



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.09.1999
COM(1999) 432 final

99/0188 (COD)

Proposal for a

EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

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)

(codified version)

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. In the context of a people's Europe, the Commission attaches great importance to simplifying and clarifying Community law so as to make it clearer and more accessible to the ordinary citizen, thus giving him new opportunities and the chance to make use of the specific rights it gives him.

This aim cannot be achieved so long as numerous provisions that have been amended several times, often quite substantially, remain scattered, so that they must be sought partly in the original instrument and partly in later amending ones. Considerable research work, comparing many different instruments, is thus needed to identify the current rules.

For this reason a consolidation of rules that have frequently been amended is also essential if Community law is to be clear and transparent.

2. On 1 April 1987 the Commission therefore decided to instruct its staff that all legislative measures should be consolidated after no more than ten amendments, stressing that this was a minimum requirement and that departments should endeavour to consolidate at even shorter intervals the texts for which they were responsible, to ensure that the Community rules were clear and readily understandable.
3. The Conclusions of the Presidency of the Edinburgh European Council (December 1992) confirmed this, stressing the importance of legislative consolidation as it offers certainty as to the law applicable to a given matter at a given time.

It must be undertaken in full compliance with the normal Community legislative procedure.

Given that no changes of substance may be made to the instruments affected by legislative consolidation, Parliament, the Council and the Commission have agreed, by an interinstitutional agreement dated 20 December 1994, that an accelerated procedure may be used for the fast-track adoption of codification instruments.

4. The purpose of this proposal ⁽¹⁾ for legislative consolidation of Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from the risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC), is to undertake official codification of this type. The new Directive will supersede the various Directives incorporated in it ⁽²⁾; their content is fully preserved, and they are brought together with only such formal amendments as are required by the codification exercise itself.
5. This legislative consolidation proposal was drawn up on the basis of a preliminary consolidation, in all the official languages, of Directive 90/679/EEC and the instruments amending it, carried out by the Office for Official Publications of the European Communities, by means of the data-processing system referred to in the conclusions of the European Council meeting at Edinburgh. Although the articles have been given new numbers, the old numbering has been retained in the margin for ease of reference; the correlation between the old and new numbers is shown in a table set out in Annex IX to the consolidated Directive.

⁽¹⁾ Entered in the legislative programme for 1998.

⁽²⁾ See Annex VIII, Part A of this Proposal.

PROPOSAL FOR A
EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE

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)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF
THE EUROPEAN UNION,

Having regard to the Treaty establishing the European
Community, and in particular Article 137 (2) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social
Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the
Regions ⁽²⁾,

Acting in accordance with the procedure laid down in
Article 251 of the Treaty ⁽³⁾,

- (1) Whereas Council Directive 90/679/EEC of
26 November 1990 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) ⁽⁴⁾ has been
substantially amended on a number of occasions ⁽⁵⁾;
whereas for the sake of clarity and rationality Directive
90/679/EEC should therefore be codified;
- (2) Whereas compliance with the minimum requirements
designed to guarantee a better standard of safety and
health as regards the protection of workers from the risks
related to exposure to biological agents at work is essen-
tial to ensure the safety and health of workers;

5. 90/679/EEC

⁽¹⁾ OJ C...

⁽²⁾ OJ C...

⁽³⁾ OJ C...

⁽⁴⁾ OJ L 374, 31.12.1990, p. 1. Directive as last amended by
Commission Directive 97/65/EC (OJ L 335, 6.12.1997,
p. 17).

⁽⁵⁾ See Annex VIII, Part A.

