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 (seventh individual directive within the meaning of Article 16(1) of Directive 89/391/EEC)

# [F1ANNEX I

# INDICATIVE LIST OF ACTIVITIES (Article 4(2))

### **Textual Amendments**

**F1** Substituted by 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.

### 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.]

#### ANNEX II

BIOHAZARD SIGN (Article 6(2)(e))



## [F1ANNEX III

**COMMUNITY CLASSIFICATIONArticle 2, second paragraph, and Article 18** INTRODUCTORY NOTES

Status: EU Directives are being published on this site to aid cross referencing from UK legislation. After IP completion day (31 December 2020 11pm) no further amendments will be applied to this version.

In line with the scope of the Directive, only agents which are known to infect humans 1. 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.

# BACTERIM 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
Actinomadura madurae	W	
Actinomadura pelletieri	2	
Actinomyces gerencseriae	2	
Actinomyces israelii	2	
Actinomyces spp.	2	
Aggregatibacter actinomycetemcomitans (Actinobacillus actinomycetemcomitans)	2	
Anaplasma spp.	2	
Arcanobacterium haemolyticum (Corynebacterium haenolyticum)	2	
Arcobacter butzleri	2	
a See paragraph 8 of the introductor	ry notes.	1

Bacillus anthracis	3	T
Bacteroides fragilis	2	
Bacteroides spp.	2	
Bartonella bacilliformis	2	
Bartonella quintana (Rochalimaea quintana)	2	
Bartonella (Rochalimaea) spp.	2	
Bordetella bronchiseptica	2	
Bordetella parapertussis	2	
Bordetella pertussis	2	T, V
Bordetella spp.	2	
Borrelia burgdorferi	2	
Borrelia duttonii	2	
Borrelia recurrentis	2	
Borrelia spp.	2	
Brachyspira spp.	2	
Brucella abortus	3	
Brucella canis	3	
Brucella inopinata	3	
Brucella melitensis	3	
Brucella suis	3	
Burkholderia cepacia	2	
Burkholderia mallei (Pseudomonas mallei)	3	
Burkholderia pseudomallei (Pseudomonas pseudomallei)	3	D
Campylobacter fetus subsp. fetus	2	
Campylobacter fetus subsp. venerealis	2	
Campylobacter jejuni subsp. doylei	2	
Campylobacter jejuni subsp. jejuni	2	
Campylobacter spp.	2	
a See paragraph 8 of the introductory	notes.	

Cardiobacterium hominis	2	
Cardiobacterium valvarum	2	
Chlamydia abortus (Chlamydophila abortus)	2	
Chlamydia caviae (Chlamydophila caviae)	2	
Chlamydia felis (Chlamydophila felis)	2	
Chlamydia pneumoniae (Chlamydophila pneumoniae)	2	
Chlamydia psittaci (Chlamydophila psittaci) (avian strains)	3	
Chlamydia psittaci (Chlamydophila psittaci) (other strains)	2	
Chlamydia trachomatis (Chlamydophila trachomatis)	2	
Clostridium botulinum	2	Т
Clostridium difficile	2	T
Clostridium perfringens	2	T
Clostridium tetani	2	T, V
Clostridium spp.	2	
Corynebacterium diphtheriae	2	T, V
Corynebacterium minutissimum	2	
Corynebacterium pseudotuberculosis	2	Т
Corynebacterium ulcerans	2	T
Corynebacterium spp.	2	
Coxiella burnetii	3	
Edwardsiella tarda	2	
Ehrlichia spp.	2	
Eikenella corrodens	2	
Elizabethkingia meningoseptica (Flavobacterium meningosepticum)	2	
a See paragraph 8 of the introductory notes.		

Enterobacter aerogenes (Klebsiella mobilis)	2	
Enterobacter cloacae subsp. cloacae (Enterobacter cloacae)	2	
Enterobacter spp.	2	
Enterococcus spp.	2	
Erysipelothrix rhusiopathiae	2	
Escherichia coli (with the exception of non-pathogenic strains)	2	
Escherichia coli, verocytotoxigenic strains (e.g. O157:H7 or O103)	3ª	Т
Fluoribacter bozemanae (Legionella)	2	
Francisella hispaniensis	2	
Francisella tularensis subsp. holarctica	2	
Francisella tularensis subsp. mediasiatica	2	
Francisella tularensis subsp. novicida	2	
Francisella tularensis subsp. tularensis	3	
Fusobacterium necrophorum subsp. funduliforme	2	
Fusobacterium necrophorum subsp. necrophorum	2	
Gardnerella vaginalis	2	
Haemophilus ducreyi	2	
Haemophilus influenzae	2	V
Haemophilus spp.	2	
Helicobacter pylori	2	
Helicobacter spp.	2	
Klebsiella oxytoca	2	
Klebsiella pneumoniae subsp. ozaenae	2	
a See paragraph 8 of the introductory notes.		

