

**COMMISSION DIRECTIVE (EU) 2019/1833**  
**of 24 October 2019**  
**amending Annexes I, III, V and VI to Directive 2000/54/EC of the European Parliament and of the Council as regards purely technical adjustments**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work <sup>(1)</sup>, and in particular Article 19 thereof,

Whereas:

- (1) Principle 10 of the European Pillar of Social Rights <sup>(2)</sup>, proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to a healthy, safe and well-adapted working environment. The workers' right to a high level of protection of their health and safety at work and to a working environment that is adapted to their professional needs and that enables them to prolong their participation in the labour market includes protection from exposure to biological agents at work.
- (2) The implementation of the directives related to the health and safety of workers at work, including Directive 2000/54/EC, was the subject of an *ex-post* evaluation, referred to as a REFIT evaluation. The evaluation looked at the directives' relevance, at research and at new scientific knowledge in the various fields concerned. The REFIT evaluation, referred to in the Commission Staff Working Document <sup>(3)</sup>, concludes, among other things, that the classified list of biological agents in Annex III to Directive 2000/54/EC needs to be amended in light of scientific and technical progress and that consistency with other relevant directives should be enhanced.
- (3) In its Communication 'Safer and Healthier Work for All — Modernisation of the EU Occupational Safety and Health Legislation and Policy' <sup>(4)</sup>, the Commission reiterated that while the REFIT evaluation of the Union's *acquis* on occupational health and safety confirmed that the legislation in this field is generally effective and fit-for-purpose, there is scope for updating outdated rules and ensuring better and broader protection, compliance and enforcement on the ground. The Commission emphasises the particular need to update the list of biological agents in Annex III to Directive 2000/54/EC.
- (4) Directive 2000/54/EC lays down rules to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to biological agents at work. Directive 2000/54/EC applies to activities in which workers are exposed, or are potentially exposed, to biological agents as a result of their work, and states the measures to be taken in the case of any activity likely to involve a risk of exposure to biological agents, to determine the nature, degree and duration of workers' exposure to biological agents.
- (5) Since the results of a risk assessment can show an unintended exposure to biological agents, there could be other work activities not included in Annex I to Directive 2000/54/EC that should also be taken into consideration. Therefore, the indicative list of activities set out in Annex I to Directive 2000/54/EC should be amended to include an introductory phrase in order to clarify the non-exhaustive nature of the list.

<sup>(1)</sup> OJ L 262, 17.10.2000, p. 21.

<sup>(2)</sup> European Pillar of Social Rights, November 2017,

[https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights\\_en](https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en)

<sup>(3)</sup> SWD(2017) 10 final.

<sup>(4)</sup> COM(2017) 12.

- (6) Annex III to Directive 2000/54/EC sets out the list of biological agents known to infect humans, classified according to their level of risk of infection. In line with introductory note 6 in that Annex, the list should be amended to take into account the latest state of knowledge as regards scientific development that have brought about significant changes since the list was last updated, particularly as regards the taxonomy, nomenclature, classification and characteristics of biological agents, and the existence of new biological agents.
- (7) Annexes V and VI to Directive 2000/54/EC lay down the containment measures and levels for laboratories, animal facilities and industry. Annexes V and VI should be amended and restructured in order to be aligned with and to take into account the containment and other protective measures included in Directive 2009/41/EC of the European Parliament and of the Council <sup>(5)</sup>.
- (8) In preparing the current update of Annexes I, III V and VI to Directive 2000/54/EC, consideration was given to the need to maintain the existing levels of protection for workers who are or who are potentially exposed to biological agents through their work, and to ensure that the amendments only take into account scientific developments in the area, requiring adjustments at the workplace that are merely technical in nature.
- (9) The Advisory Committee for Safety and Health at Work was consulted on the measures resulting from the adoption of the Commission's Communication 'Safer and Healthier Work for All — Modernisation of the EU Occupational Safety and Health Legislation and Policy' that are required to keep the Union's occupational health and safety legislation effective and fit-for-purpose.
- (10) In its 'Opinion on the Modernisation of Six OSH Directives to Ensure Healthier and Safer Work for All' <sup>(6)</sup>, adopted on 6 December 2017, the Advisory Committee for Safety and Health at Work recommends that Directive 2000/54/EC should be amended to enhance its relevance and effectiveness.
- (11) In a subsequent 'Opinion on technical updates to the annexes of the Biological Agents Directive (2000/54/EC)' <sup>(7)</sup>, adopted on 31 May 2018, the Advisory Committee for Safety and Health at Work recommends that specific updates should be made to Annex I, III, V and VI, reflecting the latest technological and scientific developments in the field.
- (12) In preparing the current update of Annexes I, III, V and VI to Directive 2000/54/EC, the Commission was assisted by experts representing Member States, who provided technical and scientific support.
- (13) In accordance with the Joint Political Declaration on explanatory documents <sup>(8)</sup>, adopted by the Member States and the Commission on 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments.
- (14) The measures provided for in this Directive are in accordance with the opinion of the Committee established by Article 17 of Council Directive 89/391/EEC <sup>(9)</sup>,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

Annexes I, III, V and VI to Directive 2000/54/EC are replaced by the text in the Annex to this Directive.

<sup>(5)</sup> Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75).

<sup>(6)</sup> Advisory Committee for Safety and Health at Work Doc. 1718/2017.

<sup>(7)</sup> Advisory Committee for Safety and Health at Work Doc. 434/18.

<sup>(8)</sup> OJ C 369, 17.12.2011, p. 14.

<sup>(9)</sup> Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

*Article 2*

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 November 2021 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

*Article 3*

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

*Article 4*

This Directive is addressed to the Member States.

Done at Brussels, 24 October 2019.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX

- (1) Annex I to Directive 2000/54/EC is replaced by the following:

## 'ANNEX I

**INDICATIVE LIST OF ACTIVITIES****(Article 4(2))***Preliminary note*

Where the result of the risk assessment, carried out in accordance with Article 3 and Article 4(2) of this Directive, shows an unintentional exposure to biological agents, there may be other work activities, not included in this Annex, which should be considered.