(3) Whereas this Directive is an individual Directive within the meaning of Article 16 (1) of 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 ⁽¹⁾ ; whereas the provisions of that Directive are therefore fully applicable to the exposure of workers to biological agents, without prejudice to more stringent and/or specific provisions contained in this Directive;	6.	90/679/EEC
(4) Whereas more precise knowledge of the risks involved in exposure to biological agents can be obtained through the keeping of records;	7.	
(5) Whereas the list and classification of the biological agents must be examined regularly and revised on the basis of new scientific data;	3.	95/30/EC
(6) Whereas, for a number of biological agents details additional to their classification should be given;	4.	93/88/EEC
(7) Whereas employers must keep abreast of new developments in technology with a view to improving the protection of workers' health and safety;	8.	90/679/EEC
(8) Whereas preventive measures should be taken for the protection of the health and safety of workers exposed to biological agents;	9.	
(9) Whereas this Directive constitutes a practical aspect of the realization of the social dimension of the internal market;	10.	
(10) Whereas, pursuant to Council Decision 74/325/EEC ⁽²⁾ , the Advisory Committee on Safety, Hygiene and Health Protection at Work should be consulted by the Commission with a view to the formulation of proposals in this field; whereas it was so consulted over the formulation of proposals for the Council directives embodied in this Directive:	11.	(adapted)
	+	(adapted)
	second	(adapted)
	citation	93/88/EEC
	+	(adapted)
	second	
	citation	
(11) Whereas this Directive is without prejudice to the obligations of the Member States concerning the deadlines for transposition as set out in Annex VIII, Part B,		

HAVE ADOPTED THIS DIRECTIVE;

⁽¹⁾ OJ L 183, 29. 6. 1989, p. 1.

⁽²⁾ OJ L 185, 9. 7. 1974, p. 15; Decision as last amended by the Act of Accession of Austria, Finland and Sweden.

CHAPTER I
GENERAL PROVISIONS

Article 1

Objective

1. This Directive has as its aim the protection of 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.

It lays down particular minimum provisions in this area.

2. Directive 89/391/EEC shall apply fully to the whole area referred to in paragraph 1, without prejudice to more stringent and/or specific provisions contained in this Directive.

3. This Directive shall apply without prejudice to the provisions of Council Directive 90/219/EEC⁽¹⁾ and of Council Directive 90/220/EEC⁽²⁾.

Article 2

Definitions

For the purpose of this Directive:

- (a) 'biological agents' shall mean micro-organisms, including those which have been genetically modified, cell cultures and human endoparasites, which may be able to provoke any infection, allergy or toxicity;
- (b) 'micro-organism' shall mean a microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material;
- (c) 'cell culture' shall mean the in-vitro growth of cells derived from multicellular organisms.

'Biological agents' shall be classified into four risk groups, according to their level of risk of infection:

- 1. group 1 biological agent means one that is unlikely to cause human disease;

⁽¹⁾ Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (OJ L 117, 8. 5. 1990, p. 1). Directive as last amended by Directive 98/81/EC (OJ L 330, 5. 12. 1998, p. 13).

⁽²⁾ Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ L 117, 8. 5. 1990, p. 15). Directive as last amended by Directive 97/35/EC (OJ L 169, 27. 6. 1997, p. 72).

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Article 1

(adapted)

Article 2

2. group 2 biological agent means one that can cause human disease and might be a hazard to workers; it is unlikely to spread to the community; there is usually effective prophylaxis or treatment available;
3. group 3 biological agent means one that can cause severe human disease and present a serious hazard to workers; it may present a risk of spreading to the community, but there is usually effective prophylaxis or treatment available;
4. group 4 biological agent means one that causes severe human disease and is a serious hazard to workers; it may present a high risk of spreading to the community; there is usually no effective prophylaxis or treatment available.

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Article 3

Article 3

Scope — Determination and assessment of risks

1. This Directive shall apply to activities in which workers are or are potentially exposed to biological agents as a result of their work.

2. In the case of any activity likely to involve a risk of exposure to biological agents, the nature, degree and duration of workers' exposure must be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken.

In the case of activities involving exposure to several groups of biological agents, the risk shall be assessed on the basis of the danger presented by all hazardous biological agents present.

The assessment must be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to biological agents.

The employer must supply the competent authorities, at their request, with the information used for making the assessment.