Klebsiella pneumoniae subsp. pneumoniae	2	
Klebsiella pneumoniae subsp. rhinoscleromatis	2	
Klebsiella spp.	2	
Legionella pneumophila subsp. fraseri	2	
Legionella pneumophila subsp. pascullei	2	
Legionella pneumophila subsp. pneumophila	2	
Legionella spp.	2	
Leptospira interrogans (all serovars)	2	
Leptospira interrogans spp.	2	
Listeria monocytogenes	2	
Listeria ivanovii subsp. ivanovii	2	
Listeria invanovii subsp. londoniensis	2	
Morganella morganii subsp. morganii (Proteus morganii)	2	
Morganella morganii subsp. sibonii	2	
Mycobacterium abscessus subsp. abscessus	2	
Mycobacterium africanum	3	V
Mycobacterium avium subsp. avium (Mycobacterium avium)	2	
Mycobacterium avium subsp. paratuberculosis (Mycobacterium paratuberculosis)	2	
Mycobacterium avium subsp. silvaticum	2	
Mycobacterium bovis	3	V
Mycobacterium caprae (Mycobacterium tuberculosis subsp. caprae)	3	
a See paragraph 8 of the introductory	notes.	

Mycobacterium chelonae	2	
Mycobacterium chimaera	2	
Mycobacterium fortuitum	2	
Mycobacterium intracellulare	2	
Mycobacterium kansasii	2	
Mycobacterium leprae	3	
Mycobacterium malmoense	2	
Mycobacterium marinum	2	
Mycobacterium microti	3ª	
Mycobacterium pinnipedii	3	
Mycobacterium scrofulaceum	2	
Mycobacterium simiae	2	
Mycobacterium szulgai	2	
Mycobacterium tuberculosis	3	V
Mycobacterium ulcerans	3ª	
Mycobacterium xenopi	2	
Mycoplasma hominis	2	
Mycoplasma pneumoniae	2	
Mycoplasma spp.	2	
Neisseria gonorrhoeae	2	
Neisseria meningitidis	2	V
Neorickettsia sennetsu (Rickettsia sennetsu, Ehrlichia sennetsu)	2	
Nocardia asteroides	2	
Nocardia brasiliensis	2	
Nocardia farcinica	2	
Nocardia nova	2	
Nocardia otitidiscaviarum	2	
Nocardia spp.	2	
Orientia tsutsugamushi (Rickettsia tsutsugamushi)	3	
Pasteurella multocida subsp. gallicida (Pasteurella gallicida)	2	
a See paragraph 8 of the introductory	notes.	

Pasteurella multocida subsp. multocida	2	
Pasteurella multocida subsp. septica	2	
Pasteurella spp.	2	
Peptostreptococcus anaerobius	2	
Plesiomonas shigelloides	2	
Porphyromonas spp.	2	
Prevotella spp.	2	
Proteus mirabilis	2	
Proteus penneri	2	
Proteus vulgaris	2	
Providencia alcalifaciens (Proteus inconstans)	2	
Providencia rettgeri (Proteus rettgeri)	2	
Providencia spp.	2	
Pseudomonas aeruginosa	2	T
Rhodococcus hoagii (Corynebacterium equii)	2	
Rickettsia africae	3	
Rickettsia akari	3ª	
Rickettsia australis	3	
Rickettsia canadensis	2	
Rickettsia conorii	3	
Rickettsia heilongjiangensis	3ª	
Rickettsia japonica	3	
Rickettsia montanensis	2	
Rickettsia typhi	3	
Rickettsia prowazekii	3	
Rickettsia rickettsii	3	
Rickettsia sibirica	3	
Rickettsia spp.	2	
a See paragraph 8 of the introductory	notes	1

Salmonella enterica (choleraesuis) subsp. arizonae	2	
Salmonella Enteritidis	2	
Salmonella Paratyphi A, B, C	2	V
Salmonella Typhi	3ª	V
Salmonella Typhimurium	2	
Salmonella (other serovars)	2	
Shigella boydii	2	
Shigella dysenteriae (Type 1)	3ª	T
Shigella dysenteriae, other than Type 1	2	
Shigella flexneri	2	
Shigella sonnei	2	
Staphylococcus aureus	2	T
Streptobacillus moniliformis	2	
Streptococcus agalactiae	2	
Streptococcus dysgalactiae subsp. equisimilis	2	
Streptococcus pneumoniae	2	T, V
Streptococcus pyogenes	2	T
Streptococcus suis	2	
Streptococcus spp.	2	
Treponema carateum	2	
Treponema pallidum	2	
Treponema pertenue	2	
Treponema spp.	2	
Trueperella pyogenes	2	
Ureaplasma parvum	2	
Ureaplasma urealyticum	2	
Vibrio cholerae (including El Tor)	2	T, V
Vibrio parahaemolyticus (Benecka parahaemolytica)	2	
Vibrio spp.	2	
a See paragraph 8 of the introductory	notes.	

