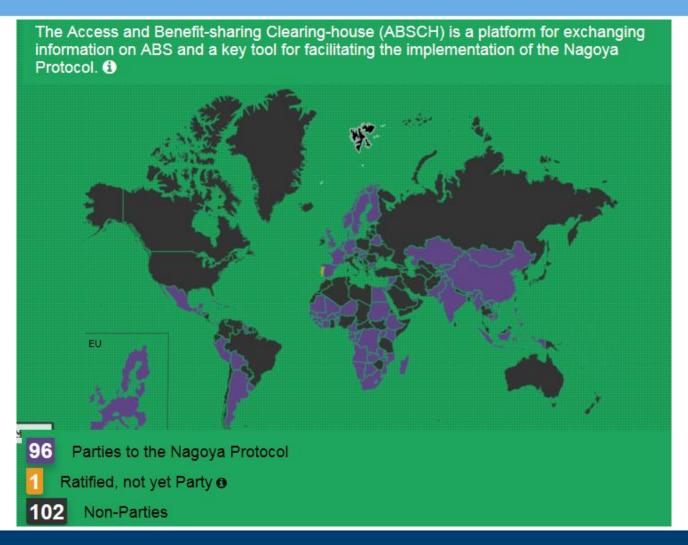


The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity is a supplementary agreement to the Convention on Biological Diversity





- Entered into force in the EU Oct 2014.
- UK Law: Nagoya Protocol (Compliance) Regulations 2015
- Legal framework to enable academic researchers, museums etc to access and utilise genetic resources(GR) & associated traditional knowledge (TK) whilst ensuring fair and equitable benefits out of the utilisation of said resources with the original provider (Access Benefit Sharing – ABS)





- GRs: Any material of plant, animal, microbial or other origin containing functional units of heredity which is of actual or potential value. Excludes human genetic material.
- Applies to resources accessed after 12 Oct 14 from States with ratified Protocol & access measures.
- Access to resources requires compliance with local access arrangements.
- University compliance: Research Policy Committee ... 'Initial advice on the Nagoya Protocol' document sent to Depts. Depts should have a Nagoya contact to liaise with Research Office. Receipt/Transfer Records; Storage & Disposals Database; Due Diligence; Awareness Training (Handbooks, Intranet)
- Dr Rhys Morgan, Research Governance & Integrity Officer rhys.morgan@admin.cam.ac.uk.



Movement and Transport of Biological Material



Movement and Transport of Biologicals – How?

- Between labs in same building
- Between buildings/departments on site (Downing Site)
- Between different sites e.g. Downing to A'brks, Babraham etc
- National: Within England or across borders (Scotland)
- International: Import / Export



Movement and Transport – How will you do it?

Walk, Cycle? Depends on what it is! Cultured HG3's across a car park?

Private car: Business insurance for activity? Other risks e.g. dry ice?

Works vehicle: Yes. Mostly. Other risks e.g. dry ice?

Taxi: If they permit it

Public transport: Bus. Train. As

Royal Mail: If they permit it

Couriers:(cycle couriers, DHL/FE

Punt: Only acceptable biologicals a

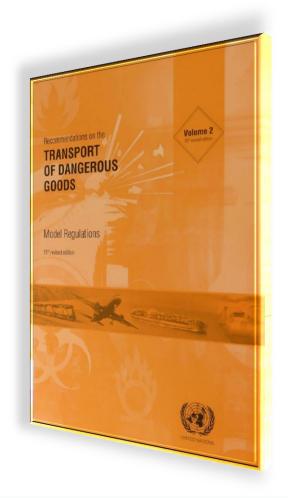






International Regulations govern the carriage of DGs by road, rail, inland waterway, sea and air.

 United Nations Dangerous Goods Experts publish minimum safety standards as Model Regs



Technical Instructions for the Safe Transport of Dangerous Goods by Air

2017-2018 Edition

The International Civil Aviation
Organisation (ICAO) lay down
internationally agreed rules for transporting
DGs by air based on the UN Model regs.