3. The assessment referred to in paragraph 2 shall be conducted on the basis of all available information including:

- (a) classification of biological agents which are or may be a hazard to human health, as referred to in Article 18;

- (b) recommendations from a competent authority which indicate that the biological agent should be controlled in order to protect workers' health when workers are or may be exposed to such a biological agent as a result of their work;
- (c) information on diseases which may be contracted as a result of the work of the workers;
- (d) potential allergenic or toxigenic effects as a result of the work of the workers;
- (e) knowledge of a disease from which a worker is found to be suffering and which has a direct connection with his work.

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Article 4

Application of the various Articles in relation to assessment of risks

1. If the results of the assessment referred to in Article 3 show that the exposure and/or potential exposure is to a group 1 biological agent, with no identifiable health risk to workers, Articles 5 to 17 and Article 19 shall not apply.

However, point 1 of Annex VI should be observed.

2. If the results of the assessment referred to in Article 3 show that the activity does not involve a deliberate intention to work with or use a biological agent but may result in the workers' being exposed to a biological agent, as in the course of the activities for which an indicative list is given in Annex I, Articles 5, 7, 8, 10, 11, 12, 13 and 14 shall apply unless the results of the assessment referred to in Article 3 show them to be unnecessary.

Article 4

CHAPTER II

EMPLOYERS' OBLIGATIONS

Article 5

Replacement

The employer shall avoid the use of a harmful biological agent if the nature of the activity so permits, by replacing it with a biological agent which, under its conditions of use, is not dangerous or is less dangerous to workers' health, as the case may be, in the present state of knowledge.

Article 5

Article 6

Reduction of risks

1. Where the results of the assessment referred to in Article 3 reveal a risk to workers' health or safety, workers' exposure must be prevented.

Article 6

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2. Where this is not technically practicable, having regard to the activity and the risk assessment referred to in Article 3, the risk of exposure must be reduced to as low a level as necessary in order to protect adequately the health and safety of the workers concerned, in particular by the following measures which are to be applied in the light of the results of the assessment referred to in Article 3:

- (a) keeping as low as possible the number of workers exposed or likely to be exposed;
- (b) design of work processes and engineering control measures so as to avoid or minimize the release of biological agents into the place of work;
- (c) collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;
- (d) hygiene measures compatible with the aim of the prevention or reduction of the accidental transfer or release of a biological agent from the workplace;
- (e) use of the biohazard sign depicted in Annex II and other relevant warning signs;
- (f) drawing up plans to deal with accidents involving biological agents;
- (g) testing, where it is necessary and technically possible, for the presence, outside the primary physical confinement, of biological agents used at work;
- (h) means for safe collection, storage and disposal of waste by workers including the use of secure and identifiable containers, after suitable treatment where appropriate;
- (i) arrangements for the safe handling and transport of biological agents within the workplace.

Article 7

Information for the competent authority

1. Where the results of the assessment referred to in Article 3 reveal risk to workers' health or safety, employers shall, when requested, make available to the competent authority appropriate information on:

- (a) the results of the assessment;
- (b) the activities in which workers have been exposed or may have been exposed to biological agents;
- (c) the number of workers exposed;
- (d) the name and capabilities of the person responsible for safety and health at work;

Article 7

- (e) the protective and preventive measures taken, including working procedures and methods;
 - (f) an emergency plan for the protection of workers from exposure to group 3 or a group 4 biological agent which might result from a loss of physical containment.
2. Employers shall inform forthwith the competent authority of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection and/or illness.
3. The list referred to in Article 11 and the medical record referred to in Article 14 shall be made available to the competent authority in cases where the undertaking ceases activity, in accordance with national laws and/or practice.

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Article 8

Article 8

Hygiene and individual protection

1. Employers shall be obliged, in the case of all activities for which there is a risk to the health or safety of workers due to work with biological agents, to take appropriate measures to ensure that:
- (a) workers do not eat or drink in working areas where there is a risk of contamination by biological agents;
 - (b) workers are provided with appropriate protective clothing or other appropriate special clothing;
 - (c) workers are provided with appropriate and adequate washing and toilet facilities, which may include eye washes and/or skin antiseptics;
 - (d) any necessary protective equipment is:
 - properly stored in a well-defined place;
 - checked and cleaned if possible before, and in any case after, each use;
 - is repaired, where defective, or is replaced before further use;
 - (e) procedures are specified for taking, handling and processing samples of human or animal origin.
2. Working clothes and protective equipment, including protective clothing referred to in paragraph 1, which may be contaminated by biological agents, must be removed on leaving the working area and, before taking the measures referred to in the second subparagraph, kept separately from other clothing.