Yersinia enterocolitica subsp. enterolitica	2	
Yersinia enterocolitica subsp. palearctica	2	
Yersinia pestis	3	
Yersinia pseudotuberculosis	2	
Yersinia spp.	2	

a 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)		
Hantaviridae (F)		
Orthohantavirus (G)		
Andes orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])	3	
Bayou orthohantavirus	3	
Black Creek Canal orthohantavirus	3	

- **a** See paragraph 7 of the introductory notes.
- b 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.
- c See paragraph 8 of the introductory notes.
- d Tick-borne encephalitis.
- e 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.
- f Only for types A and B.
- g Recommended for work involving direct contact with these agents.
- h Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
- i Variant of cowpox virus.
- i Variant of Vaccinia.
- **k** 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.

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	
Seoul orthohantavirus (Hantavirus species causing Haemorrhagic Fever with Renal Syndrome [HFRS])	3	
Sin Nombre orthohantavirus (Hantavirus species causing Hantavirus Pulmonary Syndrome [HPS])	3	

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Other hantaviruses known to be pathogenic	2	
Nairoviridae (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	
Peribunyaviridae (F)		
Orthobunyavirus (G)		
Bunyamwera orthobunyavirus (Germiston virus)	2	
California encephalitis orthobunyavirus	2	
Oropouche orthobunyavirus	3	
Other orthobunyaviruses known to be pathogenic	2	
Phenuiviridae (F)		
Phlebovirus (G)		
Bhanja phlebovirus	2	
a See paragraph 7 of the introductory	notes.	

- b 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.
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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)		
Herpesviridae (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	
6 1.5 64 1 4		

- **a** See paragraph 7 of the introductory notes.
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- k 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.

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- See paragraph 7 of the introductory notes.
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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	
Pneumoviridae (F)		
Metapneumovirus (G)		
Orthopneumovirus (G)		
Human orthopneumovirus (Respiratory syncytial virus)	2	
Rhabdoviridae (F)		
Lyssavirus (G)		
Australian bat lyssavirus	3°	V
Duvenhage lyssavirus	3°	V
European bat lyssavirus 1	3°	V
European bat lyssavirus 2	3°	V
Lagos bat lyssavirus	3°	

- See paragraph 7 of the introductory notes.
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- j Variant of Vaccinia.
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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)		
Coronaviridae (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)		
Picornaviridae (F)		
Cardiovirus (G)		
Saffold virus	2	

- **a** See paragraph 7 of the introductory notes.
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	T	
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>b</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	

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- See paragraph 8 of the introductory notes. c
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- j Variant of Vaccinia.
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Unassigned (O)		
Adenoviridae (F)	2	
Astroviridae (F)	2	
Arenaviridae (F)		
Mammarenavirus (G)		
Brazilian mammarenavirus	4	
Chapare mammarenavirus	4	
Flexal mammarenavirus	3	
Guanarito mammarenavirus	4	
Junín mammarenavirus	4	
Lassa mammarenavirus	4	
Lujo 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	
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- a See paragraph 7 of the introductory notes.
- **b** 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.
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- j Variant of Vaccinia.
- **k** 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.

