PART 2

Health and Safety Management of TSEs

HEALTH AND SAFETY LEGISLATION

The key requirements of the health and safety legislation, which is appropriate for work with TSEs, are given in Table 2a below.

Table 2a

Health and Safety at Work etc Act 1974 requires: • employers and self-employed workers to ensure they provide and maintain workplaces, equipment and systems of work that are, so far as is reasonably practicable, safe to workers and the public; • employees to take care of their own and others' health and safety, and to co-operate with their employer or any other person to enable them to comply with health and safety duties; • *A guide to the Health and Safety at Work etc Act 1974 (L1)* gives further information.	**Management of Health and Safety at Work Regulations (MHSWR) 1999** require employers and self-employed workers to: • identify the measures they need to take by carrying out risk assessments; • institute safety management systems; • appoint persons to assist in health and safety management; • ensure co-ordination and co-operation where two or more employers or self-employer persons share a workplace; • make emergency arrangements; • provide information and relevant training for employees; • *Successful health and safety management (HSG 65)* gives further information.
Control of Substances Hazardous to Health (COSHH) Regulations 2002 provide a framework of actions designed to control the risk from a range of hazardous substances including biological agents. These actions include: • assess the risk; • prevent the risk by substitution if possible; • control the risks using appropriate measures *e.g. work process, systems and engineering controls;* • control exposure at source *e.g. adequate ventilation systems and appropriate organisational measures;* • control the working environment including general ventilation; • maintain, examine and test control measures; • provide suitable personal protective equipment (PPE) when adequate control of exposure cannot be achieved by other means; • monitor exposure at the workplace; • provide information, instruction and training for workers; • make arrangements for health surveillance of workers where necessary; • *COSHH: a brief guide to the regulations (INDG131 rev1);* *Control of Substances Hazardous to Health (Fourth edition). The Control of Substances Hazardous to Health Regulations 2002. Approved Code of Practice and Guidance (L5);*	**Genetically Modified Organisms (Contained Use) Regulations 2000 and Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002** require employers and self-employed workers to: • make a risk assessment for genetically modified micro-organisms in relation to human health and environmental protection and for genetically modified animals in relation to human health; • apply appropriate containment and control; • notify the Competent Authority to the Regulations of all premises being used for genetic modification; • notify the Competent Authority of certain activities; • *A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000,* and *Contained use of genetically modified organisms (INDG86 rev2)* give further information.

Health Surveillance under COSHH: guidance for employers; *The management, design and operation of microbiological containment laboratories*; and *5 steps to risk assessment (INDG163 rev1)* give further information.	
Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995 require employers and the self-employed to: • report any infection reliably attributable to work with live or dead humans or animals, exposure to blood or fluids or any potentially infected material derived from any of the above; • report any accident or incident that could result in the release of a TSE agent (or any other biological agent categorised in Hazard Group 3 or 4). *e.g.* percutaneous exposure to known infected brain material; • *Guide to the reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995* gives further information.	**The Carriage of Dangerous Goods (Classification, Packaging and Labelling) Regulations 1996** require consigners to: • classify the biological agent or substance containing the biological agent for transport according to the criteria laid down in the 'Approved Requirements' • determine the packing group and package in accordance with the appropriate packing instruction; • appoint a Dangerous Goods Safety Adviser if necessary; • *Are you involved in the carriage of dangerous goods by road or rail?*; *Approved Carriage List: Information approved for the carriage of dangerous goods by road and rail other than explosives and radioactive material (ACL)*; *European Agreement concerning the international carriage of dangerous goods by road (ADR)*; *Approved Vehicle Requirements. Carriage of Dangerous Goods by Road Regulations 1996 (AVR)*; and *Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)* give further information.

Health and Safety Management of TSEs

2.1 The ACDP publication '*The management, design and operation of microbiological containment laboratories*' provides guidance on the management of biological agents including TSEs, in the laboratory environment. The document sets out the standards for Containment Level (CL) 2 and 3 microbiological laboratories and should be read in conjunction with this guidance.

Health and Safety Law

2.2 Employers have duties under health and safety legislation to protect employees and non-employees from risks to their health and safety arising from work activities; non-employees include students and visitors.