(adapted)

The employer must ensure that such clothing and protective equipment is decontaminated and cleaned or, if necessary, destroyed.

3. Workers may not be charged for the cost of the measures referred to in paragraphs 1 and 2.

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Article 9

Article 9

Information and training of workers

1. Appropriate measures shall be taken by the employer to ensure that workers and/or any workers' representatives in the undertaking or establishment receive sufficient and appropriate training, on the basis of all available information, in particular in the form of information and instructions, concerning:

- (a) potential risks to health;
- (b) precautions to be taken to prevent exposure;
- (c) hygiene requirements;
- (d) wearing and use of protective equipment and clothing;
- (e) steps to be taken by workers in the case of incidents and to prevent incidents.

2. The training shall be:

- (a) given at the beginning of work involving contact with biological agents
- (b) adapted to take account of new or changed risks; and
- (c) repeated periodically if necessary.

Article 10

Article 10

Worker information in particular cases

1. Employers shall provide written instructions at the workplace and, if appropriate, display notices which shall, as a minimum, include the procedure to be followed in the case of:

- (a) a serious accident or incident involving the handling of a biological agent;
- (b) handling a group 4 biological agent.

2. Workers shall immediately report any accident or incident involving the handling of a biological agent to the person in charge or to the person responsible for safety and health at work.

3. Employers shall inform forthwith the workers and/or any workers' representatives of any accident or incident which may have resulted in the release of a biological agent and which could cause severe human infection and/or illness.

In addition, employers shall inform the workers and/or any workers' representatives in the undertaking or establishment as quickly as possible when a serious accident or incident occurs, of the causes thereof, and of the measures taken or to be taken to rectify the situation.

4. Each worker shall have access to the information on the list referred to in Article 11 which relates to him personally.

5. Workers and/or any workers' representatives in the undertaking or establishment shall have access to anonymous collective information.

6. Employers shall provide workers and/or their representatives, at their request, with the information provided for in Article 7 (1).

Article 11

Article 11

List of exposed workers

1. Employers shall keep a list of workers exposed to group 3 and/or group 4 biological agents, indicating the type of work done and, whenever possible, the biological agent to which they have been exposed, as well as records of exposures, accidents and incidents, as appropriate.

2. The list referred to in paragraph 1 shall be kept for at least 10 years following the end of exposure, in accordance with national laws and/or practice.

In the case of those exposures which may result in infections:

- (a) with biological agents known to be capable of establishing persistent or latent infections;
- (b) that, in the light of present knowledge, are undiagnosable until illness develops many years later;
- (c) that have particularly long incubation periods before illness develops;
- (d) that result in illnesses which recrudesce at times over a long period despite treatment, or
- (e) that may have serious long-term sequelae,

the list shall be kept for an appropriately longer time up to 40 years following the last known exposure.

3. The doctor referred to in Article 14 and/or the competent authority for health and safety at work, and any other person responsible for health and safety at work, shall have access to the list referred to in paragraph 1.

Article 12

Consultation and participation of workers

Consultation and participation of workers and/or their representatives in connection with matters covered by this Directive shall take place in accordance with Article 11 of Directive 89/391/EEC.

Article 13

Notification to the competent authority

1. Prior notification shall be made to the competent authority of the use for the first time of:

- (a) group 2 biological agents;
- (b) group 3 biological agents;
- (c) group 4 biological agents.

The notification shall be made at least 30 days before the commencement of the work.

Subject to paragraph 2, prior notification shall also be made of the use for the first time of each subsequent group 4 biological agent and of any subsequent new group 3 biological agent where the employer himself provisionally classifies that biological agent.

2. Laboratories providing a diagnostic service in relation to group 4 biological agents shall be required only to make an initial notification of their intention.

