



**NEW CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH
REGULATIONS (COSHH) (2002): WHAT THE AMENDMENTS TO
THE BIOLOGICAL AGENTS PROVISIONS MEAN FOR YOU**

COSHH 2002 came into force on 21 November 2002. You can buy the new edition of the Regulations and Approved Code of Practice (ACOP) (see Further Reading) by contacting HSE Books (at <http://www.hsebooks.co.uk> or on 01787 881165).

As COSHH was being updated to implement the Chemical Agents Directive (CAD), the Health and Safety Commission (HSC) also took the opportunity to update the biological agents provisions of COSHH. HSC did this because research showed that there was a lack of awareness of when exposure to biological agents has to be considered by employers, especially when their employees are not intentionally working with biological agents.

The main aim of the changes to the biological agents provisions in COSHH is: to make it clear to employers that they **do** have duties under COSHH to protect their workers against biological agents; and to clearly separate general duties relating to **all hazardous substances** from those only relevant to people working **intentionally** with biological agents. This has been achieved by moving general requirements from Schedule 3 (which detailed the duties relating to work with biological agents) into the main Regulations (eg assessment, prevention and control). Schedule 3 now contains the more specific requirements relating to biological agents (eg working with biological agents in laboratories, animal rooms and industrial processes, and notification requirements relating to biological agents).

There are other important changes to the biological agents provisions in COSHH that you need to consider. These include:

- introducing a more flexible, risk-based approach to selecting control measures;
- clarifying duties relating to notification of use and consignment of biological agents (see this edition of the Bulletin for further information);
- the capacity to locally reclassify agents as if performing a provisional classification;
- keeping the list of employees exposed to certain biological agents for 40 years;
- removing the need for HSE to inform Health Ministers about notification of Hazard Group (HG) 4 agents;
- a new Part V.

There have been quite a few changes to COSHH, which you should familiarise yourself with. If you have any questions about the changes, once you have considered the new Regulations and ACOP, contact the HSE Infoline on 08701 545500.

NEW COSHH REGULATIONS: GUIDANCE ON THE UPDATED NOTIFICATION REQUIREMENTS RELATED TO BIOLOGICAL AGENTS

These guidance notes relate to notification duties under COSHH. You may have similar duties under other legislation, for example the Specified Animal Pathogens Order, and you should ensure that you have complied with all relevant requirements.

If, however, you have already made a notification of the use of biological agents under the Genetically Modified Organisms (Contained Use) Regulations, then no further notification under COSHH is required.

General

What do I need to notify?

You need to notify:

- first use of biological agents in Hazard Groups 2, 3 or 4 at a particular premises;
- subsequent use of any of agent listed in Part V of Schedule 3 at a particular premises;
- consignment of biological agents in Hazard Group 4 from/to a premises.

When should I notify?

You should let HSE have a completed form at least 20 days in advance of any planned work. This time allows HSE to assess the information you have given and request further information if required. If you need to start work in less than 20 days, then you should contact HSE by phone in the first instance so they can agree on timescales before the form is sent in.

Where do I send the form?

The completed form should be returned:

COSHH Notifications
Room 443
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3QZ

If you complete the form electronically, this should be sent as a pdf file (with any relevant attachments) to Bioagents.Notifications@hse.gsi.gov.uk.

Definitions

What is first use?

This means the first time that deliberate work with a particular Hazard Group 2, 3 or 4 agent has ever been carried out at your premises since the duty to notify first came into force in COSHH 1994 on 16 January 1995. You may have carried out work with such agents before this date. If this is the case, under the law you were not actually working with the agents when the Regulations first came into force. So if you restart work with this agent now, you should notify us as though it were the first time you had used the agent, ie first use.

Deliberate work activities (eg work involving research, development, teaching or diagnostics) involve working with a Group 2, Group 3 or Group 4 biological agent or material containing such an agent.

Even if you obtain an agent, say just to lodge in a culture collection, you will need to maintain that collection. This is likely to involve work with the agent, eg growing the agent to check on viability and so you would need to notify.

What is subsequent use?