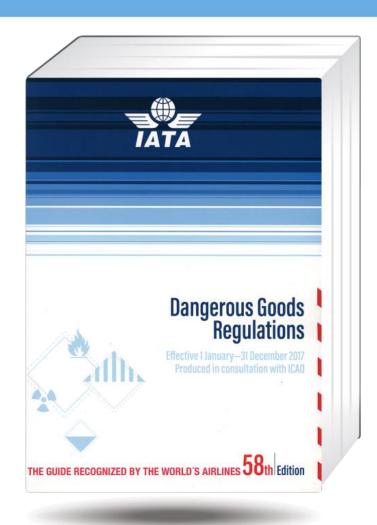
Revised every 2 years

Ensures aircraft and occupants are not put at risk.

But...



- Airlines insist we use the International Air Transport Association (IATA) DGs Regulations (in accordance with the ICAO technical instructions).
- More robust. Airline & State variations accommodated. Packing Instructions.
- Departments shipping DGs by air must have IATA DG trained staff to check that materials are packed to IATA Regs and to sign off shipment paperwork.
- University DGSA: Roadsafe Europe





Are biological materials DGs?

Division 6.1 Toxic Substances

e.g. Toxins from any plant, animal or bacterial sources (non-infectious)

UN3172 Toxins, extracted from living sources, liquid, n.o.s.

UN3462 Toxins, extracted from living sources, solid, n.o.s.



Division 6.2 Infectious Substances

'Substances known, or reasonably expected to contain pathogens...mo's (incl. bacteria, viruses, rickettsia, parasites, fungi) and other agents such as prions, which can cause disease in humans and animals'

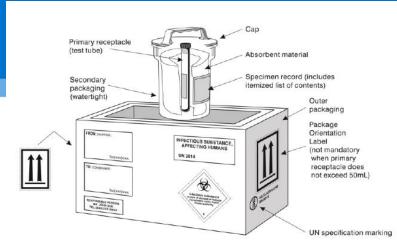
Category A – 'Infectious substances which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life threatening or fatal disease in otherwise health humans or animals.

'The real nasties' – Would we have any/ship any?...



Division 6.2 Infectious Substances

Category A Indicative Examples List



Is a non exhaustive list! Also new/emerging pathogens.

UN2814 Infectious Substance, affecting humans

Ebola virus, Marburg virus

Cultures: B. anthracis, C. botulinum, M. tb, Dengue, HIV, HBV

UN2900 Infectious Substance, affecting animals

Cultures: Foot and Mouth DV, Swine vesicular disease virus





AIR SEA BIOPACK-2TM FOR INFECTIOUS SUBSTANCES

SUITABLE FOR ALL INFECTIOUS SUBSTANCES UNDER I.C.A.O. CLASS 6.2







Optional interior fitments for the

BioJar™1.5 Litre

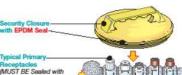
include Specimen Holders (CODES 483, 484, 489, 493).

Bubble Pouches

(CODES 510, 440, 206)

U.N. Mark

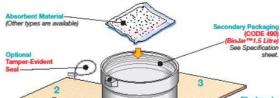
(CODE 490),



Receptacles (MUST BE Sealed with Polyester Tape). Typical— Bubble Pouch

Bubble Pouch (CODE 510)

Typical Specimen Holder (See other available optional interior Fitments).



Fibreboard
Outer Packaging
(CODE 491)
includes Box, Shiald,
Hazard Label and
Instructions in

Affix appropriate

INDICATION OF PROPORTION

CAUTION! DRY ICE MUST NOT BE PACKED IN THE BIOJARIM ASSEMBLY DETAILS: BIOMEDICAL PACKAGINGS FOR INFECTIOUS SUBSTANCES

SYSTEM B CODE:500



SUITABLE FOR ALL INFECTIOUS SUBSTANCES UNDER I.C.A.O. CLASS 6.2

PRIMARY RECEPTACLES
ARE PACKED IN
BUBBLE WRAP

170 x 170 x 210mm

CONTAINER Dimensions: 146 x 160mm

OTES:

This Combination Packaging can be temperature controlled in a variety of Air Sea Thermal Control Units

The approved mode of packing must be strictly adhered to in order to comply with U.N. recommendations.