3. Renotification must take place in any case where there are substantial changes of importance to safety or health at work to processes and/or procedures which render the notification out of date.

4. The notification referred to in paragraphs 1, 2 and 3 shall include:

- (a) the name and address of the undertaking and/or establishment;
- (b) the name and capabilities of the person responsible for safety and health at work;
- (c) the results of the assessment referred to in Article 3;
- (d) the species of the biological agent;
- (e) the protection and preventive measures that are envisaged.

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(adapted)

Article 12

Article 13

CHAPTER III
MISCELLANEOUS PROVISIONS

Article 14

Health surveillance

1. The Member States shall establish, in accordance with national laws and practice, arrangements for carrying out relevant health surveillance of workers for whom the results of the assessment referred to in Article 3 reveal a risk to health or safety.

2. The arrangements referred to in paragraph 1 shall be such that each worker shall be able to undergo, if appropriate, relevant health surveillance:

- (a) prior to exposure;
- (b) at regular intervals thereafter.

Those arrangements shall be such that it is directly possible to implement individual and occupational hygiene measures.

3. The assessment referred to in Article 3 should identify those workers for whom special protective measures may be required.

When necessary, effective vaccines should be made available for those workers who are not already immune to the biological agent to which they are exposed or are likely to be exposed.

When employers make vaccines available, they should take account of the recommended code of practice set out in Annex VII.

If a worker is found to be suffering from an infection and/or illness which is suspected to be the result of exposure, the doctor or authority responsible for health surveillance of workers shall offer such surveillance to other workers who have been similarly exposed.

In that event, a reassessment of the risk of exposure shall be carried out in accordance with Article 3.

4. In cases where health surveillance is carried out, an individual medical record shall be kept for at least 10 years following the end of exposure, in accordance with national laws and practice.

In the special cases referred to in Article 11 (2) second subparagraph, an individual medical record shall be kept for an appropriately longer time up to 40 years following the last known exposure.

5. The doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual worker.

6. Information and advice must be given to workers regarding any health surveillance which they may undergo following the end of exposure.

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Article 14

93/88/EEC - Art. 1 (1)

90/679/EEC

7. In accordance with national laws and/or practice:
- (a) workers shall have access to the results of the health surveillance which concern them, and
 - (b) the workers concerned or the employer may request a review of the results of the health surveillance.
8. Practical recommendations for the health surveillance of workers are given in Annex IV.
9. All cases of diseases or death identified in accordance with national laws and/or practice as resulting from occupational exposure to biological agents shall be notified to the competent authority.

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Article 15

Article 15

Health and veterinary care facilities other than diagnostic laboratories

1. For the purpose of the assessment referred to in Article 3, particular attention should be paid to:
- (a) uncertainties about the presence of biological agents in human patients or animals and the materials and specimens taken from them;
 - (b) the hazard represented by biological agents known or suspected to be present in human patients or animals and materials and specimens taken from them;
 - (c) the risks posed by the nature of the work.
2. Appropriate measures shall be taken in health and veterinary care facilities in order to protect the health and safety of the workers concerned.
- The measures to be taken shall include in particular:
- (a) specifying appropriate decontamination and disinfection procedures, and
 - (b) implementing procedures enabling contaminated waste to be handled and disposed of without risk.
3. In isolation facilities where there are human patients or animals who are, or who are suspected of being, infected with group 3 or group 4 biological agents, containment measures shall be selected from those in Annex V column A, in order to minimize the risk of infection.

Article 16

**Special measures for industrial processes, laboratories
and animal rooms**

1. The following measures must be taken in laboratories, including diagnostic laboratories, and in rooms for laboratory animals which have been deliberately infected with group 2, 3 or 4 biological agents or which are or are suspected to be carriers of such agents:

- (a) Laboratories carrying out work which involves the handling of group 2, 3 or 4 biological agents for research, development, teaching or diagnostic purposes shall determine the containment measures in accordance with Annex V, in order to minimize the risk of infection.
- (b) Following the assessment referred to in Article 3, measures shall be determined in accordance with Annex V, after fixing the physical containment level required for the biological agents according to the degree of risk.