Whitewater Arroyo mammarenavirus  Caliciviridae (F)  Norovirus (G)  Norovirus (Norwalk virus)  Other Caliciviridae known to be pathogenic  Hepadnaviridae (F)  Orthohepadnavirus (G)  Hepatitis B virus  Hepeviridae (F)  Orthohepevirus (G)  Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F)  Flavivirus (G)  Dengue virus  Japanese encephalitis virus  Kyasanur Forest disease virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever virus  Omsk haemorrhagic fever virus			
Norovirus (G)  Norovirus (Norwalk virus)  Other Caliciviridae known to be pathogenic  Hepadnaviridae (F)  Orthohepadnavirus (G)  Hepatitis B virus  Gorthohepevirus (G)  Orthohepevirus (G)  Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F)  Flaviviridae (F)  Flavivirus (G)  Dengue virus  Japanese encephalitis virus  Kyasanur Forest disease virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  Other Caliciviridae known to be pathogenic and part of the pathogenic and patho		3	
Norovirus (Norwalk virus)  Other Caliciviridae known to be pathogenic  Hepadnaviridae (F)  Orthohepadnavirus (G)  Hepatitis B virus  Separate V, D  Hepeviridae (F)  Orthohepevirus (G)  Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F)  Flaviviridae (F)  Dengue virus  Japanese encephalitis virus  Kyasanur Forest disease virus  Louping ill virus  Omsk haemorrhagic fever  Othohepevirus A (Hepatitis E virus)  V  V  V  Omsk haemorrhagic fever	Caliciviridae (F)		
Other Caliciviridae known to be pathogenic  Hepadnaviridae (F)  Orthohepadnavirus (G)  Hepatitis B virus  Hepeviridae (F)  Orthohepevirus (G)  Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F)  Flaviviridae (F)  Flavivirus (G)  Dengue virus  Japanese encephalitis virus  Kyasanur Forest disease virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  Orthohepevirus A (Hepatitis 2  E virus)  V  V  V  Omsk haemorrhagic fever  3	Norovirus (G)		
be pathogenic  Hepadnaviridae (F)  Orthohepadnavirus (G)  Hepatitis B virus  Begin in the provided of the patitis B virus  Orthohepevirus (G)  Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F)  Flavivirus (G)  Dengue virus  Japanese encephalitis virus  Kyasanur Forest disease virus  Louping ill virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  Orthohepevirus A (Hepatitis 2  V, D  V V  V V  V V  V V  V V  Omsk haemorrhagic fever  3	Norovirus (Norwalk virus)	2	
Orthohepadnavirus (G)  Hepatitis B virus  3° V, D  Hepeviridae (F)  Orthohepevirus (G)  Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F)  Flavivirus (G)  Dengue virus  3  Japanese encephalitis virus  Kyasanur Forest disease virus  V  Kyasanur Forest disease virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  V, D  V, D  V   V   V   V		2	
Hepatitis B virus 3° V, D  Hepeviridae (F)  Orthohepevirus (G)  Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F)  Flavivirus (G)  Dengue virus 3  Japanese encephalitis virus 3  Kyasanur Forest disease virus 3  Louping ill virus 3°  Murray Valley encephalitis virus 3  Murray Valley encephalitis virus 3  Omsk haemorrhagic fever 3	Hepadnaviridae (F)		
Hepeviridae (F) Orthohepevirus (G) Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F) Flavivirus (G) Dengue virus Japanese encephalitis virus Kyasanur Forest disease virus V  Louping ill virus  Murray Valley encephalitis virus  Murray Valley encephalitis virus  Omsk haemorrhagic fever  3	Orthohepadnavirus (G)		
Orthohepevirus (G)  Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F)  Flavivirus (G)  Dengue virus  Japanese encephalitis virus  Kyasanur Forest disease virus  Louping ill virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  3	Hepatitis B virus	3°	V, D
Orthohepevirus A (Hepatitis E virus)  Flaviviridae (F)  Flavivirus (G)  Dengue virus  Japanese encephalitis virus  Kyasanur Forest disease virus  Louping ill virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  3	Hepeviridae (F)		
E virus)  Flaviviridae (F)  Flavivirus (G)  Dengue virus  Japanese encephalitis virus  Kyasanur Forest disease virus  Louping ill virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  3	Orthohepevirus (G)		
Flavivirus (G)  Dengue virus  3  Japanese encephalitis virus  Kyasanur Forest disease virus  Louping ill virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  3		2	
Dengue virus  Japanese encephalitis virus  Kyasanur Forest disease virus  Louping ill virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  3	Flaviviridae (F)		
Japanese encephalitis virus 3 V  Kyasanur Forest disease virus 3 V  Louping ill virus 3 <sup>c</sup> Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever 3	Flavivirus (G)		
Kyasanur Forest disease virus 3  Louping ill virus 3  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever 3	Dengue virus	3	
Louping ill virus  Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever  3	Japanese encephalitis virus	3	V
Murray Valley encephalitis virus (Australia encephalitis virus)  Omsk haemorrhagic fever 3	Kyasanur Forest disease virus	3	V
virus (Australia encephalitis virus)  Omsk haemorrhagic fever 3	Louping ill virus	3°	
	virus (Australia encephalitis	3	
		3	

- a See paragraph 7 of the introductory notes.
- b 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.
- **c** See paragraph 8 of the introductory notes.
- d Tick-borne encephalitis.
- e 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.
- f Only for types A and B.
- g Recommended for work involving direct contact with these agents.
- **h** Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
- i Variant of cowpox virus.
- j Variant of Vaccinia.
- **k** 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.