2.3 A summary of the principal legal requirements relevant to work with TSEs is given in Table 2a.

2.4 Biological agents, as defined in the Control of Substances Hazardous to Health (COSHH) Regulations, include the agents that cause transmissible spongiform encephalopathies (TSEs). COSHH applies both to deliberate work with TSEs (*e.g.* in a laboratory) and to incidental exposure, as may occur in, for example, health care workers, farm workers and abattoir workers. COSHH outlines the requirements that apply for work with biological agents. General duties, which are relevant to all hazardous substances, including biological agents and chemicals, can be found in the main Regulations. Additional requirements relating to just biological agents are outlined in Schedule 3 of COSHH.

2.5 A risk assessment should be made for both these types of work. Reducing and controlling the risk for incidental exposure may be more reliant on safe systems of work and the use of PPE rather than the use of containment, although preventing or controlling exposure by this means should be considered in the first instance (as set out in the hierarchical approach required by COSHH). Guidance on managing and controlling both deliberate exposure and incidental exposure for health care workers is given in later sections of this document. Guidance on incidental exposure for farm and abattoir workers involved in the slaughter and processing of cattle can be found in the general guidance document '*BSE (Bovine spongiform encephalopathy): Background and general occupational guidance'* and in the supplement '*Guidance for handling meat and bone meal material*'.

Legal classification of biological agents

2.6 The appropriate control measures for laboratory work with biological agents are determined largely by the Hazard Group classification of the agent. The EC Classification of Biological Agents established a list of biological agents as part of the Council Directive on the protection of workers from risks related to exposure to biological agents at work (2000/54/EC). Details can be found in the ACDP publication "Categorisation of biological agents according to hazard and categories of containment" and the 2000 supplement *[currently under review]*.

2.7 Classification of a biological agent is based on the risk of infection to a healthy worker using well-established criteria. In determining the appropriate hazard grouping of a biological agent, note is taken of the pathogenicity (disease producing capability) of the organism to man, the hazard to workers, the potential for transmission to the community and the seriousness of any illness that might result after taking into account the availability of prophylaxis or effective treatment. TSE agents, excluding scrapie and others not linked to BSE, are classified as Hazard Group (HG) 3 on the basis of these criteria. Part 3 of this document on laboratory containment and control measures provides further detail on classification of TSE agents.

General Principles of Control

2.8 For laboratories and animal rooms the appropriate containment level is derived from the hazard classification of the agent, or from what is suspected about the possible presence of an agent. COSHH requires that when working with an agent in a particular hazard group, the containment level selected should match the hazard group

of the agent. TSEs should normally be worked on in CL3 because they are classified as HG3 agents. (See paragraph 2.13 for advice about changing containment measures). Detailed guidance on control and containment measures in laboratories and animal rooms is given in Part 3 of this document.

2.9 When patients infected with a TSE agent are to be accommodated, for example on a hospital ward, the choice of controls and containment, as in other cases, should be on the basis of risk assessment. The level of risk should be the prime consideration. The controls selected should reflect the requirements outlined in COSHH with appropriate measures selected from Part II of Schedule 3 of COSHH. Detailed guidance on control and containment measures for TSE-infected humans is given in Part 4 of this document.

Risk Assessment

2.10 The Management of Health and Safety at Work Regulations (MHSWR) require all employers and self-employed people to assess the risks to their employees and others who may be affected by their work activity. More specifically COSHH requires assessment of the risks of work with substances hazardous to health. Where an assessment is carried out for the purposes of COSHH, or other more specific legislation, it does not have to be repeated for the purpose of MHSWR because the duties laid down in COSHH go beyond those in MHSWR and the more stringent requirements must be met. The risk assessment required by COSHH must be reviewed regularly and revised when conditions change, an incident occurs, a deficiency is noted or if, for any other reason, it is suspected that the assessment is no longer valid. It must include a review of all working procedures. For example, a review of procedural controls, arrangements for the safe disposal of waste, the potential for the dispersal of infectious material in the working environment and the contamination of equipment and apparatus.