ALL Primary Receptacle tops must be sealed with Polyester Tape. VOIDS must be filled with Bubble Wrap.

Air Sea Containers Limited stocks a wide range of packagings for the transport of Dangerous Goods.

Further details on Request.

" Denotes year of manufacture



AIR SEA CONTAINERS LTD.
521 Cavendish Street
Birkenhead, CH41 8FZ
Great Britain
Tel: +44 (0) 151 653 1500
Fax: +44 (0) 151 653 1515
Web site: www.air-sea.co.uk
E-mail: sales@air-sea.co.uk





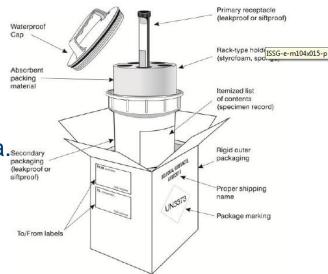
Division 6.2 Infectious Substances

UN3373 Biological Substances, Category B

An infectious substance which does not meet the criteria for inclusion in Category A

Exceptions exist as long as not subject to other criteria.

- Substances non-pathogenic to humans/animals
- Neutralised/inactivated substances no health risk
- Enviro. samples not thought to pose risk of infection
- Dried blood spots
- Patient specimens with min risk of pathogens subject to criteria
- Class 9 Miscellaneous
 UN 3245 Genetically modified organisms not toxic or infectious



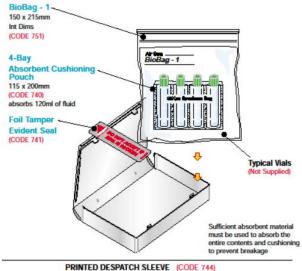


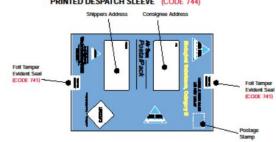


AIR SEA POSTALPACK "FOR BIOLOGICAL SUBSTANCE, CATEGORY B



Conforms with the I.C.A.O. Packaging instruction 650





CAUTIONS

This packaging is NOT a U.N. Certificated Packaging for the transport of class 6.2 infectious Substances, Category A and does not conform to LCA.O./I.A.T.A. Packaging instructions 620

BIOMEDICAL PACKAGINGS

CODE: 760

COMPLETE PACKAGING FOR THE TRANSPORT AND STORAGE OF BIOLOGICAL SUBSTANCE, CATEGORY B

BOX Dimensions:

EXTERNAL: 200x125x30mm INTERNAL: 190x115x26mm

NOTES.

The PostalPack is designed to be delivered via regular Royal Mail. This kit is fully refurbishable for repeated use, low cost and highly efficient. The PostalPack comes complete with Outer Casing and Code 740, 4-Cell Absorbent Pouch, Code 751, 95Kpa BloBlag 1 Code 741, Security Seal.

All can be re-ordered separately

The PostalPack printed Despatch Sleeve (CODE 744) enables easy identification of specimens. If required, a full data report may be written on the reverse side of the sleeve which when sealed, remains confloential during shipping. In the laboratory, with the sleeve reversed, a full description is shown on the outside of the PostalPack, for reference purposes. The sleeve is protected from ice packs by a polythene sheath.

THERMAL CONTROL

A variety of Thermal Control Units for transportation in dry ice or coolpack are available, please see our Thermal Control Unit brochure

It is the Shippers responsibility to ensure that packagings conform to the Reievant Transport Regulations.