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 <sup>d</sup>	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)		
-		

- **a** See paragraph 7 of the introductory notes.
- b 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.
- c See paragraph 8 of the introductory notes.
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- e 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.
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- $\label{eq:g_def} {\bf g} \qquad \text{Recommended for work involving direct contact with these agents}.$
- h Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
- i Variant of cowpox virus.
- j Variant of Vaccinia.
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ANNEX III
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Hepacivirus C (Hepatitis C virus)	3°	D
Orthomyxoviridae (F)		
Gammainfluenzavirus (G)		
Influenza C virus	2	V <sup>f</sup>
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 <sup>f</sup>
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 <sup>f</sup>
Thogoto virus (G)		
Dhori virus (Tick-borne orthomyxoviridae: Dhori)	2	
Thogoto virus (Tick-borne orthomyxoviridae: Thogoto)	2	
C 1.7 Cd 1.4	•	•

- **a** See paragraph 7 of the introductory notes.
- b 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.
- **c** See paragraph 8 of the introductory notes.
- d Tick-borne encephalitis.
- e 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.
- f Only for types A and B.
- **g** Recommended for work involving direct contact with these agents.
- h Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
- i Variant of cowpox virus.
- j Variant of Vaccinia.
- **k** 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.

Papillomaviridae (F)	2	$D^{g}$
Parvoviridae (F)		
Erythroparvovirus (G)		
Primate erythroparvovirus 1 (Human parvovirus, B 19 virus)	2	
Polyomaviridae (F)		
Betapolyomavirus (G)		
Human polyomavirus 1 (BK virus)	2	$D^{g}$
Human polyomavirus 2 (JC virus)	2	$D^{g}$
Poxviridae (F)		
Molluscipoxvirus (G)		
Molluscum contagiosum virus	2	
Orthopoxvirus (G)		
Cowpox virus	2	
Monkeypox virus	3	V
Vaccinia virus (incl. Buffalopox virus <sup>h</sup> , Elephantpox virus <sup>i</sup> , Rabbitpox virus <sup>j</sup> )	2	
Variola (major and minor) virus	4	V
Parapoxvirus (G)		

- **a** See paragraph 7 of the introductory notes.
- b 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.
- **c** See paragraph 8 of the introductory notes.
- d Tick-borne encephalitis.
- e 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.
- f Only for types A and B.
- **g** Recommended for work involving direct contact with these agents.
- h Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
- i Variant of cowpox virus.
- j Variant of Vaccinia.
- **k** 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.

		7
Orf virus	2	
Pseudocowpox virus (Milkers' node virus, parapoxvirus bovis)	2	
Yatapoxvirus (G)		
Tanapox virus	2	
Yaba monkey tumor virus	2	
Reoviridae (F)		
Seadornavirus (G)		
Banna virus	2	
Coltivirus (G)	2	
Rotaviruses (G)	2	
Orbivirus (G)	2	
Retroviridae (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

- **a** See paragraph 7 of the introductory notes.
- b 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.
- c See paragraph 8 of the introductory notes.
- d Tick-borne encephalitis.
- e 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.
- f Only for types A and B.
- $\label{eq:gradient} {\bf g} \qquad \text{Recommended for work involving direct contact with these agents}.$
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- i Variant of cowpox virus.
- j Variant of Vaccinia.
- k 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.

Simian Immunodeficiency Virus (SIV) <sup>k</sup>	2	
Togaviridae (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	

- **a** See paragraph 7 of the introductory notes.
- b 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.
- **c** See paragraph 8 of the introductory notes.
- d Tick-borne encephalitis.
- e 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.
- f Only for types A and B.
- **g** Recommended for work involving direct contact with these agents.
- ${f h}$  Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
- i Variant of cowpox virus.
- j Variant of Vaccinia.
- **k** 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.