2.11 The COSHH risk assessment for TSEs should consider:

- whether there is a deliberate intention to work with the agent, or if any exposure would be incidental to the work;
- the hazard group of the agent (see paragraph 2.7 above);
- the origin of the agent;
- the type of tissue handled (this will give an indication of the likely level of infectivity) (see Annex A);
- knowledge of expression of the agent in any experimental model and whether the work is likely to result in a high titre of infectivity;
- assessment of the type of task (*e.g.* concentration/propagation/purification); and
- the frequency of contact with the agents or materials likely to contain them;

- the possible routes of exposure including the potential for inoculation injury.

2.12 The local risk assessment for work involving propagation and concentration should be authorised by senior management.

Changing Containment Measures

2.13 All TSE agents should normally be worked on in Containment Level (CL) 3 conditions because they are HG3 agents. Scrapie, however, is not allocated to a hazard group as there is, to date, no evidence of transmission of disease to humans. Recent concern about BSE transmission from sheep has led to a debate on whether all scrapie strains should be handled at CL3. As this debate is ongoing, a precautionary approach should be adopted in which well characterised laboratory strains of scrapie should continue to be worked on at CL2, but extra precautions may be necessary for handling unidentified field isolates.

2.14 In some circumstances consideration may be given to changing the containment measures to reflect the likely exposure of workers to TSE agents in a particular circumstance. **Any decision to change the containment conditions should only be taken on the basis of a local risk assessment that takes into account:**

- **the type of work;**
- **the quantity of material;**
- **the likely infectivity to humans; and**
- **the procedures and equipment that will be used to propagate, concentrate or analyse the agent.**

2.15 Detailed guidance on the type of changes that could be made to the containment level is given in Part 3. If you are in any doubt about the basis for making changes to the containment measures you should consult HSE.

Local Safety Policies and Codes of Practice

2.16 The local health and safety policy sets out in general terms how management intend to develop and maintain a safe working environment. It should reference the ways in which the safe day-to-day working of the laboratory will be achieved and managed.

2.17 Specific information on the arrangements for working safely day-to-day can best be set out in local codes of practice. A guide to the main areas that should be covered is given in Infobox 1 below.

2.18 All employees must have a clear understanding of any identifiable risks to their health arising from work, and the actions to be taken in dealing with situations in which exposure may occur. Local codes of practice form part of this process of giving information on safe working, but thorough training and instruction on their day-to-day application is needed in order to make them work effectively. Employers have a responsibility to make the policy and codes freely accessible, either by putting

them on display or by individual issue. All staff, including all newcomers and temporary workers, must be made aware of them.

2.19 Employers have a duty to consult employees on health and safety matters. Further information and details of additional guidance can be found in the leaflet 'Consulting employees on health and safety: A guide to the law' (INDG232L).

INFOBOX 1. TOPICS TO BE COVERED IN A LOCAL CODE

- **Introduction:**
  state the reasons for having a code;
  refer to other relevant health and safety documents;
  detail the arrangements for making staff aware of the nature of the TSE agent to which they might be exposed, the possible source of infection and the containment (physical and procedural) measures to be used; and
  training and supervision arrangements for working in the laboratory.

- **General Procedures:**
  specify which staff (or grade of staff) are authorised to carry out particular procedures; and
  provide appropriate guidance for ancillary and maintenance staff, contractors and visitors.

- **Operation of Unit**
  detail start up procedures, operation of safety cabinet, ventilation controls, procedures for operating equipment, use of personal protective equipment and cleaning procedures.

- **Local Rules**
  these should cover the circumstances in which changed containment measures may be used, eg automated analysis of low risk specimens.

- **Waste**
  detail waste disposal policy and disinfection policy including cleaning of fragile laboratory equipment, eg automated analyser, and what to do in the event of spillage.

- **Staff Health**
  arrangements for reporting and recording incidents, including the name of the person to whom incidents should be reported.

- **Testing and Maintenance**
  arrangements for the maintenance and testing procedures on engineering controls to be carried out.

- **Emergency Procedures**
  procedures for dealing with accidents involving TSE agents including the name of the person to whom accidents should be reported.