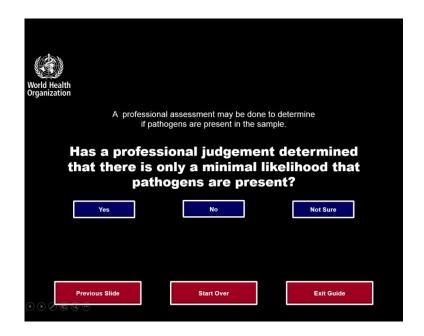


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Website: www.air-sea.co.uk
Ernail: sales@air-sea.co.uk



- IATA DG by Air training Safety Office (6.2 1 day / Full 3 day)
- WHO Guide (but read in context with IATA)





http://www.who.int/ihr/infectious_substances/en/



Transport of Biologicals - Failures

Dangerous Goods:

- Unscreened human blood (Africa) brought in on passenger aircraft by a visiting scientist. Samples later discovered unattended in a lab & destroyed. UN3373 must not be carried on or checked in.
- Mouse embryos (Greece) Persistent loss of dry ice. Other couriers refusing to ship materials if no DG trained person in dept to check/sign off. Specialist couriers (eg Biocaire) expensive.

Live animals:

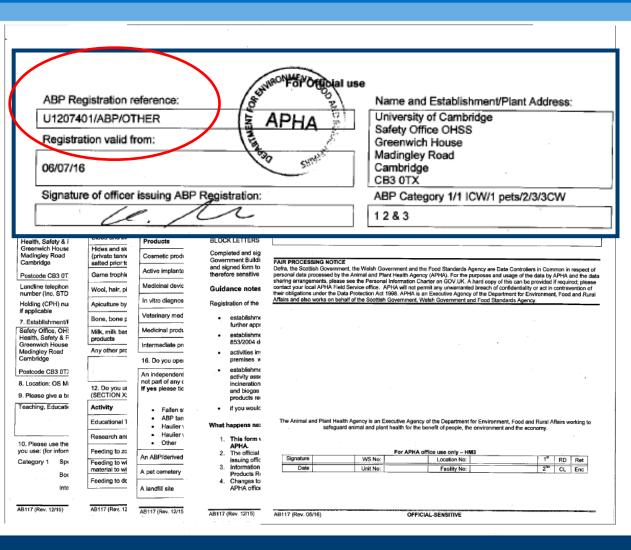
• **Drosophila (EU):** Arrived in UK at Stansted by air courier – immediately destroyed. Drosophila not permitted by air couriers. Only Air Mail.



Animal By-Products (ABP)



AB117: ABP Notification of Registration...



- Univ Safety Office notified University as a whole (Cambridge based)
- Check to see ABP categories have been notified to APHA
- The Registration reference number is required for 'IV58' applications to import specific ABPs not covered by a 'General Licence'

Importing & Exporting of Biological Material



Import/Export Licences...

- If you plan to import or export plants, animals, their pathogens, carriers (eg wool, soil) of pathogens, animal based products or live animals – you must check to see if you need a licence.
- Whether you need a licence will in part depend on where they are coming from
- For animals/animal products veterinary health certificates may be required
- Imports of plants controlled by phytosanitary certificates where possible if not then under a Fera licence
- Exports of flowers, plants, seeds outside EU speak to Fera Inspector
- Within EU may require plant passport



Animal Products Import Licences...

Certain **animals and products of animal origin** including some that are covered by EU regulations must have an **import licence or authorisation** to be imported into Great Britain.

Research and diagnostic samples, trade samples and display items coming from other member states do not need to be licenced or authorised, but must comply with EU rules on animal by-products.

A 'Facilitation letter' can be downloaded and added to any consignments from EU countries.

https://www.gov.uk/guidance/importing-live-animals-or-animal-products-from-non-eu-countries-general-licences-and-authorisations#research-and-diagnostic-samples-trade-samples-and-display-items



Animal Products Import Licences...

