

ANNEX D

TRANSPORT OF TSE INFECTED MATERIAL

CONTENTS and INDEX

Legislative Background	2
International and national carriage of dangerous goods	2
National carriage by sea	2
National carriage by air	3
National carriage by road and rail	3
Application of relevant legislation	3
Transporting TSE infected material by road, rail and air in Great Britain	3
Classification.....	4
Category A.....	4
Category B.....	4
Packaging.....	5
Marking/Labelling.....	6
Transporting.....	7
Training	8
Transport of animals	8
Transport of livestock.....	8
Transport of small live animals.....	9
Transport of dead animals.....	10
Appendix 1 – Links to regulations, legislation and guidance	12
United Nations recommendations.....	12
International agreements and regulations on the transport of dangerous goods...12	
National regulations for the transport of dangerous goods.....	12
Other regulations.....	13
Relevant guidance.....	14
Appendix 2 – Contact details	16

For legislation concerning transport of dangerous goods within, to or from Northern Ireland, see [Appendix 2](#) for contact details for enquiries.

Legislative Background

International and national carriage of dangerous goods

- D1. The **international carriage** of dangerous goods by road, rail, sea and air is explained in full at the Department for Transport's website:
<http://www.dft.gov.uk/pgr/freight/dgt1/overview/international/internationaltransport>
Importation of TSE-infected material by air or sea to the UK may involve customs forms and import permits for individual countries outside Europe.
- D2. This document outlines the regulations and stipulations for **national carriage** of dangerous goods by road, rail, sea and air. However, as will be clear from the information below, many of these national regulations are derived from the international regulations for the carriage of dangerous goods, and thus the same rules apply for classification, packaging, marking and transporting.

National carriage by sea

- D3. The safe transport of dangerous goods by sea in the UK, and internationally, is set out in the [International Maritime Dangerous Goods \(IMDG\) Code](#).
- D4. The carriage of dangerous goods by inland waterway in the UK is subject to the [Dangerous Substances in Harbour Areas Regulations 1987](#) or British Waterways by-laws. The amount of dangerous goods moved by this mode within the UK is small. Most estuarial waterways are open to sea-going vessels and are therefore governed by the International Maritime Dangerous Goods (IMDG) Code.
- D5. The carriage, loading, unloading and storage of dangerous goods in harbour areas in the UK is controlled by the Dangerous Substances in Harbour Areas Regulations 1987. Provisions are made under the Merchant Shipping Acts for ships' crews by way of the [Merchant Shipping \(Dangerous Goods and Marine Pollutants\) Regulations 1997](#) which bring in the IMDG Code for domestic transport.

National carriage by air

- D6. Requirements for the carriage of dangerous goods in the UK, and internationally, by air are set out by the International Civil Aviation Organisation (ICAO) in the [ICAO Technical Instructions for Safe Transport of Dangerous Goods by Air](#), which are revised every two years. [The Air Navigation \(Dangerous Goods\) Regulations 2002](#), and subsequent amendment regulations, bring the ICAO Technical Instructions into domestic legislation.

National carriage by road and rail

- D7. Carriage of dangerous goods by road and rail within Great Britain is required to comply with the [European agreement concerning the international carriage of dangerous goods by road](#) (ADR) and the Regulations concerning the international carriage of dangerous goods by rail (RID) subject to agreed derogations, exemptions etc. as set out in the [Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2007](#), which came into force on 1st July 2007. Note that these are expected to be replaced by updated regulations in July 2009. ADR and RID are in turn based on the [UN Recommendations on the Transport of Dangerous Goods \(Model Regulations\)](#).
- D8. For enquiries on legislation concerning transport of dangerous goods by road or rail in Northern Ireland – see [Appendix 2](#) for contact details.

Application of relevant legislation

Transporting TSE infected material by road, rail and air in Great Britain

- D9. There are 4 steps involved in the safe transport of TSE infected material by road, rail and air in Great Britain. These are:
- (i) Classification of the samples to be transported
 - (ii) Packaging
 - (iii) Marking
 - (iv) Transporting

Classification

D10. All TSE infected specimens of human and animal origin are classified for transport purposes as Dangerous Goods, in Class 6.2 Infectious Substances. The UN Model Regulations define infectious substances as: “*substances known or reasonably expected to contain pathogens*” and pathogens are defined as micro-organisms including (bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as TSEs which can cause disease in humans or animals. Class 6.2 covers biological products used for diagnosis or research, genetically modified micro-organisms (GMMs), genetically modified organisms (GMOs), and clinical/biological waste. Determination of which UN number to assign within Class 6.2 Infectious Substances is based on whether the materials meet the criteria for a Category A or a Category B.