1. Work in food production plants.
  2. Work in agriculture.
  3. Work activities where there is contact with animals and/or products of animal origin.
  4. Work in healthcare, including isolation and post-mortem units.
  5. Work in clinical, veterinary and diagnostic laboratories, excluding diagnostic microbiological laboratories.
  6. Work in refuse disposal plants.
  7. Work in sewage purification installations.'
- (2) Annex III to Directive 2000/54/EC is replaced by the following:

## 'ANNEX III

**COMMUNITY CLASSIFICATION****Article 2, second paragraph, and Article 18**

## INTRODUCTORY NOTES

1. In line with the scope of the Directive, only agents which are known to infect humans are to be included in the classified list.

Where appropriate, indicators are given of the toxic and allergic potential of these agents.

Animal and plant pathogens which are known not to affect man are excluded.

In drawing up this list of classified biological agents consideration has not been given to genetically modified micro-organisms.

2. The list of classified agents is based on the effect of those agents on healthy workers.

No specific account is taken of particular effects on those whose susceptibility may be affected for one or other reason such as pre-existing disease, medication, compromised immunity, pregnancy or breast feeding.

Additional risk to such workers should be considered as part of the risk assessment required by the Directive.

In certain industrial processes, certain laboratory work or certain work with animals involving actual or potential exposure to biological agents of groups 3 or 4, any technical precautions taken must comply with Article 16 of the Directive.

3. Biological agents which have not been classified for inclusion in groups 2 to 4 of the list are not implicitly classified in group 1.

For genera where more than one species is known to be pathogenic to man, the list will include those species which are known to be the most frequently responsible for diseases, together with a more general reference to the fact that other species of the same genus may affect health.

When a whole genus is mentioned in the classified list of biological agents, it is implicit that the species and strains known to be non-pathogenic are excluded.

4. Where a strain is attenuated or has lost known virulence genes, then the containment required by the classification of its parent strain need not necessarily apply, subject to assessment appropriate for risk in the workplace.

This is the case, for example, when such a strain is to be used as a product or part of a product for prophylactic or therapeutic purposes.

5. The nomenclature of classified agents used to establish this list reflects and is in conformity with the latest international agreements of the taxonomy and nomenclature of agents at the time the list was prepared.

6. The list of classified biological agents reflects the state of knowledge at the time that it was devised.

It will be updated as soon as it no longer reflects the latest state of knowledge.

7. Member States are to ensure that all viruses which have already been isolated in humans and which have not been assessed and allocated in this Annex are classified in group 2 as a minimum, except where Member States have proof that they are unlikely to cause disease in humans.

8. Certain biological agents classified in group 3 which are indicated in the appended list by two asterisks (\*\*), may present a limited risk of infection for workers because they are not normally infectious by the airborne route.

Member States shall assess the containment measures to be applied to such agents, taking account of the nature of specific activities in question and of the quantity of the agent involved, with a view to determining whether, in particular circumstances, some of these measures may be dispensed with.

9. The requirements as to containment consequent on the classification of parasites apply only to stages in the life cycle of the parasite in which it is liable to be infectious to humans at the workplace.

10. This list also gives a separate indication in cases where the biological agents are likely to cause allergic or toxic reactions, where an effective vaccine is available, or where it is advisable to keep a list of exposed workers for more than 10 years.

These indications are shown by the following letters:

A: Possible allergic effects

D: List of workers exposed to this biological agent to be kept for more than 10 years after the end of last known exposure

T: Toxin production

V: Effective vaccine available and registered within the EU

The application of preventive vaccination should take account of the code of practice given in Annex VII.

**BACTERIA****and similar organisms**

NB: For biological agents appearing on this list, the entry of the whole genus with the addition of "spp." refers to other species belonging to this genus that have not specifically been included in the list, but which are known pathogens in humans. See introductory note 3 for further details.

Biological agent	Classification	Notes
<i>Actinomadura madurae</i>	W	
<i>Actinomadura pelletieri</i>	2	
<i>Actinomyces gerencseriae</i>	2	
<i>Actinomyces israelii</i>	2	
<i>Actinomyces</i> spp.	2	
<i>Aggregatibacter actinomycetemcomitans</i> ( <i>Actinobacillus actinomycetemcomitans</i> )	2	
<i>Anaplasma</i> spp.	2	
<i>Arcanobacterium haemolyticum</i> ( <i>Corynebacterium haemolyticum</i> )	2	
<i>Arcobacter butzleri</i>	2	
<i>Bacillus anthracis</i>	3	T
<i>Bacteroides fragilis</i>	2	
<i>Bacteroides</i> spp.	2	
<i>Bartonella bacilliformis</i>	2	
<i>Bartonella quintana</i> ( <i>Rochalimaea quintana</i> )	2	
<i>Bartonella</i> ( <i>Rochalimaea</i> ) spp.	2	
<i>Bordetella bronchiseptica</i>	2	
<i>Bordetella parapertussis</i>	2	
<i>Bordetella pertussis</i>	2	T, V
<i>Bordetella</i> spp.	2	
<i>Borrelia burgdorferi</i>	2	
<i>Borrelia duttonii</i>	2	
<i>Borrelia recurrentis</i>	2	
<i>Borrelia</i> spp.	2	
<i>Brachyspira</i> spp.	2	
<i>Brucella abortus</i>	3	
<i>Brucella canis</i>	3	
<i>Brucella inopinata</i>	3	
<i>Brucella melitensis</i>	3	
<i>Brucella suis</i>	3	
<i>Burkholderia cepacia</i>	2	
<i>Burkholderia mallei</i> ( <i>Pseudomonas mallei</i> )	3	
<i>Burkholderia pseudomallei</i> ( <i>Pseudomonas pseudomallei</i> )	3	D