General Licences:

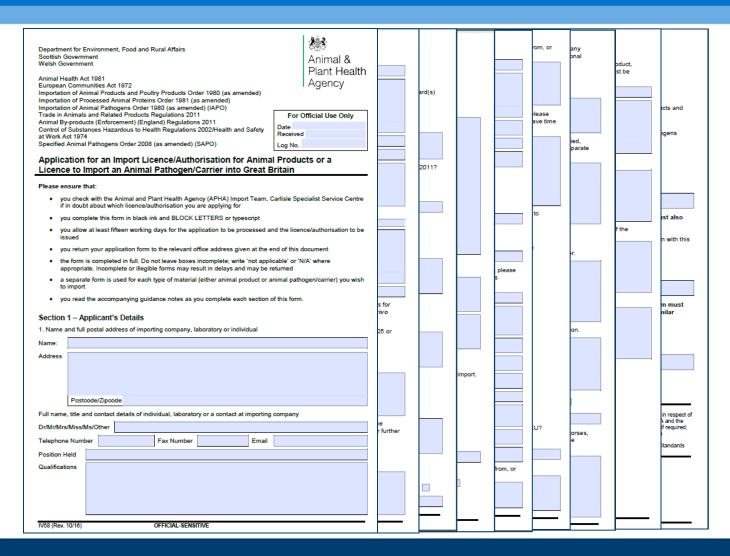
- ABP legislation require research & diagnostic samples to be authorised before they are imported.
- Some GLs & authorisations may need to be read together with a separate amendment notice, listed alongside it in the list of GLs.

https://www.gov.uk/guidance/importing-live-animals-or-animal-products-from-non-eu-countries-general-licences-and-authorisations#research-and-diagnostic-samples-trade-samples-and-display-items

- Free to download.
- Read the licence T&Cs CAREFULLY!
- Licences change periodically. Check every time.
- Can't find a suitable licence? Check with APHA International Trade, Carlisle.
- An IV58 Application likely...



IV58: Importing APs, Pathogens and Carriers





IV58: Importing APs, Pathogens and Carriers

Department for Environment, Food and Rural Affairs Scottish Government Welsh Government Animal Health Act 1981 European Communities Act 1972 Importation of Animal Products and Poultry Products Order 1980 (as amended) Importation of Processed Animal Proteins Order 1981 (as amended) Importation of Animal Pathogens Order 1980 (as amended) (IAPO) Trade in Animals yand Related Products Regulations 2011 Animal By-products (Enforcement) (England) Regulations 2011	Animal & Plant Health Agency
Control of Substances Hazardous to Health Regulations 2002/Health and Safety at Work Act 1974 Specified Animal Pathogens Order 2008 (as amended) (SAPO)	Date Received Log No.
Application for an Import Licence/Authorisation for Animal Products or a Licence to Import an Animal Pathogen/Carrier into Great Britain Please ensure that: you check with the Animal and Plant Health Agency (APHA) Import Team, Carlisle Specialist Service Centre if in doubt about which licence/authorisation you are applying for you complete this form in black ink and BLOCK LETTERS or typescript you allow at least fifteen working days for the application to be processed and the licence/authorisation to be issued you return your application form to the relevant office address given at the end of this document the form is completed in full. Do not leave boxes incomplete; write 'not applicable' or 'NIA' where appropriate. Incomplete or illegible forms may result in delays and may be returned	
a separate form is used for each type of material (either animal product or a to import you read the accompanying guidance notes as you complete each section of Section 1 — Applicant's Details 1. Name and full postal address of importing company, laboratory or individual Name: Address Postcode/Zipcode	
Full name, title and contact details of individual, laboratory or a contact at importing	company
Dr/Mr/Mrs/Miss/Ms/Other	
Telephone Number Fax Number Email	
Position Held Qualifications	
IV58 (Rev. 10/16) OFFICIAL-SENSITIVE	

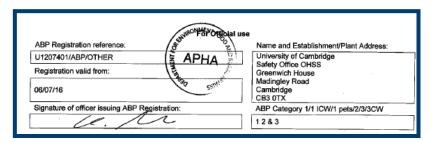
- PLAN AHEAD!
- Read IV59 Supporting Guidance Doc
- Check Customer Information Notes (CINs) and Importer Information Notes (IIN)
- COMPLETE entire form using N/A for blanks
- Applications allow 15 days