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Rubivirus (G)		
Rubella virus	2	V
Unassigned (F)		
Deltavirus (G)		
Hepatitis delta virus <sup>e</sup>	2	V, D

- **a** See paragraph 7 of the introductory notes.
- **b** 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.
- c See paragraph 8 of the introductory notes.
- d Tick-borne encephalitis.
- e 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.
- f Only for types A and B.
- **g** Recommended for work involving direct contact with these agents.
- h Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.
- i Variant of cowpox virus.
- j Variant of Vaccinia.
- **k** 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	3ª	$D_{\mathfrak{p}}$
Variant Agent of Creutzfeldt- Jakob disease	3ª	$D_{p}$
Agent of Bovine Spongiform Encephalopathy (BSE) and other related animal TSEs	3ª	$D_{\mathfrak{p}}$
Agent of Gerstmann- Sträussler-Scheinker syndrome	3ª	Dp
Agent of Kuru	3ª	$D_p$
Agent of Scrapie	2	

- a See paragraph 8 of the introductory notes.
- **b** 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
Acanthamoeba castellani	2	
Ancylostoma duodenale	2	
Angiostrongylus cantonensis	2	
Angiostrongylus costaricensis	2	
Anisakis simplex	2	A
Ascaris lumbricoides	2	A
Ascaris suum	2	A
Babesia divergens	2	
Babesia microti	2	
Balamuthia mandrillaris	3	
Balantidium coli	2	
Brugia malayi	2	
Brugia pahangi	2	
Brugia timori	2	
Capillaria philippinensis	2	
Capillaria spp.	2	
Clonorchis sinensis (Opisthorchis sinensis)	2	
Clonorchis viverrini (Opisthirchis viverrini)	2	
Cryptosporidium hominis	2	
Cryptosporidium parvum	2	
Cyclospora cayetanensis	2	
Dicrocoelium dentriticum	2	
Dipetalonema streptocerca	2	
Diphyllobothrium latum	2	
Dracunculus medinensis	2	
Echinococcus granulosus	3ª	
Echinococcus multilocularis	3ª	
Echinococcus oligarthrus	3ª	
Echinococcus vogeli	3ª	
Entamoeba histolytica	2	
Enterobius vermicularis	2	
a See paragraph 8 of the introductory	notes.	

Enterocytozoon bieneusi	2			
Fasciola gigantica	2			
Fasciola hepatica	2			
Fasciolopsis buski	2			
Giardia lamblia (Giardia duodenalis, Giardia intestinalis)	2			
Heterophyes spp.	2			
Hymenolepis diminuta	2			
Hymenolepis nana	2			
Leishmania aethiopica	2			
Leishmania braziliensis	3ª			
Leishmania donovani	3ª			
Leishmania guyanensis (Viannia guyanensis)	3ª			
Leishmania infantum (Leishmania chagasi)	3ª			
Leishmania major	2			
Leishmania mexicana	2			
Leishmania panamensis (Viannia panamensis)	3ª			
Leishmania peruviana	2			
Leishmania tropica	2			
Leishmania spp.	2			
Loa loa	2			
Mansonella ozzardi	2			
Mansonella perstans	2			
Mansonella streptocerca	2			
Metagonimus spp.	2			
Naegleria fowleri	3			
Necator americanus	2			
Onchocerca volvulus	2			
Opisthorchis felineus	2			
Opisthorchis spp.	2			
Paragonimus westermani	2			
a See paragraph 8 of the introductory	a See paragraph 8 of the introductory notes.			

Paragonimus spp.	2	
Plasmodium falciparum	3ª	
Plasmodium knowlesi	3ª	
Plasmodium spp. (human and simian)	2	
Sarcocystis suihominis	2	
Schistosoma haematobium	2	
Schistosoma intercalatum	2	
Schistosoma japonicum	2	
Schistosoma mansoni	2	
Schistosoma mekongi	2	
Strongyloides stercoralis	2	
Strongyloides spp.	2	
Taenia saginata	2	
Taenia solium	3ª	
Toxocara canis	2	
Toxocara cati	2	
Toxoplasma gondii	2	
Trichinella nativa	2	
Trichinella nelsoni	2	
Trichinella pseudospiralis	2	
Trichinella spiralis	2	
Trichomonas vaginalis	2	
Trichostrongylus orientalis	2	
Trichostrongylus spp.	2	
Trichuris trichiura	2	
Trypanosoma brucei brucei	2	
Trypanosoma brucei gambiense	2	
Trypanosoma brucei rhodesiense	3ª	
Trypanosoma cruzi	3ª	
Wuchereria bancrofti	2	
a See paragraph 8 of the introductory	notes	