Biological agent	Classification	Notes
<i>Campylobacter fetus</i> subsp. <i>fetus</i>	2	
<i>Campylobacter fetus</i> subsp. <i>venerealis</i>	2	
<i>Campylobacter jejuni</i> subsp. <i>doylei</i>	2	
<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	2	
<i>Campylobacter</i> spp.	2	
<i>Cardiobacterium hominis</i>	2	
<i>Cardiobacterium valvarum</i>	2	
<i>Chlamydia abortus</i> ( <i>Chlamydophila abortus</i> )	2	
<i>Chlamydia caviae</i> ( <i>Chlamydophila caviae</i> )	2	
<i>Chlamydia felis</i> ( <i>Chlamydophila felis</i> )	2	
<i>Chlamydia pneumoniae</i> ( <i>Chlamydophila pneumoniae</i> )	2	
<i>Chlamydia psittaci</i> ( <i>Chlamydophila psittaci</i> ) (avian strains)	3	
<i>Chlamydia psittaci</i> ( <i>Chlamydophila psittaci</i> ) (other strains)	2	
<i>Chlamydia trachomatis</i> ( <i>Chlamydophila trachomatis</i> )	2	
<i>Clostridium botulinum</i>	2	T
<i>Clostridium difficile</i>	2	T
<i>Clostridium perfringens</i>	2	T
<i>Clostridium tetani</i>	2	T, V
<i>Clostridium</i> spp.	2	
<i>Corynebacterium diphtheriae</i>	2	T, V
<i>Corynebacterium minutissimum</i>	2	
<i>Corynebacterium pseudotuberculosis</i>	2	T
<i>Corynebacterium ulcerans</i>	2	T
<i>Corynebacterium</i> spp.	2	
<i>Coxiella burnetii</i>	3	
<i>Edwardsiella tarda</i>	2	
<i>Ehrlichia</i> spp.	2	
<i>Eikenella corrodens</i>	2	
<i>Elizabethkingia meningoseptica</i> ( <i>Flavobacterium meningosepticum</i> )	2	
<i>Enterobacter aerogenes</i> ( <i>Klebsiella mobilis</i> )	2	
<i>Enterobacter cloacae</i> subsp. <i>cloacae</i> ( <i>Enterobacter cloacae</i> )	2	
<i>Enterobacter</i> spp.	2	
<i>Enterococcus</i> spp.	2	
<i>Erysipelothrix rhusiopathiae</i>	2	
<i>Escherichia coli</i> (with the exception of non-pathogenic strains)	2	
<i>Escherichia coli</i> , verocytotoxigenic strains (e.g. O157:H7 or O103)	3 (*)	T
<i>Fluoribacter bozemanii</i> ( <i>Legionella</i> )	2	
<i>Francisella hispaniensis</i>	2	

Biological agent	Classification	Notes
<i>Francisella tularensis</i> subsp. <i>holarctica</i>	2	
<i>Francisella tularensis</i> subsp. <i>mediasiatica</i>	2	
<i>Francisella tularensis</i> subsp. <i>novicida</i>	2	
<i>Francisella tularensis</i> subsp. <i>tularensis</i>	3	
<i>Fusobacterium necrophorum</i> subsp. <i>funduliforme</i>	2	
<i>Fusobacterium necrophorum</i> subsp. <i>necrophorum</i>	2	
<i>Gardnerella vaginalis</i>	2	
<i>Haemophilus ducreyi</i>	2	
<i>Haemophilus influenzae</i>	2	V
<i>Haemophilus</i> spp.	2	
<i>Helicobacter pylori</i>	2	
<i>Helicobacter</i> spp.	2	
<i>Klebsiella oxytoca</i>	2	
<i>Klebsiella pneumoniae</i> subsp. <i>ozaenae</i>	2	
<i>Klebsiella pneumoniae</i> subsp. <i>pneumoniae</i>	2	
<i>Klebsiella pneumoniae</i> subsp. <i>rhinoscleromatis</i>	2	
<i>Klebsiella</i> spp.	2	
<i>Legionella pneumophila</i> subsp. <i>fraseri</i>	2	
<i>Legionella pneumophila</i> subsp. <i>pascaliei</i>	2	
<i>Legionella pneumophila</i> subsp. <i>pneumophila</i>	2	
<i>Legionella</i> spp.	2	
<i>Leptospira interrogans</i> (all serovars)	2	
<i>Leptospira interrogans</i> spp.	2	
<i>Listeria monocytogenes</i>	2	
<i>Listeria ivanovii</i> subsp. <i>ivanovii</i>	2	
<i>Listeria ivanovii</i> subsp. <i>londoniensis</i>	2	
<i>Morganella morganii</i> subsp. <i>morganii</i> ( <i>Proteus morganii</i> )	2	
<i>Morganella morganii</i> subsp. <i>sibonii</i>	2	
<i>Mycobacterium abscessus</i> subsp. <i>abscessus</i>	2	
<i>Mycobacterium africanum</i>	3	V
<i>Mycobacterium avium</i> subsp. <i>avium</i> ( <i>Mycobacterium avium</i> )	2	
<i>Mycobacterium avium</i> subsp. <i>paratuberculosis</i> ( <i>Mycobacterium paratuberculosis</i> )	2	
<i>Mycobacterium avium</i> subsp. <i>silvaticum</i>	2	
<i>Mycobacterium bovis</i>	3	V
<i>Mycobacterium caprae</i> ( <i>Mycobacterium tuberculosis</i> subsp. <i>caprae</i> )	3	
<i>Mycobacterium chelonae</i>	2	
<i>Mycobacterium chimaera</i>	2	
<i>Mycobacterium fortuitum</i>	2	