Activities involving the handling of a biological agent must be carried out:

- only in working areas corresponding to at least containment level 2, for a group 2 biological agent;
 - only in working areas corresponding to at least containment level 3, for a group 3 biological agent;
 - only in working areas corresponding to at least containment level 4, for a group 4 biological agent.
- (c) Laboratories handling materials in respect of which there exist uncertainties about the presence of biological agents which may cause human disease but which do not have as their aim working with biological agents as such (i.e. cultivating or concentrating them) should adopt containment level 2 at least. Containment levels 3 or 4 must be used, when appropriate, where it is known or it is suspected that they are necessary, except where guidelines provided by the competent national authorities show that, in certain cases, a lower containment level is appropriate.

2. The following measures concerning industrial processes using group 2, 3 or 4 biological agents must be taken:

- (a) The containment principles set out in the second subparagraph of paragraph 1 (b) should also apply to industrial processes on the basis of the practical measures and appropriate procedures given in Annex VI.

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Article 16

(h) In accordance with the assessment of the risk linked to the use of group 2, 3 or 4 biological agents, the competent authorities may decide on appropriate measures which must be applied to the industrial use of such biological agents.

3. For all activities covered by paragraphs 1 and 2 where it has not been possible to carry out a conclusive assessment of a biological agent but concerning which it appears that the use envisaged might involve a serious health risk for workers, activities may only be carried out in workplaces where the containment level corresponds at least to level 3.

Article 17

Use of data

The Commission shall have access to the use made by the competent national authorities of the information referred to in Article 14 (9).

Article 18

Classification of biological agents

1. Community classification shall be on the basis of the definitions in the second paragraph of Article 2, points 2 to 4 (groups 2 to 4).

2. Pending Community classification Member States shall classify biological agents that are or may be a hazard to human health on the basis of the definition in the second paragraph of Article 2, points 2 to 4 (groups 2 to 4).

3. If the biological agent to be assessed cannot be classified clearly in one of the groups defined in the second paragraph of Article 2, it must be classified in the highest risk group among the alternatives.

Article 19

Annexes

Purely technical adjustments to the Annexes in the light of technical progress, changes in international regulations or specifications and new findings in the field of biological agents shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.

Article 20

Notifying the Commission

Member States shall communicate to the Commission the provisions of national law already adopted or which they adopt in the future in the field governed by this Directive.

90/679/EEC

Article 17

Article 18

(adapted)

Article 19

(adapted)

Article 20

Article 21

Repeal

Directive 90/679/EEC, amended by the Directives referred to in Annex VIII, Part A is repealed, without prejudice to the obligations of the Member States in respect of the deadlines for transposition laid down in Annex VIII, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be correlated in accordance with the correlation table set out in Annex IX.

Article 22

Entry into force

This Directive enters into force on the twentieth day following that of its publication in the *Official Journal of the European Communities*.

Article 23

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament

For the Council

The President

The President

ANNEX I

INDICATIVE LIST OF ACTIVITIES

(Article 4 (2))

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 health care, 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.
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90/679/EEC

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



90/679/EEC

ANNEX III

COMMUNITY CLASSIFICATION

(Article 18 and Article 2, second paragraph)

93/88/EEC - Art. 1 (2)

(adapted)

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 agents 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 air-borne 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 upon 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

The application of preventive vaccination should take account of the Code of Practice given in Annex VII.

93/88/EEC - Art. 1 (2)

Corrigendum OJ L 217, 23. 8. 1994, p. 18.

BACTERIA
and similar organisms

NB: For biological agents appearing on this list, "spp." refers to other species which are known pathogens in humans.