**a** See paragraph 8 of the introductory notes.

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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
Aspergillus flavus	2	A
Aspergillus fumigatus	2	A
Aspergillus spp.	2	
Blastomyces dermatitidis (Ajellomyces dermatitidis)	3	
Blastomyces gilchristii	3	
Candida albicans	2	A
Candida dubliniensis	2	
Candida glabrata	2	
Candida parapsilosis	2	
Candida tropicalis	2	
Cladophialophora bantiana (Xylohypha bantiana, Cladosporium bantianum, trichoides)	3	
Cladophialophora modesta	3	
Cladophialophora spp.	2	
Coccidioides immitis	3	A
Coccidioides posadasii	3	A
Cryptococcus gattii (Filobasidiella neoformans var. bacillispora)	2	A
Cryptococcus neoformans (Filobasidiella neoformans var. neoformans)	2	A
Emmonsia parva var. parva	2	
Emmonsia parva var. crescens	2	
Epidermophyton floccosum	2	A
Epidermophyton spp.	2	
Fonsecaea pedrosoi	2	
Histoplasma capsulatum	3	
Histoplasma capsulatum var. farciminosum	3	

Histoplasma duboisii	3	
Madurella grisea	2	
Madurella mycetomatis	2	
Microsporum spp.	2	A
Nannizzia spp.	2	
Neotestudina rosatii	2	
Paracoccidioides brasiliensis	3	A
Paracoccidioides lutzii	3	
Paraphyton spp.	2	
Rhinocladiella mackenziei	3	
Scedosporium apiospermum	2	
Scedosporium prolificans (inflatum)	2	
Sporothrix schenckii	2	
Talaromyces marneffei (Penicillium marneffei)	2	A
Trichophyton rubrum	2	A
Trichophyton tonsurans	2	A
Trichophyton spp.	2	]

### ANNEX IV

## PRACTICAL RECOMMENDATIONS FOR THE HEALTH SURVEILLANCE OF WORKERS (Article 14(8))

- 1. The doctor and/or the authority responsible for the health surveillance of workers exposed to biological agents must be familiar with the exposure conditions or circumstances of each worker.
- 2. Health surveillance of workers must be carried out in accordance with the principles and practices of occupational medicine: it must include at least the following measures:
- keeping records of a worker's medical and occupational history,
- a personalised assessment of the worker's state of health.
- where appropriate, biological monitoring, as well as detection of early and reversible effects.

Further tests may be decided on for each worker when he is the subject of health surveillance, in the light of the most recent knowledge available to occupational medicine.

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# IF1ANNEX 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	B. Containment levels		
measures	2	3	4
Workplace			
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
Facilities			
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
Equipment	1		
4. Input air and extract air to the workplace are to be filtered using (HEPA <sup>a</sup> ) 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
impervious to water	floor	and other surfaces determined by risk	

a HEPA: High efficiency particulate air

**b** 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.]

7. Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
System of work			
8. Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock <sup>b</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
Waste	1	1	
13. Validated inactivation process for the safe disposal of animal carcases	Recommended	Yes, on or off site	Yes, on site
Other measures			
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
TYPED A TYLE OF T	and the second s		

# [F1ANNEX VI

# **CONTAINMENT FOR INDUSTRIAL PROCESSES** (Article 4(1) and Article 16(2)(a))

Preliminary note

a HEPA: High efficiency particulate air

b 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.]

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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	B. Containment levels		
measures	2	3	4
General			
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	No	Recommended	Yes

a HEPA: High efficiency particulate air

**b** Closed system: A system that physically separates the process from the environment (e.g. incubator vats, tanks, etc.).

c 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.]

entire contents of the closed system				
7. The controlled area should be sealable to permit fumigation	No	Recommended	Yes	
Facilities				
8. Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes	
Equipment				
9. Input air and extract air to the controlled area should be HEPA <sup>a</sup> 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	
System of work	1			
12. Closed systems <sup>b</sup> 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 <sup>c</sup>	
15. Personnel should shower before leaving the controlled area	No	Recommended	Yes	
a HEPA: High efficiency particulate air				

a HEPA: High efficiency particulate air

**b** Closed system: A system that physically separates the process from the environment (e.g. incubator vats, tanks, etc.).

c 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.]

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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
a HEPA: High efficiency particulate air			

**b** Closed system: A system that physically separates the process from the environment (e.g. incubator vats, tanks, etc.).

### ANNEX VII

# RECOMMENDED CODE OF PRACTICE ON VACCINATION (Article 14(3))

- 1. If the assessment referred to in Article 3(2) reveals that there is a risk to the health and safety of workers due to their exposure to biological agents for which effective vaccines exist, their employers should offer them vaccination.
- 2. Vaccination should be carried out in accordance with national law and/or practice.

Workers should be informed of the benefits and drawbacks of both vaccination and non-vaccination.

- 3. Vaccination must be offered free of charge to workers.
- 4. A vaccination certificate may be drawn up which should be made available to the worker concerned and, on request, to the competent authorities.