Biological agent	Classification	Notes
<i>Mycobacterium intracellulare</i>	2	
<i>Mycobacterium kansasii</i>	2	
<i>Mycobacterium leprae</i>	3	
<i>Mycobacterium malmoeense</i>	2	
<i>Mycobacterium marinum</i>	2	
<i>Mycobacterium microti</i>	3 (*)	
<i>Mycobacterium pinnipedii</i>	3	
<i>Mycobacterium scrofulaceum</i>	2	
<i>Mycobacterium simiae</i>	2	
<i>Mycobacterium szulgai</i>	2	
<i>Mycobacterium tuberculosis</i>	3	V
<i>Mycobacterium ulcerans</i>	3 (*)	
<i>Mycobacterium xenopi</i>	2	
<i>Mycoplasma hominis</i>	2	
<i>Mycoplasma pneumoniae</i>	2	
<i>Mycoplasma</i> spp.	2	
<i>Neisseria gonorrhoeae</i>	2	
<i>Neisseria meningitidis</i>	2	V
<i>Neorickettsia sennetsu</i> ( <i>Rickettsia sennetsu</i> , <i>Ehrlichia sennetsu</i> )	2	
<i>Nocardia asteroides</i>	2	
<i>Nocardia brasiliensis</i>	2	
<i>Nocardia farcinica</i>	2	
<i>Nocardia nova</i>	2	
<i>Nocardia otitidiscaviarum</i>	2	
<i>Nocardia</i> spp.	2	
<i>Orientia tsutsugamushi</i> ( <i>Rickettsia tsutsugamushi</i> )	3	
<i>Pasteurella multocida</i> subsp. <i>gallicida</i> ( <i>Pasteurella gallicida</i> )	2	
<i>Pasteurella multocida</i> subsp. <i>multocida</i>	2	
<i>Pasteurella multocida</i> subsp. <i>septica</i>	2	
<i>Pasteurella</i> spp.	2	
<i>Peptostreptococcus anaerobius</i>	2	
<i>Plesiomonas shigelloides</i>	2	
<i>Porphyromonas</i> spp.	2	
<i>Prevotella</i> spp.	2	
<i>Proteus mirabilis</i>	2	
<i>Proteus penneri</i>	2	
<i>Proteus vulgaris</i>	2	
<i>Providencia alcalifaciens</i> ( <i>Proteus inconstans</i> )	2	

Biological agent	Classification	Notes
<i>Providencia rettgeri</i> ( <i>Proteus rettgeri</i> )	2	
<i>Providencia</i> spp.	2	
<i>Pseudomonas aeruginosa</i>	2	T
<i>Rhodococcus hoagii</i> ( <i>Corynebacterium equii</i> )	2	
<i>Rickettsia africae</i>	3	
<i>Rickettsia akari</i>	3 (*)	
<i>Rickettsia australis</i>	3	
<i>Rickettsia canadensis</i>	2	
<i>Rickettsia conorii</i>	3	
<i>Rickettsia heilongjiangensis</i>	3 (*)	
<i>Rickettsia japonica</i>	3	
<i>Rickettsia montanensis</i>	2	
<i>Rickettsia typhi</i>	3	
<i>Rickettsia prowazekii</i>	3	
<i>Rickettsia rickettsii</i>	3	
<i>Rickettsia sibirica</i>	3	
<i>Rickettsia</i> spp.	2	
<i>Salmonella enterica</i> ( <i>choleraesuis</i> ) subsp. <i>arizonae</i>	2	
<i>Salmonella</i> Enteritidis	2	
<i>Salmonella</i> Paratyphi A, B, C	2	V
<i>Salmonella</i> Typhi	3 (*)	V
<i>Salmonella</i> Typhimurium	2	
<i>Salmonella</i> (other serovars)	2	
<i>Shigella boydii</i>	2	
<i>Shigella dysenteriae</i> (Type 1)	3 (*)	T
<i>Shigella dysenteriae</i> , other than Type 1	2	
<i>Shigella flexneri</i>	2	
<i>Shigella sonnei</i>	2	
<i>Staphylococcus aureus</i>	2	T
<i>Streptobacillus moniliformis</i>	2	
<i>Streptococcus agalactiae</i>	2	
<i>Streptococcus dysgalactiae</i> subsp. <i>equisimilis</i>	2	
<i>Streptococcus pneumoniae</i>	2	T, V
<i>Streptococcus pyogenes</i>	2	T
<i>Streptococcus suis</i>	2	
<i>Streptococcus</i> spp.	2	
<i>Treponema carateum</i>	2	
<i>Treponema pallidum</i>	2	

Biological agent	Classification	Notes
<i>Treponema pertenuae</i>	2	
<i>Treponema</i> spp.	2	
<i>Trueperella pyogenes</i>	2	
<i>Ureaplasma parvum</i>	2	
<i>Ureaplasma urealyticum</i>	2	
<i>Vibrio cholerae</i> (including El Tor)	2	T, V
<i>Vibrio parahaemolyticus</i> ( <i>Benecka parahaemolytica</i> )	2	
<i>Vibrio</i> spp.	2	
<i>Yersinia enterocolitica</i> subsp. <i>enterolitica</i>	2	
<i>Yersinia enterocolitica</i> subsp. <i>palaearctica</i>	2	
<i>Yersinia pestis</i>	3	
<i>Yersinia pseudotuberculosis</i>	2	
<i>Yersinia</i> spp.	2	

(\*) See paragraph 8 of the introductory notes.

#### VIRUSES (\*)

(\*) See paragraph 7 of the introductory notes.

NB: Viruses have been listed according to their order (O), family (F) and genus (G).