Category A

D11. An infectious substance which is carried in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals and should be assigned to Category A, UN2814 (humans) or UN2900 (animals).

D12. Specimens would be assigned to Category A for transport if the source patient or animal has or may have a serious human or animal disease which can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatment and preventive measures are not usually available.

Note: An exposure occurs when an infectious substance is released outside of the protective packaging resulting in physical contact with humans or animals.

D13. **TSE samples are not considered to be Category A for transport** as TSEs are not considered to be readily transmissible.

Category B

D14. An infectious substance which does not meet the criteria for Category A, and does not appear on the indicative list for Category A, should be assigned to Category B and UN 3373.

TSE samples are considered to be Category B for transport, and thus transport of all TSE samples must follow the requirements of UN 3373.

D15. Category B substances, which are assigned to UN 3373, should be deemed to include specimens of human or animal material, including but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs and body parts, being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention, but excluding live infected animals.

All TSE material including brain/spinal cord tissue and body fluid samples such as CSF, blood, urine and faeces must be sent as UN3373 Category B.

D16. Cell lines known to be infected with a TSE agent are considered biological agents under the Control of Substances Hazardous to Health Regulations (CoSHH), so should be transported as dangerous goods.

Packaging

D17. Category B specimens of TSE assigned to UN3373 must be packed in accordance with ADR packing instruction 650 for road and rail transport, and ICAO packing instruction P650 for airfreight (the ICAO packing instructions are also shown in the IATA Dangerous Goods Regulations). For full packaging details, particularly if transporting refrigerated or frozen specimens using ice, dry ice or liquid nitrogen, packaging instruction 650 should be consulted. Details of this packaging instruction are included in the [Department for Transport's guidance document on transport of infectious substances](#).

D18. Packaging for Category B substances is not required to be UN-type approved, however it must meet all the requirements of P650 and the [Department for Transport guidance document](#) (as above). A P650 consists of a triple layer packaging system, comprising a primary receptacle, secondary packaging and outer packaging. For airfreight, the outer packaging must be rigid; for road and rail transport either the secondary or outer packaging must be rigid. The packaging supplier MUST provide clear instructions on filling and closing the package.

- D19. There are no weight limits on the quantity of Category B material contained within either the primary receptacle(s) or the total package for transport by road or rail. This is in contrast to transport by air where other than for body parts, organs or whole bodies the outer package must not contain more than 4kg
- On both passenger and cargo aircraft there is a 4L/4kg limit per outer package, with a 1L limit per primary receptacle for liquids, whereas for solids the primary receptacle must not exceed the outer packaging mass limit of 4kg
 - A whole organ such as brain is regarded as an exceptional consignment and as such the restriction of the weight of material that can be placed in the primary does not apply.
- D20. It is permissible to have mixtures of samples within the same outer packaging providing each individual sample meets its specific requirements under packaging instruction 650.

Marking/Labelling

- D21. Packaging must be clearly labelled with the delivery address and sender's details. The UN Number **MUST** be used with the proper shipping name which is "BIOLOGICAL SUBSTANCE CATEGORY B" in text that is at least 6mm high. The text 'UN3373' must be placed in a diamond-shaped mark. The length of the line shall be at least 50mm, the width of the line shall be at least 2mm and the lettering shall be at least 6mm high.



D22. TSE samples being sent as Category B substances must be marked and labelled as follows:

1. "UN 3373 BIOLOGICAL SUBSTANCE CATEGORY B"
2. Name and full address of both shipper and consignee
3. Name and telephone number of the person responsible for the shipment (emergency contact)
4. In addition, the following labels must be placed on the overpack for shipments involving solid carbon dioxide (dry ice):
 - Hazard label for solid carbon dioxide (dry ice)
 - Net weight of dry ice
 - The overpack must be marked as "OVERPACK"

Transporting

D23. Consignors should always discuss the transport requirements with their chosen carrier.