IV58: Importing APs, Pathogens and Carriers

c. Is the destination premises approved under SAPO containment requirements	
Yes No (Please tick one option)	
f yes please specify	
SAPO Containment Level 2 Level 3 Level 4	
d. Does the destination premises meet ACDP or GMO containment standard(s) and if so specify which standard(s) and to what level	
Please give details:	
ACDP Containment Level 2 3 4	
e. Is the destination premises registered/approved under the Animal By-Products (Enforcement) Regulations 2011?	
Yes No (Please tick one option)	
If yes please specify the registration/approval number:	
Has the destination premises carried out a risk assessment for receipt and storage of the specified animal pathogens/carriers/animal products? Yes No (Please tick one option) If yes, please provide full details.	
8. Is the material likely to come into contact with ruminating animals, swine, equidae or birds? Yes No (Please tick one option) If yes, please provide full details.	
7. Do any of the laboratory personnel who will be handling the material have contact with ruminants, swine, equidae, captive birds or poultry not involved in the proposed work? Yes No (Please tick one option)	
f yes, please give details.	
8. What is the intended use of the animal product or pathogen/carrier? (Please tick all relevant options)	
Technical Pharmaceutical Cosmetic Laboratory	
Sampling/evaluation Research Human consumption Animal consumption	
Diagnostics Other (please specify)	
IV58 (Rev. 10/16) OFFICIAL-SENSITIVE	

4c SAPO Specified Animal Pathogen Order Work with SAPs is done by a limited number of laboratories in Cambridge. This is carried out under a separate University SAPO licence. Work with SAPs/carriers (incl. their import/export) **must** be notified to Dr Androulla Gilliland BEFORE starting.

4e University ABP Registration Reference number



Safety Office is the registered address for University work with ABPs BUT you record department names/addresses in section 1 of the IV58 form, not the SO.



Import of ABPs – Challenges, Failures, Successes

- Borneo: Student sending Orangutan faeces to Cambridge Didn't apply for permit until ready to return to UK
- 2. USA: Mouse embryos (BSA), Sperm (3% Skimmed Milk) World Couriers refused as no Import Auth for ABPs
- 3. South Africa: Meerkat bloods, tissues. Changed Alcohol to Trizol to kill potential MO (M.bovis?). Licence still prohibited movement of tissues from Cam to Scotland without a movement authorisation.
- **4. Africa: Elephant tissues** CITES approval. Import authorisation to affiliated organisation, but PDN had to be named in it to receive.
- **5. Non EU: Cell Cultures** in Bovine Serum 3%/10% General Licences?
- 6. EXPORTS to Canada: Sheep ovary tissue. Vet Zoosanitary cert.



Import of ABPs - Challenges, Failures, Successes

South Africa: 3 x Golden Mole heads in 70% EtOH:
PI studies biology of the inner ear. Destination: PDN.
Applied to APHA for Import Authorisation (IA) via IV58



Work in CL2 - but Itd CL2 space.

APHA IA T&Cs challenging to meet:

Dept to Notify as ABP user – Univ prev. notified as a whole

CT in Zoology: a 2ndary transient destination. Diff M'gmt. Not CL2.

Risk v low (geography/species/EtOH). Case made for relaxation CL1.



Import of ABPs – Challenges, Failures, Successes

Authorisation changed *subject to pre-agreed handling/movement SOP* **Comply with IATA,** *PLUS additional info for shipment..*

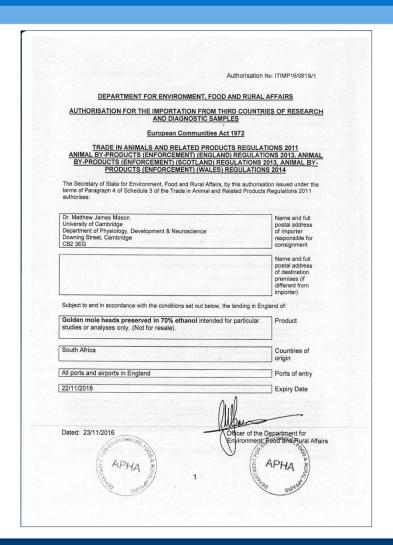
- Declaration of health status on UoC headed paper, enclosed
- Contents listed on package
- Words 'In Vitro Use for Research Only' & 'Not for Human or Animal Consumption'
- Min 24hrs in 70% EtOH prior to shipment

Records to be kept: where/how much/disposal for traceability (2 yrs)

APHA can (and do) spot check audits at Universities



Import of ABPs







Import of ABPs – Elsewhere

How dangerous is drum making?