List of workers exposed to TSE agents

2.20 Under certain circumstances COSHH requires employers to keep a list of employees who are exposed to HG3 or 4 agents. **The decision to keep a list depends on the local risk assessment.** For TSE agents a list is only required where employees deliberately work with the agent. For example:

- those involved in laboratory research work and veterinary clinical work with a TSE agent;
- staff performing invasive clinical procedures on patients suspected to be suffering from CJD of any type, particularly where there is a risk of exposure to central nervous tissue, eye tissue or other tissues known to contain CJD infectivity (see table on infectivity of tissues in Annex A1);
- laboratory staff handling tissue specimens from patients with CJD of any type, in either routine or specialist neuropathology laboratories; or
- staff undertaking post-mortem examinations of patients who have died of CJD of any type or where CJD of any type is suspected.

2.21 The routine clinical care of patients with CJD or a related disorder is unlikely to pose a significant risk of exposure to CJD of any type and staff working with such patients would not need to be included on such a list.

2.22 In cases of unintentional exposure, a list may be required if the risk assessment shows that there is a significant risk. The risk is deemed to be significant if more than basic hygiene measures are necessary to protect staff or if the control measures listed in COSHH are specifically applied. The list should be kept where there is a likelihood of exposure and not simply when there has been a known incident or accident, although it should also include details of these. Recording details of incidents or accidents on this list is not the same as the requirement to report certain diseases and accidents to HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR).

2.23 The information that should be recorded includes the type of work done and, where known, any specific exposure, accident or incident. Because of the long latency period of TSE agents and their serious long-term sequelae, the list must be kept for 40 years after the last known exposure. This list is in addition to the health record (which is required for the purposes of health surveillance under COSHH or MHSWR) and must be made available to any doctor appointed to carry out health surveillance, *e.g.* the occupational health physician. It must also be available to any employee who is specifically responsible for health and safety.

2.24 Each employee recorded on the list must have access to the information that relates to him or her personally. The list may be kept with the individual's occupational health record. Data protection requirements will apply to the information being held; see Infobox 2.

INFOBOX 2: THE DATA PROTECTION ACT 1998

The requirements of the Data Protection Act 1998 may apply to any records (computerised or manual) kept about individuals (such as employees) in connection with health and safety legislation, eg health surveillance records. These requirements may include informing people that certain information is held on them and granting them access to that information, should they request it. Guidance on the Act can be requested from the Office of the Data Protection Commissioner, Wycliffe house, Water lane, Wilmslow, Cheshire SK9 5AF (Tel. 01625 545745) or by e-mail at data@dataprotection.gov.uk. (See the website at www.dataprotection.gov.uk for more information.)

RIDDOR

2.25 RIDDOR requires some accidents and exposures to be notified to HSE. These include any infection reliably attributable to work with live or dead humans or animals, exposure to blood or body fluids or any potentially infected material derived from any of the above. Accidents or incidents, which result in or could result in the release or escape of a TSE agent, must also be reported under RIDDOR as a dangerous occurrence.

Health Surveillance

2.26 Where appropriate both MHSWR and COSHH Regulations require employees to be under suitable health surveillance. Under MHSWR health surveillance must be provided, as appropriate, with regard to the risks identified by the risk assessment. Under COSHH, health surveillance must be provided where:

- there is an identifiable disease or adverse health effect that may be related to exposure in the workplace;
- there is a reasonable likelihood that the disease or effect may occur under the particular conditions of work; or
- there are valid techniques for detecting indications of the disease or effect.

2.27 There are no valid techniques for detecting early indications of TSE disease at the present time. Health surveillance is therefore limited to setting up and maintaining individual health records for employees likely to be exposed to TSE agents. However, employers must remain aware to any new techniques that become available and adopt them as appropriate.

2.28 The health record is supplementary to the list of workers exposed to TSE agents (see paragraph 2.23). The minimum information that should be recorded is:

- personal details of the individual including full name (and maiden name for women if appropriate), date of birth, gender, permanent address and post code, national insurance number and the date when the present employment started;
- the type of work the employee does;
- records of accidents and incidents involving exposure to the TSE agent; and
- a historical record of jobs in the present employment which involve exposure to infectious or potentially infectious TSE material.