D24. In general, samples that are travelling as UN3373 Biological substance Category B can be sent via the postal service (UK only) or using a courier. A dangerous goods document is not required for the transport of a Category B substance going by road or rail within Great Britain, or on an international RID/ADR journey within Europe. A copy of the emergency response procedure (see paragraph D27 below for an example of this), details of the sample enclosed, and a packing list must be provided with any package.

D25. If you are intending to import or export human body parts and tissue for non-therapeutic purposes then the guidance outlined in ["The import and export of human body parts and tissue for non-therapeutic purposes Code of Practice"](#) should be followed.

D26. Example emergency response sheet for TSE-infected material

- Dangerous goods are infectious substances affecting humans Class 6.2, UN number 3373
- No immediate hazard to health unless ingested or injected into the body
- No risk of fire or explosion
- In event of accident wear disposable gloves and other necessary personal protective clothing for handling the material
- For spillages, cover areas with 2M sodium hydroxide or sodium hypochlorite (20,000ppm available chlorine). Note that both sodium hydroxide and sodium hypochlorite are caustic chemicals that may produce dangerous fumes. Appropriate personal protective clothing must be worn by handlers of these chemicals
- Use absorbent material to clean up the spillage
- Dispose of waste by incineration

Training

D27. All personnel involved in the transport of infectious substances should be given the appropriate training.

Transport of animals

D28. Exposure to agents in intact large animals, whether alive or dead, can be considered to be remote.

D29. Regulations covering the transport of live animals infected with a TSE agent are the responsibility of the Home Office and Defra in England, and the devolved administrations in Scotland and Wales (see [Appendix 1](#)). For information on transport of live animals within, to or from Northern Ireland, see [Appendix 2](#) for contact details for enquiries.

Transport of livestock

D30. Farm livestock, particularly adult cattle, but also sheep and pigs, pose no significant risks from exposure to TSEs for the stockman, haulier or anyone else

involved in livestock transport. There are, however, considerable physical risks to these occupations due to the unpredictable behaviour of large animals especially when they are moved to unfamiliar surroundings (see HSE [Guidance on Handling and Housing Cattle](#)). Livestock must be transported in accordance with animal welfare and animal identification legislation. Transport of animals exhibiting clinical signs of TSE is inadvisable.

- D31. Although the incidence of Bovine Spongiform Encephalopathy (BSE) in the national herd is rapidly diminishing, TSE research with infected livestock is still ongoing and scrapie cases are routinely transported. If you need to transport clinical TSE cases then further guidance can be obtained from Animal Health (see [Appendix 2](#) for contact details). *(Note: a special licence is required under the [Animals \(Scientific Procedures\) Act 1986](#) for all experimental work on animals).*
- D32. One exception to the remote risk of exposure to BSE when transporting cattle is where an animal has been orally dosed with BSE (or other TSEs) for experimental purposes. This procedure results in a risk of the agent being voided from the gut. A precautionary 28-day risk period has been agreed, and thus livestock that have been orally dosed within the last 28 days must not be transported. Where exceptional circumstances prevail, advice should be sought from HSE (see [Appendix 2](#) for contact details).

Transport of small live animals

- D33. Small live animals such as mice infected with TSE agents could pose a greater threat to humans than larger animals because of the risk from exposure to bites and scratches. There are unlikely to be many situations when infected small animals would need to be transported; however, in cases where there is no alternative then advice should be sought from HSE (see contacts information in [Appendix 2](#)) and the following adhered to:
- A thorough risk assessment must be carried out, which assesses:
 - i. the time in transit
 - ii. the infective agent
 - iii. the number of animals

- iv. supervision by experienced staff
- v. emergency procedures
- Animals must be transported in secure containers that protect the handler from the animals. The animals themselves can be considered to be the primary containment
- Containers must be fitted with suitable filters
- Animals must **not** be transported when there is a possibility of infectivity from the inoculum being shed in excrement and/or urine

D34. In addition the following regulations should be considered:

- [The Animals \(Scientific Procedures\) Act 1986](#);
- [The Welfare of Animals \(Transport\) \(England\) Order 2006](#) (SI 2006/3260)
- [The Welfare of Animals \(Transport\) \(Wales\) Order 2007](#) (WSI 2007/1047(W.105))
- [The Welfare of Animals \(Transport\) \(Scotland\) Regulations 2006](#) (SSI 2006/606)
- [The Transmissible Spongiform Encephalopathy \(England\) Regulations 2008](#) (SI 2008/1881)
- [The Transmissible Spongiform Encephalopathies \(Wales\) Regulations 2006](#) (WSI 2006/1226 (W.117))
- [The Transmissible Spongiform Encephalopathies \(Scotland\) Regulations 2006](#) (SSI 2006/530)

Also see legislation on animal identification.

Transport of dead animals

D35. [The Animal By-Products Regulations \(ABPR\) 2005](#) (parallel legislation in Scotland and Wales) lay down rules for the collection, transport and disposal of animal by-products. Animal by-products are defined as entire bodies or parts of animals or products of animal origin referred to in Article 4, 5 and 6 of Regulation (EC) No.1774/2002 not intended for human consumption, including ova, embryos and semen.

D36. **Dead animals infected with TSEs, and any TSE-infected tissue of animal origin, must be transported in accordance with ABPR 2005.**

- D37. Intact, dead, large animals do not pose a significant risk of transmitting TSE to humans. The animal itself can be considered to be the primary containment. In the TSE context, TSE infectivity will not be aerosolised, excreted, secreted or otherwise liberated from the central nervous system (CNS).
- D38. Methods of killing which involve penetrating the cranial cavity should not be used for animals suspected of being affected with a TSE, as there is a risk of leakage of CSF fluid and possibly macerated neural tissue. The use of injectable barbiturates is the preferred method of euthanasia in such cases. If there is no alternative and a method of killing which involves penetrating the cranial cavity is used, the hole should be stoppered with an appropriately designed plug and the head enclosed in two layers of robust plastic sacks tied off at the neck of the animal.
- D39. Only hauliers who have the necessary competences, training and appreciation of the risks involved should transport livestock and carcasses. Hauliers need to comply with the following:
- Vehicles and containers must be leak proof and:
- Cleaned, washed and disinfected after each use
 - Maintained in a clean condition
 - Clean and dry before use
 - Reusable containers must be dedicated to the carriage of a particular product to the extent necessary to avoid cross contamination
 - Packaging must be incinerated or disposed of after use in accordance with instructions from the competent authority
- D40. Bovine heads and whole brains must be double bagged, tied, and placed in robust plastic boxes (e.g. 'Arca System' boxes) before being transported by courier.

ANNEX D – APPENDIX 1

Links to regulations, legislation and guidance

United Nations recommendations

- UN recommendations on the Transport of Dangerous Goods Model Regulations
http://www.unece.org/trans/danger/publi/unrec/rev13/13files_e.html

International agreements and regulations on the transport of dangerous goods

- European agreement concerning the International Carriage of Dangerous Goods by Road (ADR) 2007 edition.
<http://www.unece.org/trans/danger/publi/adr/adr2007/07ContentsE.html>
- Regulations concerning the International Carriage of Dangerous Goods by Rail (RID), Appendix C to the [Convention Concerning International Carriage by Rail](#), 2007 edition. ISBN 10: 8086206289.
- International Maritime Dangerous Goods (IMDG) Code
http://www.imo.org/Safety/mainframe.asp?topic_id=158
- ICAO Technical Instructions for Safe Transport of Dangerous Goods by Air, 2007-2008 edition
<http://www.icao.int/anb/FLS/DangerousGoods/TechnicalInstructions/>

National regulations for the transport of dangerous goods

- Dangerous Substances in Harbour Areas Regulations 1987
http://www.opsi.gov.uk/si/si1987/Uksi_19870037_en_1.htm
- Merchant Shipping (Dangerous Goods and Marine Pollutants) Regulations 1997
<http://www.opsi.gov.uk/si/si1997/19972367.htm>