### ANNEX VIII

### PART A

### Repealed Directive with its successive amendments

(referred to in Article 21)

Council Directive 90/679/EEC (OJ L 374, 31.12.1990, p. 1)

Council Directive 93/88/EEC (OJ L 268, 29.10.1993, p. 71)

c 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.]

Commission Directive 95/30/EC (OJ L 155, 6.7.1995, p. 41)

Commission Directive 97/59/EC (OJ L 282, 15.10.1997, p. 33)

Commission Directive 97/65/EC (OJ L 335, 6.12.1997, p. 17)

### PART B

### DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW

(referred to in Article 21)

Directive	Deadline for transposition
90/679/EEC	28 November 1993
93/88/EEC	30 April 1994
95/30/EC	30 November 1996
97/59/EC	31 March 1998
97/65/EC	30 June 1998

### ANNEX IX

## **CORRELATION TABLE**

Directive 90/679/EEC	This Directive
Article 1	Article 1
Article 2, point (a)	Article 2, first paragraph, point (a)
Article 2, point (b)	Article 2, first paragraph, point (b)
Article 2, point (c)	Article 2, first paragraph, point (c)
Article 2, point (d)	Article 2, second paragraph
Article 3(1)	Article 3(1)
Article 3(2)(a)	Article 3(2), first subparagraph
Article 3(2)(b)	Article 3(2), second subparagraph
Article 3(2)(c)	Article 3(2), third subparagraph
Article 3(2)(d)	Article 3(2), fourth subparagraph
Article 3(3), first indent	Article 3(3)(a)
Article 3(3), second indent	Article 3(3)(b)
Article 3(3), third indent	Article 3(3)(c)
Article 3(3), fourth indent	Article 3(3)(d)
Article 3(3), fifth indent	Article 3(3)(e)
Article 4	Article 4

Article 5	Article 5
Article 6	Article 6
Article 7(1), first indent	Article 7(1)(a)
Article 7(1), second indent	Article 7(1)(b)
Article 7(1), third indent	Article 7(1)(c)
Article 7(1), fourth indent	Article 7(1)(d)
Article 7(1), fifth indent	Article 7(1)(e)
Article 7(1), sixth indent	Article 7(1)(f)
Article 7(2)	Article 7(2)
Article 7(3)	Article 7(3)
Article 8(1)(a) to (e)	Article 8(1)(a) to (e)
Article 8(2)(a)	Article 8(2), first subparagraph
Article 8(2)(b)	Article 8(2), second subparagraph
Article 8(3)	Article 8(3)
Article 9(1)(a) to (e)	Article 9(1)(a) to (e)
Article 9(2), first indent	Article 9(2)(a)
Article 9(2), second indent	Article 9(2)(b)
Article 9(2), third indent	Article 9(2)(c)
Article 10(1), first indent	Article 10(1)(a)
Article 10(1), second indent	Article 10(1)(b)
Article 10(2) to (6)	Article 10(2) to (6)
Article 11(1)	Article 11(1)
Article 11(2), second subparagraph, first indent	Article 11(2), second subparagraph, (a)
Article 11(2), second subparagraph, second indent	Article 11(2), second subparagraph, (b)
Article 11(2), second subparagraph, third indent	Article 11(2), second subparagraph, (c)
Article 11(2), second subparagraph, fourth indent	Article 11(2), second subparagraph, (d)
Article 11(2), second subparagraph, fifth indent	Article 11(2), second subparagraph, (e)
Article 11(3)	Article 11(3)
Article 12	Article 12
Article 13(1), first indent	Article 13(1)(a)
Article 13(1), second indent	Article 13(1)(b)
	•

	rticle 13(1)(c)
Article 13(2) to (4)	rticle 13(2) to (4)
Article 14(1)	rticle 14(1)
Article 14(2), first indent A	rticle 14(2)(a)
Article 14(2), second indent A	rticle 14(2)(b)
Article 14(3) to (6)	rticle 14(3) to (6)
Article 14(7), first indent	rticle 14(7)(a)
Article 14(7), second indent A	rticle 14(7)(b)
Article 14(8)	rticle 14(8)
Article 14(9) A	rticle 14(9)
Article 15 A	rticle 15
Article 16(1) A	rticle 16(1)
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Article 16(2)(b)	rticle 16(2)(b)
Article 16(2)(c) A	rticle 16(3)
Article 17 A	rticle 17
Article 18(1)	_
Article 18(2)	rticle 18(1)
Article 18(3)	rticle 18(2)
Article 18(4)	rticle 18(3)
Article 19 A	rticle 19
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A	rticle 21
A	rticle 22
A	rticle 23
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Directive 2000/54/EC of the European Parliament and of the Council of 18 September	
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