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Bunyavirales (O)		
<i>Hantaviridae</i> (F)		
Orthohantavirus (G)		
Andes orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])	3	
Bayou orthohantavirus	3	
Black Creek Canal orthohantavirus	3	
Cano Delgadito orthohantavirus	3	
Choclo orthohantavirus	3	
Dobrava-Belgrade orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
El Moro Canyon orthohantavirus	3	
Hantaan orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
Laguna Negra orthohantavirus	3	
Prospect Hill orthohantavirus	2	
Puumala orthohantavirus (Hantavirus species causing Nephropathia Epidemica [NE])	2	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Seoul orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
Sin Nombre orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])	3	
Other hantaviruses known to be pathogenic	2	
<i>Nairoviridae</i> (F)		
Orthonairovirus (G)		
Crimean-Congo haemorrhagic fever orthonairovirus	4	
Dugbe orthonairovirus	2	
Hazara orthonairovirus	2	
Nairobi sheep disease orthonairovirus	2	
Other nairoviruses known to be pathogenic	2	
<i>Peribunyaviridae</i> (F)		
Orthobunyavirus (G)		
Bunyamwera orthobunyavirus (Germiston virus)	2	
California encephalitis orthobunyavirus	2	
Oropouche orthobunyavirus	3	
Other orthobunyaviruses known to be pathogenic	2	
<i>Phenuiviridae</i> (F)		
Phlebovirus (G)		
Bhanja phlebovirus	2	
Punta Toro phlebovirus	2	
Rift Valley fever phlebovirus	3	
Sandfly fever Naples phlebovirus (Toscana Virus)	2	
SFTS phlebovirus (Severe Fever with Thrombocytopenia Syndrome-Virus)	3	
Other phleboviruses known to be pathogenic	2	
Herpesvirales (O)		
<i>Herpesviridae</i> (F)		
Cytomegalovirus (G)		
Human betaherpesvirus 5 (Cytomegalovirus)	2	
Lymphocryptovirus (G)		
Human gammaherpesvirus 4 (Epstein-Barr virus)	2	
Rhadinoovirus (G)		
Human gammaherpesvirus 8	2	D
Roseolovirus (G)		
Human betaherpesvirus 6A (Human B-lymphotropic virus)	2	
Human betaherpesvirus 6B	2	
Human betaherpesvirus 7	2	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Simplexvirus (G)		
Macacine alphaherpesvirus 1 (Herpesvirus simiae, Herpes B virus)	3	
Human alphaherpesvirus 1 (Human herpesvirus 1, Herpes simplex virus type 1)	2	
Human alphaherpesvirus 2 (Human herpesvirus 2, Herpes simplex virus type 2)	2	
Varicellovirus (G)		
Human alphaherpesvirus 3 (Herpesvirus varicella-zoster)	2	V
Mononegavirales (O)		
<i>Filoviridae</i> (F)		
Ebola virus (G)	4	
Marburg virus (G)		
Marburg marburgvirus	4	
<i>Paramyxoviridae</i> (F)		
Avulavirus (G)		
Newcastle disease virus	2	
Henipavirus (G)		
Hendra henipavirus	4	
Nipah henipavirus	4	
Morbillivirus (G)		
Measles morbillivirus	2	V
Respirovirus (G)		
Human respirovirus 1 (Parainfluenza virus 1)	2	
Human respirovirus 3 (Parainfluenza virus 3)	2	
Rubulavirus (G)		
Mumps rubulavirus	2	V
Human rubulavirus 2 (Parainfluenza virus 2)	2	
Human rubulavirus 4 (Parainfluenza virus 4)	2	
<i>Pneumoviridae</i> (F)		
Metapneumovirus (G)		
Orthopneumovirus (G)		
Human orthopneumovirus (Respiratory syncytial virus)	2	
<i>Rhabdoviridae</i> (F)		
Lyssavirus (G)		
Australian bat lyssavirus	3 (**)	V
Duvenhage lyssavirus	3 (**)	V
European bat lyssavirus 1	3 (**)	V
European bat lyssavirus 2	3 (**)	V

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Lagos bat lyssavirus	3 (**)	
Mokola lyssavirus	3	
Rabies lyssavirus	3 (**)	V
Vesiculovirus (G)		
Vesicular stomatitis virus, Alagoas vesiculovirus	2	
Vesicular stomatitis virus, Indiana vesiculovirus	2	
Vesicular stomatitis virus, New Jersey vesiculovirus	2	
Piry vesiculovirus (Piry virus)	2	
Nidovirales (O)		
<i>Coronaviridae</i> (F)		
Betacoronavirus (G)		
Severe acute respiratory syndrome-related coronavirus (SARS-virus)	3	
Middle East respiratory syndrome coronavirus (MERS-virus)	3	
Other <i>Coronaviridae</i> known to be pathogenic	2	
Picornavirales (O)		
<i>Picornaviridae</i> (F)		
Cardiovirus (G)		
Saffold virus	2	
Cosavirus (G)		
Cosavirus A	2	
Enterovirus (G)		
Enterovirus A	2	
Enterovirus B	2	
Enterovirus C	2	
Enterovirus D, Human Enterovirus type 70 (Acute haemorrhagic conjunctivitis virus)	2	
Rhinoviruses	2	
Poliovirus, type 1 and 3	2	V
Poliovirus, type 2 <sup>(1)</sup>	3	V
Hepatovirus (G)		
Hepatovirus A (Hepatitis A virus, Human Enterovirus type 72)	2	V
Kobuvirus (G)		
Aichivirus A (Aichi virus 1)	2	
Parechovirus (G)		
Parechoviruses A	2	
Parechoviruses B (Ljungan virus)	2	
Other <i>Picornaviridae</i> known to be pathogenic	2	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Unassigned (O)		
<i>Adenoviridae</i> (F)	2	
<i>Astroviridae</i> (F)	2	
<i>Arenaviridae</i> (F)		
Mammarenavirus (G)		
Brazilian mammarenavirus	4	
Chapare mammarenavirus	4	
Flexal mammarenavirus	3	
Guanarito mammarenavirus	4	
Junín mammarenavirus	4	
Lassa mammarenavirus	4	
Lujó mammarenavirus	4	
Lymphocytic choriomeningitis mammarenavirus, neurotropic strains	2	
Lymphocytic choriomeningitis mammarenavirus (other strains)	2	
Machupo mammarenavirus	4	
Mobala mammarenavirus	2	
Mopeia mammarenavirus	2	
Tacaribe mammarenavirus	2	
Whitewater Arroyo mammarenavirus	3	
<i>Caliciviridae</i> (F)		
Norovirus (G)		
Norovirus (Norwalk virus)	2	
Other <i>Caliciviridae</i> known to be pathogenic	2	
<i>Hepadnaviridae</i> (F)		
Orthohepadnavirus (G)		
Hepatitis B virus	3 (**)	V, D
<i>Hepeviridae</i> (F)		
Orthohepevirus (G)		
Orthohepevirus A (Hepatitis E virus)	2	
<i>Flaviviridae</i> (F)		
Flavivirus (G)		
Dengue virus	3	
Japanese encephalitis virus	3	V
Kyasanur Forest disease virus	3	V
Louping ill virus	3 (**)	
Murray Valley encephalitis virus (Australia encephalitis virus)	3	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
Omsk haemorrhagic fever virus	3	
Powassan virus	3	
Rocio virus	3	
St. Louis encephalitis virus	3	
Tick-borne encephalitis virus		
Absettarov virus	3	
Hanzalova virus	3	
Hypr virus	3	
Kumlinge virus	3	
Negishi virus	3	
Russian spring-summer encephalitis (a)	3	V
Tick-borne encephalitis virus Central European subtype	3 (**)	V
Tick-borne encephalitis virus Far Eastern Subtype	3	
Tick-borne encephalitis virus Siberian subtype	3	V
Wesselsbron virus	3 (**)	
West Nile fever virus	3	
Yellow fever virus	3	V
Zika virus	2	
Other flaviviruses known to be pathogenic	2	
Hepacivirus (G)		
Hepacivirus C (Hepatitis C virus)	3 (**)	D
<i>Orthomyxoviridae</i> (F)		
Gammainfluenzavirus (G)		
Influenza C virus	2	V (e)
Influenzavirus A (G)		
Highly Pathogenic Avian Influenza Viruses HPAIV (H5), e.g. H5N1	3	
Highly Pathogenic Avian Influenza Viruses HPAIV (H7), e.g. H7N7, H7N9	3	
Influenza A virus	2	V (e)
Influenza A virus A/New York/1/18 (H1N1) (Spanish flu 1918)	3	
Influenza A virus A/Singapore/1/57 (H2N2)	3	
Low Pathogenic Avian Influenza Virus (LPAI) H7N9	3	
Influenzavirus B (G)		
Influenza B virus	2	V (e)
Thogoto virus (G)		
Dhori virus (Tick-borne <i>orthomyxoviridae</i> : Dhori)	2	
Thogoto virus (Tick-borne <i>orthomyxoviridae</i> : Thogoto)	2	