If you have made a first notification under COSHH in respect of any agent in Hazard Group 3 or 4 and certain Hazard Group 2 agents (listed in Part V to Schedule 3), and then decide to use a different agent from that in the original notification, you will need to notify us. In practice, this means if you work with a different Part V agent after COSHH 2002 comes into force to that which you were working with before that date, you need to notify this change under subsequent use.

What agents are in Part V?

All Hazard Group 3 and 4 agents (including those which you may have provisionally classified in these groups), as well as the following Hazard Group 2 agents:

- *Bordetella pertussis*;
- *Corynebacterium diphtheriae*;
- *Neisseria meningitidis*.

What if I am working with materials that contain biological agents?

Many types of diagnostic work, eg in haematology, immunology or clinical chemistry laboratories, will involve handling specimens etc which are likely to contain biological agents. As long as the work that is undertaken with such specimens does not require the **deliberate** propagation or concentration of the agents, then there is no need to notify either first use or subsequent use.

If, however, you provide a diagnostic service for a Hazard Group 4 agent(s), then you need to notify in advance of carrying this out for the first time.

What if the agent I want to work with doesn't appear on the Approved List of Biological Agents?

COSHH requires that if you work with an agent that does not have an approved classification, you must classify the agent yourself according to the criteria in Schedule 3. If the agent is classified as being in either Hazard Group 2, 3 or 4, then work with agent will need to be notified (or renotified, as appropriate).

Information to be provided

Who is the person responsible for health and safety?

This is not the health and safety advisor/officer or biological safety advisor/officer. The legal responsibility for health and safety rests primarily with the employer, but in practice the responsibility is delegated down the line management chain. You should give details of the local 'manager' who has responsibility for health and safety in the department etc where the work is to be carried out (see *The management, design and operation of microbiological containment laboratories* – see Further Reading).

How much information must I give about risk assessments and preventative and protective measures?

It is not sufficient to simply state that you are using an agent in HG3 and will be using Containment Level (CL)3 containment. Although this is not an approval system, HSE need sufficient information to demonstrate that you have identified hazards associated with the agent **in conjunction** with the work that is to be carried out. You should then be able to identify in what circumstances staff (and others) could be exposed to a source of infection during the work, ie the risk(s).

The measures that will be applied to prevent or control that risk may be standalone procedures, eg a local code of practice, or else they may be contained in standard operating procedures/protocols. Again, HSE need sufficient information to indicate the measures that will be used for the work that is to be carried out – these may vary according to particular activities being undertaken, although the work may constitute, for example one research project.

Transport

What should I notify?

You need to notify if you intend to transport a HG4 agent from your premises to another in the UK. You also need to notify if you are importing a HG4 agent into the UK from elsewhere.

You only have to notify if you are moving the HG4 agent itself, not if you are sending material containing, or thought to contain, the HG4 agent for:

- diagnostic purposes, eg a clinical specimen; or,
- disposal, eg a human or animal remains or contaminated material.

You don't need to notify if you are transporting a patient (human or animal) infected with a HG4 agent for the purposes of medical treatment. There is advice available on the transport of human patients contained in ACDP's guidance on the *Management and control of viral haemorrhagic fevers* and the DH guidance *Hendra virus and nipah virus management and control* (see Further Reading).

When should I notify?

You should let HSE have a completed form at least 30 days before any planned movement of the agent. This time allows HSE to assess the information you have given and request further information if required. If you need to transport the agent in less than 30 days, then you should contact HSE by phone in the first instance, so timescales can be agreed before the form is sent to HSE.

What packaging should I use?

Packages that are being sent by road or rail should comply with the requirements set out in the Carriage of Dangerous Goods (Classification, Packaging and Labelling) Regulations and Use of Transportable Pressure Receptacles Regulations and the accompanying *Approved requirements and test methods for the classification and packaging of dangerous goods for carriage* (see Further Reading).