- The Carriage of Dangerous Goods and use of Transportable Pressure Equipment Regulations 2007

http://www.opsi.gov.uk/si/si2007/uksi_20071573_en_1

Note that these are expected to be replaced by updated regulations in July 2009

- Air Navigation (Dangerous Goods) Regulations 2002

<http://www.opsi.gov.uk/si/si2002/20022786.htm>

Other regulations

- The Animal By-Products Regulations (ABPR) 2005 (parallel legislation in Scotland and Wales) <http://www.opsi.gov.uk/si/si2005/20052347.htm> and <http://www.defra.gov.uk/Animalh/by-prods/default.htm>

- The Animals (Scientific Procedures) Act 1986

<http://www.archive.official-documents.co.uk/document/hoc/321/321-xa.htm>

- The Welfare of Animals (Transport) (England) Order 2006 (SI 2006/3260)

<http://www.opsi.gov.uk/SI/si2006/20063260.htm>

- The Welfare of Animals (Transport) (Wales) Order 2007 (WSI 2007/1047(W.105))

http://www.opsi.gov.uk/legislation/wales/wsi2007/wsi_20071047_en_1

- The Welfare of Animals (Transport) (Scotland) Regulations 2006 (SSI 2006/606)

<http://www.opsi.gov.uk/legislation/scotland/ssi2006/20060606.htm>

- The Transmissible Spongiform Encephalopathy (England) Regulations 2008 (SI 2008/1881)

http://www.opsi.gov.uk/si/si2008/pdf/uksi_20081881_en.pdf

- The Transmissible Spongiform Encephalopathies (Wales) Regulations 2006 (WSI 2006/1226 (W.117))

<http://www.opsi.gov.uk/legislation/wales/wsi2006/20061226e.htm>

- The Transmissible Spongiform Encephalopathies (Scotland) Regulations 2006 (SSI 2006/530)
<http://www.opsi.gov.uk/legislation/scotland/ssi2006/20060530.htm>
- The Control of Substances Hazardous to Health Regulations 2002
<http://www.opsi.gov.uk/SI/si2002/20022677.htm>

Relevant guidance

- Department for Transport guidance on international transport of dangerous goods
<http://www.dft.gov.uk/pgr/freight/dgt1/overview/domestic/nationaltransport>
- Department for Transport guidance on national transport of dangerous goods
<http://www.dft.gov.uk/pgr/freight/dgt1/overview/international/internationaltransport>
- Department for Transport guidance on transport of infectious substances
<http://www.dft.gov.uk/pgr/freight/dgt1/guidance/guidancenonclass7/guidanceontransportofinfecti3186>
- Carriage of Dangerous Goods Manual – HSE
<http://www.hse.gov.uk/cdg/manual/index.htm>
- Biological agents: Managing the risks in laboratories and healthcare premises. Advisory Committee on Dangerous Pathogens.
<http://www.hse.gov.uk/biosafety/biologagents.pdf>
- Defra guidance on Animal Welfare During Transport Requirements
<http://www.defra.gov.uk/animalh/welfare/farmed/transport.htm>
- Defra guidance on Animal Identification Requirements
<http://www.defra.gov.uk/animalh/id-move/index.htm>
- Defra guidance on Animal By-Products Requirements
<http://www.defra.gov.uk/animalh/by-prods/default.htm>

- Guidance on Handling and Housing Cattle
<http://www.hse.gov.uk/pubns/ais35.pdf>
- BSE Occupational Guidance
<http://www.hse.gov.uk/pubns/web22.pdf>
- Royal Mail Advice
<http://www.royalmail.com/portal/rm/jump2?catId=400023&mediaId=400044>
- The import and export of human body parts and tissues for non-therapeutic uses.
Department of Health Publications
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4009963

ANNEX D – APPENDIX 2

Contact details

- **Department for Transport Dangerous Goods Division**
Email: dgenquiries@vca.gov.uk
Telephone: 01372 226111

- **For information on transportation within, to and from Northern Ireland:**
Mr William Burns
Health and Safety Inspector
Health and Safety for Northern Ireland
83 Ladas Drive
Belfast
Northern Ireland
BT6 9FR
Telephone: 0289 0546903
Email: William.burns@detini.gov.uk

- **For advice on animal health and welfare:**
<http://www.defra.gov.uk/animalhealth/about-us/contact-us/animal-health-offices.htm>

- **For general advice, contact HSE:**
Website: www.hse.gov.uk
Email: hse.infoline@natbrit.com