Biological agent (virus species or indicated taxonomy order)	Classification	Notes
<i>Papillomaviridae</i> (F)	2	D <sup>(d)</sup>
<i>Parvoviridae</i> (F)		
Erythroparvovirus (G)		
Primate erythroparvovirus 1 (Human parvovirus, B 19 virus)	2	
<i>Polyomaviridae</i> (F)		
Betapolyomavirus (G)		
Human polyomavirus 1 (BK virus)	2	D <sup>(d)</sup>
Human polyomavirus 2 (JC virus)	2	D <sup>(d)</sup>
<i>Poxviridae</i> (F)		
Molluscipoxvirus (G)		
Molluscum contagiosum virus	2	
Orthopoxvirus (G)		
Cowpox virus	2	
Monkeypox virus	3	V
Vaccinia virus (incl. Buffalopox virus <sup>(e)</sup> , Elephantpox virus <sup>(f)</sup> , Rabbitpox virus <sup>(g)</sup> )	2	
Variola (major and minor) virus	4	V
Parapoxvirus (G)		
Orf virus	2	
Pseudocowpox virus (Milkers' node virus, parapoxvirus bovis)	2	
Yatapoxvirus (G)		
Tanapox virus	2	
Yaba monkey tumor virus	2	
<i>Reoviridae</i> (F)		
Seadornavirus (G)		
Banna virus	2	
Coltivirus (G)	2	
Rotaviruses (G)	2	
Orbivirus (G)	2	
<i>Retroviridae</i> (F)		
Deltaretrovirus (G)		
Primate T-lymphotropic virus 1 (Human T-cell lymphotropic virus, type 1)	3 (**)	D
Primate T-lymphotropic virus 2 (Human T-cell lymphotropic virus, type 2)	3 (**)	D
Lentivirus (G)		
Human immunodeficiency virus 1	3 (**)	D
Human immunodeficiency virus 2	3 (**)	D
Simian Immunodeficiency Virus (SIV) <sup>(h)</sup>	2	

Biological agent (virus species or indicated taxonomy order)	Classification	Notes
<i>Togaviridae</i> (F)		
Alphavirus (G)		
Cabassouvirus	3	
Eastern equine encephalomyelitis virus	3	V
Bebaru virus	2	
Chikungunya virus	3 (**)	
Everglades virus	3 (**)	
Mayaro virus	3	
Mucambo virus	3 (**)	
Ndumu virus	3 (**)	
O'nyong-nyong virus	2	
Ross River virus	2	
Semliki Forest virus	2	
Sindbis virus	2	
Tonate virus	3 (**)	
Venezuelan equine encephalomyelitis virus	3	V
Western equine encephalomyelitis virus	3	V
Other alphaviruses known to be pathogenic	2	
Rubivirus (G)		
Rubella virus	2	V
<i>Unassigned</i> (F)		
Deltavirus (G)		
Hepatitis delta virus <sup>(b)</sup>	2	V, D

(\*) See paragraph 7 of the introductory notes.

(<sup>1</sup>) Classification according to WHO Global Action Plan to minimize poliovirus facility-associated risk after type-specific eradication of wild polioviruses and sequential cessation of oral polio vaccine use.

(\*\*) See paragraph 8 of the introductory notes.

(<sup>2</sup>) Tick-borne encephalitis.

(<sup>3</sup>) Hepatitis delta virus is pathogenic in workers only in the presence of simultaneous or secondary infection caused by hepatitis B virus. Vaccination against hepatitis B virus will therefore protect workers who are not affected by hepatitis B virus against hepatitis delta virus.

(<sup>4</sup>) Only for types A and B.

(<sup>5</sup>) Recommended for work involving direct contact with these agents.

(<sup>6</sup>) Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.

(<sup>7</sup>) Variant of cowpox virus.

(<sup>8</sup>) Variant of Vaccinia.

(<sup>9</sup>) At present there is no evidence of disease in humans caused by the other retroviruses of simian origin. As a precaution containment level 3 is recommended for work with them.

## PRION DISEASE AGENTS

Biological agent	Classification	Notes
Agent of Creutzfeldt-Jakob disease	3 (*)	D (e)
Variant Agent of Creutzfeldt-Jakob disease	3 (*)	D (e)
Agent of Bovine Spongiform Encephalopathy (BSE) and other related animal TSEs	3 (*)	D (e)
Agent of Gerstmann-Sträussler-Scheinker syndrome	3 (*)	D (e)
Agent of Kuru	3 (*)	D (e)
Agent of Scrapie	2	

(\*) See paragraph 8 of the introductory notes.

(e) Recommended for work involving direct contact with these agents.

## PARASITES

NB: For biological agents appearing on this list, the entry of the whole genus with the addition of “spp.” refers to other species belonging to this genus that have not specifically been included in the list, but which are known pathogens in humans. See introductory note 3 for further details.