A HG4 agent would be classified as Class 6.2 under the Regulations, as it is an infectious substance for the purposes of transport. It would be assigned to UN No 2814: Infectious substance affecting humans. The packaging would need to meet the requirements of Packaging Instruction 620, which consists of:

- inner packaging comprising:
 - leakproof primary receptacle(s);
 - a leakproof secondary packaging; and
 - other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple primary receptacles are placed in a single secondary packaging, they shall be individually wrapped, so as to prevent contact between them;

- an outer packaging of adequate strength for its capacity, mass and intended use. The smallest external diameter should be at least 100 mm.

Packages being sent by air should comply with the IATA Regulations - the packaging requirements are essentially similar. If you are notifying the importation of a HG4 agent from overseas, the person sending the package should have ensured that the IATA Regulations are complied with, but you should discuss this with them. Packages that have been packaged in accordance with the IATA Regulations are suitable for transport by road or rail.

Because of the special nature of the agents, transport of HG4 biological agents means that those carrying out the consignment have to comply with certain other requirements of the Carriage of Dangerous Goods Regulations, such as the appointment of dangerous goods safety advisors. Although the driver training requirements only apply to vehicles over 3.5 tonnes, drivers should still have sufficient training to enable them to carry out any relevant duties under the Regulations.

What arrangements should I make for the day of transport itself?

If you are transporting the agent by road, you need to ensure that:

- the package is accompanied by a competent person with knowledge of the biological agent and the appropriate action to take if there is an accident;
- the vehicle used for transport is equipped with suitable means for effective decontamination in the event of a spillage, eg protective clothing and gloves, disinfectant, absorbent materials and a container for contaminated waste. The details of the decontamination procedure should be included in the risk assessment for the consignment;
- a means of prompt communication to a second party will be available in the event of an incident, eg by a person following the carrier in a separate vehicle, or by use of a cellular telephone. This provides a back-up for decontamination in the event of an accident and continuing the journey, if the carrier vehicle can no longer be used;
- you inform the recipient of the package of the date, precise time of dispatch, and the route to be followed. They should then make sure they are available to receive the package and notify you of its safe arrival;
- your local police force and that of the recipient should be informed of the date and time of dispatch, and the route to be followed. If the route crosses the boundaries of other forces, then these too should be informed. The police should also be instructed that in the event of an

incident they should:

- not tamper with the package;
- notify you (if the person accompanying the package is unable to assist) and the recipient, who may be required to advise on the appropriate action to be taken; and
- notify HSE.

If you are transporting the agent by air, you should ensure that:

- the airport authority is notified as far as possible in advance and arrangements made for the movement of the consignment by liaison with other authorities where appropriate;
- if, on arrival at the airport, transportation is to continue by road, then the guidance given above applies;
- you notify the recipient of the date, time of despatch and flight details, ie flight number, route and time of arrival. As above, the recipient should then be available to receive the package and notify you of safe arrival;
- if you import the agent from another country, you should ensure that a suitable and sufficient risk assessment has been carried out and the all appropriate regulatory requirements are met (for example, export licence).

GUIDANCE UPDATES

Guidance under revision

Biological agents: Managing the risks

Work is continuing on this new guidance that will be replacing the existing ACDP categorisation guidance. Two focus group meetings with representatives from the human and animal healthcare sectors have provided

a useful steer in deciding the approach and content of the guidance. It is hoped that the revised guidance will be published later this year.

Guidance in preparation

Containment Level 4 guidance

Work is continuing on the preparation of this new guidance entitled *Biological agents: Managing the risks with Hazard Group 4 agents*. It is hoped that the guidance will be ready for publication later this year.

Infection at work: Are you at risk?

In addition to preparing guidance for the laboratory and healthcare sector (see above), ACDP are also preparing simple, generic guidance on controlling the risks of infection in the workplace. The nature of the risks is explained, along with guidance on risk assessment and appropriate controls. A final draft of this guidance will be considered by ACDP when they meet in March and it is hoped to publish the guidance later this year.

Other new and revised guidance

Transmissible spongiform encephalopathy agents (TSEs): Safe working and the prevention of infection

The Advisory Committee on Dangerous Pathogens (ACDP) and Spongiform Encephalopathy Advisory Committee (SEAC) joint working group (JWG) continues to drive forward revisions to the 1998 version of the TSE guidance.