WHO, WHAT, WHY? The Magazine answers...

A second drum maker in two years has died after apparently inhaling anthrax spores from animal skins. What are the risks of this seemingly safe job?

Fernando Gomez had been in intensive care for more than a week after handling animal skins at his drum-making workshop in London. But his condition deteriorated over the weekend and



Animal skin, used for the drum head, can be infected with anthrax

the 35-year-old died from inhalation anthrax on Sunday night.



Last Updated: Thursday, 13 December 2007, 14:03 GMT

E-mail this to a friend

Printable version

Man caught anthrax from drum skin

An inquiry into a man's death from anthrax has concluded that "on balance of probabilities" he contracted it from playing or handling West African drums.



Christopher Norris, of Stobs, near Hawick in the Scottish Borders died from the disease in July last year.

Timeline: Borders anthrax death

A report by NHS Borders said it was the first case of "inhalation anthrax" in the UK for more than a century.

Cutaneous Anthrax Associated with Drum Making Using Goat Hides from West Africa --- Connecticut, 2007

On August 29, 2007, the Connecticut Department of Public Health was notified by a physician of suspect cutaneous anthrax involving a drum maker and one of his three children. The drum maker had been working with untreated goat hides from Guinea in West Africa. This report summarizes results of the joint epidemiologic and environmental investigation conducted by public health officials, environmental agencies, and law enforcement authorities. The investigation revealed that the drum maker was exposed while working with a contaminated goat hide from Guinea and that his workplace and home were contaminated with anthrax. His child was most likely exposed from cross-contamination of the home. The findings underscore the potential hazard of working with untreated animal hides from areas with epizootic anthrax and the potential for secondary cases from environmental contamination.



Importing Plant Materials

- Licences perpetual
- Annual visit from Fera inspector
- Annual report of holdings
- Notification of any planned changes (new materials before doing so!
- 'Letter of Authority' Annual renewal for imports
- Algae Innovation Centre (AIC)
- Algae from Antarctic, other parts of world
- Algae from culture collection in Scotland
- Lab quarantine
- Phytosanitary certificates = no licence
- Cant always get them so a licence is required instead





Licensed Activities & BSOs

- Unlike work with Dangerous Pathogens (CoSHH) or work with GMOs, many licensed activities are not strictly risk based.
- Little flexibility. strict!
- Do EXACTLY what the licence & approved SOPs say!
- BSOs should be AWARE of licensed activities and controls
- Monitor compliance
- Ensure detailed records are being maintained
- Discuss at Biological Safety Committee
- Notify Safety Office / School Safety Officers of any Planned/Unplanned visits from Inspectors





Security of Biological Material

Q: Are there any special security requirements for transporting biological materials?

- Transport of 'High Consequence Dangerous Goods' by air/road
 - Potential for misuse in terrorist event
 - Category A Infectious Substances (e.g. HIV Cultures)
 - Requires a University DG Security Plan BEFORE moving.
 Consult Safety Office/DGSA

Security of Biological Material

Q: Is the material notifiable to the Home Office under the Anti-Terrorism Crime and Security Act 2001?

Schedule 5 Pathogens and Toxins

- It is an offence to store or work with certain organisms or toxins without prior permission.
- Pathogens categorised into security levels (Restricted Document)
- Requirements for very expensive security measures; Security plans
- Check list of human/animal pathogens
- Advice from Univ Contingency Planning & Compliance Officer





Biosafety

It's just a picnic in the park



Mark Elsdon – School of the Biological Sciences Safety Officer