Biological agent	Classification	Notes
<i>Acanthamoeba castellani</i>	2	
<i>Ancylostoma duodenale</i>	2	
<i>Angiostrongylus cantonensis</i>	2	
<i>Angiostrongylus costaricensis</i>	2	
<i>Anisakis simplex</i>	2	A
<i>Ascaris lumbricoides</i>	2	A
<i>Ascaris suum</i>	2	A
<i>Babesia divergens</i>	2	
<i>Babesia microti</i>	2	
<i>Balamuthia mandrillaris</i>	3	
<i>Balantidium coli</i>	2	
<i>Brugia malayi</i>	2	
<i>Brugia pahangi</i>	2	
<i>Brugia timori</i>	2	
<i>Capillaria philippinensis</i>	2	
<i>Capillaria</i> spp.	2	
<i>Clonorchis sinensis</i> ( <i>Opisthorchis sinensis</i> )	2	
<i>Clonorchis viverrini</i> ( <i>Opisthorchis viverrini</i> )	2	
<i>Cryptosporidium hominis</i>	2	
<i>Cryptosporidium parvum</i>	2	
<i>Cyclospora cayatanensis</i>	2	
<i>Dicrocoelium dentriticum</i>	2	

Biological agent	Classification	Notes
<i>Dipetalonema streptocerca</i>	2	
<i>Diphyllobothrium latum</i>	2	
<i>Dracunculus medinensis</i>	2	
<i>Echinococcus granulosus</i>	3 (*)	
<i>Echinococcus multilocularis</i>	3 (*)	
<i>Echinococcus oligarthrus</i>	3 (*)	
<i>Echinococcus vogeli</i>	3 (*)	
<i>Entamoeba histolytica</i>	2	
<i>Enterobius vermicularis</i>	2	
<i>Enterocytozoon bieneusi</i>	2	
<i>Fasciola gigantica</i>	2	
<i>Fasciola hepatica</i>	2	
<i>Fasciolopsis buski</i>	2	
<i>Giardia lamblia</i> ( <i>Giardia duodenalis</i> , <i>Giardia intestinalis</i> )	2	
<i>Heterophyes</i> spp.	2	
<i>Hymenolepis diminuta</i>	2	
<i>Hymenolepis nana</i>	2	
<i>Leishmania aethiopica</i>	2	
<i>Leishmania braziliensis</i>	3 (*)	
<i>Leishmania donovani</i>	3 (*)	
<i>Leishmania guyanensis</i> ( <i>Viannia guyanensis</i> )	3 (*)	
<i>Leishmania infantum</i> ( <i>Leishmania chagasi</i> )	3 (*)	
<i>Leishmania major</i>	2	
<i>Leishmania mexicana</i>	2	
<i>Leishmania panamensis</i> ( <i>Viannia panamensis</i> )	3 (*)	
<i>Leishmania peruviana</i>	2	
<i>Leishmania tropica</i>	2	
<i>Leishmania</i> spp.	2	
<i>Loa loa</i>	2	
<i>Mansonella ozzardi</i>	2	
<i>Mansonella perstans</i>	2	
<i>Mansonella streptocerca</i>	2	
<i>Metagonimus</i> spp.	2	
<i>Naegleria fowleri</i>	3	
<i>Necator americanus</i>	2	
<i>Onchocerca volvulus</i>	2	
<i>Opisthorchis felineus</i>	2	

Biological agent	Classification	Notes
<i>Opisthorchis</i> spp.	2	
<i>Paragonimus westermani</i>	2	
<i>Paragonimus</i> spp.	2	
<i>Plasmodium falciparum</i>	3 (*)	
<i>Plasmodium knowlesi</i>	3 (*)	
<i>Plasmodium</i> spp. (human and simian)	2	
<i>Sarcocystis suis hominis</i>	2	
<i>Schistosoma haematobium</i>	2	
<i>Schistosoma intercalatum</i>	2	
<i>Schistosoma japonicum</i>	2	
<i>Schistosoma mansoni</i>	2	
<i>Schistosoma mekongi</i>	2	
<i>Strongyloides stercoralis</i>	2	
<i>Strongyloides</i> spp.	2	
<i>Taenia saginata</i>	2	
<i>Taenia solium</i>	3 (*)	
<i>Toxocara canis</i>	2	
<i>Toxocara cati</i>	2	
<i>Toxoplasma gondii</i>	2	
<i>Trichinella nativa</i>	2	
<i>Trichinella nelsoni</i>	2	
<i>Trichinella pseudospiralis</i>	2	
<i>Trichinella spiralis</i>	2	
<i>Trichomonas vaginalis</i>	2	
<i>Trichostrongylus orientalis</i>	2	
<i>Trichostrongylus</i> spp.	2	
<i>Trichuris trichiura</i>	2	
<i>Trypanosoma brucei brucei</i>	2	
<i>Trypanosoma brucei gambiense</i>	2	
<i>Trypanosoma brucei rhodesiense</i>	3 (*)	
<i>Trypanosoma cruzi</i>	3 (*)	
<i>Wuchereria bancrofti</i>	2	

(\*) See paragraph 8 of the introductory notes.

## FUNGI

NB: For biological agents appearing on this list, the entry of the whole genus with the addition of "spp." refers to other species belonging to this genus that have not specifically been included in the list, but which are known pathogens in humans. See introductory note 3 for further details.

Biological agent	Classification	Notes
<i>Aspergillus flavus</i>	2	A
<i>Aspergillus fumigatus</i>	2	A
<i>Aspergillus</i> spp.	2	
<i>Blastomyces dermatitidis</i> ( <i>Ajellomyces dermatitidis</i> )	3	
<i>Blastomyces gilchristii</i>	3	
<i>Candida albicans</i>	2	A
<i>Candida dubliniensis</i>	2	
<i>Candida glabrata</i>	2	
<i>Candida parapsilosis</i>	2	
<i>Candida tropicalis</i>	2	
<i>Cladophialophora bantiana</i> ( <i>Xylohypha bantiana</i> , <i>Cladosporium bantianum</i> , <i>trichoides</i> )	3	
<i>Cladophialophora modesta</i>	3	
<i>Cladophialophora</i> spp.	2	
<i>Coccidioides immitis</i>	3	A
<i>Coccidioides posadasii</i>	3	A
<i>Cryptococcus gattii</i> ( <i>Filobasidiella neoformans</i> var. <i>bacillispora</i> )	2	A
<i>Cryptococcus neoformans</i> ( <i>Filobasidiella neoformans</i> var. <i>neoformans</i> )	2	A
<i>Emmonsia parva</i> var. <i>parva</i>	2	
<i>Emmonsia parva</i> var. <i>crescens</i>	2	
<i>Epidermophyton floccosum</i>	2	A
<i>Epidermophyton</i> spp.	2	
<i>Fonsecaea pedrosoi</i>	2	
<i>Histoplasma capsulatum</i>	3	
<i>Histoplasma capsulatum</i> var. <i>farciminosum</i>	3	
<i>Histoplasma duboisii</i>	3	
<i>Madurella grisea</i>	2	
<i>Madurella mycetomatis</i>	2	
<i>Microsporium</i> spp.	2	A
<i>Nannizzia</i> spp.	2	
<i>Neotestudina rosatii</i>	2	
<i>Paracoccidioides brasiliensis</i>	3	A
<i>Paracoccidioides lutzii</i>	3	
<i>Paraphyton</i> spp.	2	
<i>Rhinocladiella mackenziei</i>	3	