Finalised sections of the guidance will be published on the Internet, as they are ready, not when the whole document has been revised. BAB will alert readers when sections are available, giving details of how to access them. The first 'tranche' of sections expected to be published are:

- Part 2 (Health and safety management of TSEs);
- Part 4 (Infection control of CJD and related disorders in the healthcare setting);
- Annex A (Distribution of infectivity in tissues and body fluids);
- Annex B (Diagnostic criteria);
- Annex E (Quarantining of surgical instruments); and,
- Annex H (After death).

It is also planned that the revised guidance will include:

- Part 1 (A general introduction and background);
- Part 3 (Laboratory containment and control measures);
- Annex C (Cleaning, decontamination and waste disposal);
- Annex D (Transport);
- Annex F (Endoscopes); and,
- Annex G (Specialised Equipment).

ADDITIONAL ADVICE ON THE MANAGEMENT OF EXPOSURE TO SIMIAN HERPES B VIRUS

This additional advice on the management of exposure to Simian Herpes B virus should be read in conjunction with the Advisory Committee on Dangerous Pathogens (ACDP) simian guidance *Working safely with simians: Management of infection risks* (see URL at the end of this section).

At the ACDP meeting of 11 September 2002, the Committee was asked to reconsider its advice on the prophylactic therapy for Simian Herpes B virus (B virus) infection following a monkey bite. This advice is set out in Annex 1 of the ACDP simian guidance. ACDP welcomed the opportunity to consider new developments in this area and to ensure that the procedures they recommended were consistent with what actually happens in the workplace.

Appendix 1 of the ACDP simian guidance considers the management of exposure to this virus. The guidance states that, unless the monkey is known to be B virus negative, the person injured by the monkey bite should start prophylactic acyclovir treatment as soon as possible after the incident. After debating this issue, ACDP did not feel that there was any new evidence to suggest the need to update their advice. However, they did think it was worth highlighting a number of key points that were raised in discussion. It was felt that these would be of interest to duty holders working with simians (eg in zoos and safari parks), as well as laboratory workers.

ACDP recognised that, in some laboratories (eg where specific pathogen-free simians are used) and in some wildlife parks, the status of simians is monitored routinely. Where current information indicates that a simian is not infected with B virus, then ACDP accepted that it may not be appropriate to start prophylactic treatment immediately. This is seen as an appropriate step given that there are some risks associated with the treatment, such as:

- early acyclovir will suppress virus replication and reduce antibody response, the markers required for an early, confirmed diagnosis;
- the prophylactic treatment would suppress B virus replication, but it is likely that unrecognised infection might rebound on stopping treatment;
- since B virus is a lifelong persistent infection, acyclovir treatment, once initiated to suppress infection, could not be stopped without the potential for virus reactivation and consequent life-threatening disease.

ACDP stressed that where this is any doubt relating to the infection status of a simian, prophylactic treatment should be given immediately. However, where there is strong evidence that a simian is not infected with B Virus, ACDP accepts that other approaches could be adopted to effectively manage the potential exposure.

You should consider the following points, among others relevant to the circumstances of your work with simians, when preparing your risk assessment:

- determine the risk of a monkey being infected with B virus, by identifying the monkey type involved, and the monkey colony location;
- review any screening results on the monkey concerned and request, if possible, a serum sample from the animal involved.

For all potential exposures to Simian Herpes B virus you should:

- request a serum sample from the patient as a baseline; and
- recommend that the patient is monitored clinically for 21 days for any unusual symptoms, such as headaches, fevers, unusual sensation or the appearance of lesions (blisters/vesicles) around the bite site.

As a result of the risk assessment and the circumstances of your employee's accident you can then:

- review the need for prophylaxis.