2.29 Further information on health surveillance can be found in Regulation 11(3) of the COSHH Approved Code of Practice.

References for Part 2

Legislation:

Health and Safety at Work etc Act 1974. SI1974/1439.
The Stationary Office 1974. ISBN 0 11 141439 X

Management of Health and Safety at Work Regulations (MHSWR) 1999.
SI1999/3242. The Stationary Office 1999. ISBN 0 11 0856252 2

Control of Substances Hazardous to Health (COSHH) Regulations 2002. SI2002/2677
The Stationary Office 2002. ISBN 0 11 042919 2

Genetically Modified Organisms (Contained Use) Regulations 2000. SI2000/2831.
The Stationary Office 2000. ISBN 0 11 018676 1

Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002.
SI2002/63 The Stationary Office 2002. ISBN 0 11 039273 6

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)
1995. SI1995/3163. The Stationary Office 1995. ISBN 01 1053 7523

The Carriage of Dangerous Goods (Classification, Packaging and Labelling)
Regulations 1994. SI1994/669. The Stationary Office 1994. ISBN 01 1043 6695

The Data Protection Act 1998.
The Stationary Office 1998. ISBN 0 10 542998 8

2000/54/EC. Protection of workers from risks related to exposure of biological agents at work (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC). OJ L262. 17.10.2000

Guidance:

A guide to the Health and Safety at Work etc Act 1974 (L1)
HSE Books 1990. ISBN 0 7176 0441 1 (A priced publication)

Successful health and safety management (HSG 65) 2nd ed.
HSE Books 1997. ISBN 0 7176 2034 4 (A priced publication)

COSHH: a brief guide to the regulations (INDG131 rev1)
HSE Books 2002. (Free as single copies)

Control of Substances Hazardous to Health (Fourth edition). The Control of Substances Hazardous to Health Regulations 2002. Approved Code of Practice and Guidance (L5)
HSE Books 2002. ISBN 0 7176 2534 6 (A priced publication)

Health Surveillance under COSHH: guidance for employers.
HSE Books 1990. ISBN 0 717604918. (A priced publication)

The management, design and operation of microbiological containment laboratories
HSE Books 1995. ISBN 0 7176 2034 4 (A priced publication)

5 steps to risk assessment (INDG163 rev1) HSE Books 1998. (Free as single copies)

A guide to the Genetically Modified Organisms (Contained Use) Regulations 2000
HSE Books 2000. ISBN 0 7176 1758 0 (A priced publication)

Contained use of genetically modified organisms (INDG86 rev2)
HSE Books 2001. ISBN 0 7176 1771 (Free as single copies)

Guide to the reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (L73)
HSE Books 1998. ISBN 0 7176 1012 8

Are you involved in the carriage of dangerous goods by road or rail? (INDG234)
HSE Books 2000. ISBN 0 7176 1676 2 (A free leaflet)

Approved Carriage List: Information approved for the carriage of dangerous goods by road and rail other than explosives and radioactive material (ACL) (L90)
HSE Books (Third ed) ISBN 0 7176 1681 9 (A priced publication)

European Agreement concerning the international carriage of dangerous goods by road (ADR)
The Stationary Office. ISBN 0 11 941712 X

Approved Vehicle Requirements. Carriage of Dangerous Goods by Road Regulations 1996 (AVR) (L89)
HSE Books (Second ed) ISBN 0 7176 1680 0

Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)
The Stationary Office 1998. ISBN 0 11 552032 5

The management, design and operation of microbiological containment laboratories.
HSE Books 2001. ISBN 0 7176 2034 4 (A priced publication)

BSE (Bovine Spongiform Encephalopathy): Background and general occupational guidance.
HSE Books 1996. ISBN 0 7176 1212 0 (A priced publication)

Supplement to “BSE (Bovine Spongiform Encephalopathy): Background and general occupational guidance” Guidance for handling meat and bone meal material.
HSE Books

Categorisation of biological agents according to hazard and categories of containment (Fourth ed) 1995.

HSE Books 1995. ISBN 0 7176 1038 1 (A priced publication)

Second supplement to "Categorisation of biological agents according to hazard and categories of containment" (MISC 208)
HSE Books 2000.

Consulting employees on health and safety: A guide to the law. (INDG 232)
HSE Books 1999. ISBN 0 71761650. (Available in priced packs or can be downloaded for free from www.hsebooks.co.uk)