Biological agent	Classification	Notes
<i>Scedosporium apiospermum</i>	2	
<i>Scedosporium prolificans (inflatum)</i>	2	
<i>Sporothrix schenckii</i>	2	
<i>Talaromyces marneffei (Penicillium marneffei)</i>	2	A
<i>Trichophyton rubrum</i>	2	A
<i>Trichophyton tonsurans</i>	2	A
<i>Trichophyton</i> spp.	2'	

(3) Annex V to Directive 2000/54/EC is replaced by the following:

‘ANNEX V

**INDICATIONS CONCERNING CONTAINMENT MEASURES AND CONTAINMENT LEVELS**

**(Articles 15(3) and 16(1)(a) and (b))**

*Preliminary note*

The measures contained in this Annex shall be applied according to the nature of the activities, the assessment of risk to workers, and the nature of the biological agent concerned.

In the table, “Recommended” means that the measures should in principle be applied, unless the results of the assessment referred to in Article 3(2) indicate otherwise.

A. Containment measures	B. Containment levels		
	2	3	4
<b>Workplace</b>			
1. The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
2. The workplace is to be sealable to permit fumigation	No	Recommended	Yes
<b>Facilities</b>			
3. Infected material including any animal is to be handled in a safety cabinet or isolation or other suitable containment	Where appropriate	Yes, where infection is by airborne route	Yes
<b>Equipment</b>			
4. Input air and extract air to the workplace are to be filtered using (HEPA (!)) or likewise	No	Yes, on extract air	Yes, on input and extract air
5. The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
6. Surfaces impervious to water and easy to clean	Yes, for bench and floor	Yes, for bench, floor and other surfaces determined by risk assessment	Yes, for bench, walls, floor and ceiling

A. Containment measures	B. Containment levels		
	2	3	4
7. Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
<b>System of work</b>			
8. Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock <sup>(2)</sup>
9. Efficient vector control, for example rodents and insects	Recommended	Yes	Yes
10. Specified disinfection procedures	Yes	Yes	Yes
11. Safe storage of a biological agent	Yes	Yes	Yes, secure storage
12. Personnel should shower before leaving the contained area	No	Recommended	Recommended
<b>Waste</b>			
13. Validated inactivation process for the safe disposal of animal carcasses	Recommended	Yes, on or off site	Yes, on site
<b>Other measures</b>			
14. A laboratory is to contain its own equipment	No	Recommended	Yes
15. An observation window, or, alternative, is to be present, so that occupants can be seen	Recommended	Recommended	Yes'

<sup>(1)</sup> HEPA: High efficiency particulate air

<sup>(2)</sup> Airlock: Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

(4) Annex VI to Directive 2000/54/EC is replaced by the following:

‘ANNEX VI

**CONTAINMENT FOR INDUSTRIAL PROCESSES**

**(Article 4(1) and Article 16(2)(a))**

*Preliminary note*

In the table, “Recommended” means that the measures should in principle be applied, unless the results of the assessment referred to in Article 3(2) indicate otherwise.

Group 1 biological agents

For work with group 1 biological agents including live attenuated vaccines, the principles of good occupational safety and hygiene should be observed.

Groups 2, 3 and 4 biological agents

It may be appropriate to select and combine containment requirements from different categories below on the basis of a risk assessment related to any particular process or part of a process.



A. Containment measures	B. Containment levels		
	2	3	4
<b>General</b>			
1. Viable organisms should be handled in a system which physically separates the process from the environment	Yes	Yes	Yes
2. Exhaust gases from the closed system should be treated so as to:	Minimise release	Prevent release	Prevent release
3. Sample collection, addition of materials to a closed system and transfer of viable organisms to another closed system, should be performed so as to:	Minimise release	Prevent release	Prevent release
4. Bulk culture fluids should not be removed from the closed system unless the viable organisms have been:	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimise release	Prevent release	Prevent release
6. The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Recommended	Yes
7. The controlled area should be sealable to permit fumigation	No	Recommended	Yes
<b>Facilities</b>			
8. Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
<b>Equipment</b>			
9. Input air and extract air to the controlled area should be HEPA (1) filtered	No	Recommended	Yes
10. The controlled area should be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
11. The controlled area should be adequately ventilated to minimise air contamination	Recommended	Recommended	Yes
<b>System of work</b>			
12. Closed systems (2) should be located within a controlled area	Recommended	Recommended	Yes, and purpose-built
13. Biohazard signs should be posted	Recommended	Yes	Yes
14. Access should be restricted to nominated personnel only	Recommended	Yes	Yes, via an airlock (3)

A. Containment measures	B. Containment levels		
	2	3	4
15. Personnel should shower before leaving the controlled area	No	Recommended	Yes
16. Personnel should wear protective clothing	Yes, work clothing	Yes	Yes, complete change
Waste			
17. Effluent from sinks and showers should be collected and inactivated before release	No	Recommended	Yes
18. Effluent treatment before final discharge	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means'

(<sup>1</sup>) HEPA: High efficiency particulate air

(<sup>2</sup>) Closed system: A system that physically separates the process from the environment (e.g. incubator vats, tanks, etc.).

(<sup>3</sup>) Airlock: Entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.