For further guidance please refer to the ACDP booklet *Working safely with simians: Management of infection risks*. This is no longer available in print from HSE books. However, an electronic copy of the guidance may be found on HSE's website at the following URL:

<http://www.hse.gov.uk/pubns/misc134.pdf>

LEGIONELLA SEMINAR

HSE invites you to find out more about:

- our new video on controlling legionella; looking at risk assessments, treatment and control, monitoring, and cleaning and disinfection;
- a new leaflet for residential accommodation providers;
- the results of our independent evaluation into the suitability of the new legionella ACOP and guidance (See Further Reading)

When?

- 23 May 2003, from 10.30 am.

Where?

- The Rose and Globe Room
Health and Safety Executive
2 Southwark Bridge
London SE1 9HS

Who would be interested?

- Dutyholders responsible for cooling towers, and hot and cold water systems.
- Residential accommodation providers – local authorities, universities, housing associations (including housing companies), charities, hostels, landlords in the private sector, managing agents, hoteliers, B&B owners, guest house owners, holiday camp owners, caravan and camping site owners (including fixed caravan sites).
- Anyone else who uses the legionella ACOP.

Why come along?

- The video provides an introduction to the control of legionella in water systems; explains your duties under health and safety law, guiding you through the ACOP and guidance. It focuses on cooling towers and hot and cold

water systems, explaining how the risks from exposure to legionella should be managed and controlled. The video is also accompanied by a series of checklists to allow you to audit the arrangements you have in place to control legionella.

- The leaflet will tell you, as a residential accommodation provider, about the important changes we have made to our ACOP, and the actions you need to take to control the risk of exposure to legionella in your premises.
- Our contractors will tell you about their work to find out what users think of the ACOP, the recommendations they have made to HSE and how we will be tackling these.
- You will have the opportunity to put questions to those involved about any aspects of the development and content of the video and leaflet, and the outcomes of the research.

Register to attend

- Due to limited places you will need to register to attend this event. The closing date for registration is 9 May 2003.
- To register, e-mail or phone Sarah Senior at:

e-mail: sarah.senior@hse.gsi.gov.uk

Tel: 020 7717 6266

When you register we would like to know the following information (to ensure we are reaching our target audience):

- the name of the organisation/company you represent;

- the size of your company;
- the role of your organisation, eg professional body, or company, eg dutyholder, consultant, designer;
- why you are interested in attending the seminar.

FURTHER READING

Current ACDP publications and other free and priced publications relating to working with biological agents may be obtained from HSE Books, the Department of Health or the Stationery Office (TSO) (details at the end of this Bulletin).

Approved requirements and test methods for the classification and packaging of dangerous goods for carriage. Carriage of Dangerous Goods (Classification, Packaging and Labelling) and Use of Transportable Pressure Receptacles Regulations 1996. Approved requirements L88 HSE Books 1996 ISBN 0 7176 1221 X

Control of substances hazardous to health. The Control of Substances Hazardous to Health Regulations 2002. Approved Code of Practice and guidance L5 (Fourth edition) HSE Books 2002 ISBN 0 7176 2534 6

Hendra virus and nipah virus management and control Department of Health 2000

Legionnaires' disease. The control of legionella bacteria in water systems. Approved Code of Practice and guidance L8 (Second edition) HSE Books 2000 ISBN 0 7176 1772 6

Management and control of viral haemorrhagic fevers: Summary of guidance from the Advisory Committee on Dangerous Pathogens Department of Health 1998

The management, design and operation of microbiological containment laboratories Guidance HSE Books 2001 ISBN 0 7176 2034 4

ADDRESSES FOR OBTAINING PUBLICATIONS

HSE Books, PO Box 1999, Sudbury, Suffolk CO10 2WA Tel: 01787 881165
Fax: 01787 881165 Website: <http://www.hsebooks.co.uk> (HSE priced publications are also available from bookshops)

Department of Health, PO Box 777, London SE1 6XH Tel: 08701 555455 Fax: 01623 724524 Website: <http://www.doh.gov/acdp/publications.htm>

The Stationery Office, PO Box 276, London SW8 5DT Tel: 0870 600 5522
Fax: 0870 6005533 Website: <http://www.tso.co.uk> (TSO publications are also available from bookshops)

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