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Biological agent	Classification	Notes
<i>Actinobacillus actinomycetemcomitans</i>	2	
<i>Actinomadura madurae</i>	2	
<i>Actinomadura pelletieri</i>	2	
<i>Actinomyces gerencseriae</i>	2	
<i>Actinomyces israelii</i>	2	
<i>Actinomyces pyogenes</i>	2	
<i>Actinomyces</i> spp.	2	
<i>Arcanobacterium haemolyticum</i> (<i>Corynebacterium haemolyticum</i>)	2	
<i>Bacillus anthracis</i>	3	
<i>Bacteroides fragilis</i>	2	
<i>Bartonella bacilliformis</i>	2	
<i>Bartonella (Rochalimaea)</i> spp.	2	
<i>Bartonella quintana (Rochalimaea quintana)</i>	2	
<i>Bordetella bronchiseptica</i>	2	
<i>Bordetella parapertussis</i>	2	
<i>Bordetella pertussis</i>	2	V
<i>Borrelia burgdorferi</i>	2	
<i>Borrelia duttonii</i>	2	
<i>Borrelia recurrentis</i>	2	
<i>Borrelia</i> spp.	2	
<i>Brucella abortus</i>	3	
<i>Brucella canis</i>	3	
<i>Brucella melitensis</i>	3	
<i>Brucella suis</i>	3	
<i>Burkholderia mallei (Pseudomonas mallei)</i>	3	
<i>Burkholderia pseudomallei (Pseudomonas pseudomallei)</i>	3	
<i>Campylobacter fetus</i>	2	
<i>Campylobacter jejuni</i>	2	
<i>Campylobacter</i> spp.	2	
<i>Cardiobacterium hominis</i>	2	
<i>Chlamydia pneumoniae</i>	2	
<i>Chlamydia trachomatis</i>	2	
<i>Chlamydia psittaci</i> (avian strains)	3	
<i>Chlamydia psittaci</i> (other strains)	2	
<i>Clostridium botulinum</i>	2	T
<i>Clostridium perfringens</i>	2	
<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	
<i>Corynebacterium</i> spp.	2	
<i>Coxiella burnetii</i>	3	
<i>Edwardsiella tarda</i>	2	
<i>Ehrlichia sennetsu (Rickettsia sennetsu)</i>	2	
<i>Ehrlichia</i> spp.	2	
<i>Eikenella corrodens</i>	2	
<i>Enterobacter aerogenes/cloacae</i>	2	

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Biological agent	Classification	Notes	
<i>Enterobacter</i> spp.	2		93/88/EEC – Art. 1 (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	97/59/EC – Art. 1
<i>Flavobacterium meningosepticum</i>	2		93/88/EEC – Art. 1 (2)
<i>Fluoribacter bozemanai</i> (<i>Legionella</i>)	2		
<i>Francisella tularensis</i> (Type A)	3		
<i>Francisella tularensis</i> (Type B)	2		
<i>Fusobacterium necrophorum</i>	2		
<i>Gardnerella vaginalis</i>	2		
<i>Haemophilus ducreyi</i>	2		
<i>Haemophilus influenzae</i>	2		
<i>Haemophilus</i> spp.	2		
<i>Helicobacter pylori</i>	2		
<i>Klebsiella oxytoca</i>	2		
<i>Klebsiella pneumoniae</i>	2		
<i>Klebsiella</i> spp.	2		
<i>Legionella pneumophila</i>	2		
<i>Legionella</i> spp.	2		
<i>Leptospira interrogans</i> (all serovars)	2		
<i>Listeria monocytogenes</i>	2		
<i>Listeria ivanovii</i>	2		
<i>Morganella morganii</i>	2		
<i>Mycobacterium africanum</i>	3	V	
<i>Mycobacterium avium/intracellulare</i>	2		
<i>Mycobacterium bovis</i> (except BCG strain)	3	V	
<i>Mycobacterium chelonae</i>	2		
<i>Mycobacterium fortuitum</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 (**)		Corrigendum OJ L 217, 23. 8. 1994, p. 18.
<i>Mycobacterium paratuberculosis</i>	2		
<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 (**)		Corrigendum OJ L 217, 23. 8. 1994, p. 18.
<i>Mycobacterium xenopi</i>	2		
<i>Mycoplasma caviae</i>	2		97/59/EC – Art. 1
<i>Mycoplasma hominis</i>	2		
<i>Mycoplasma pneumoniae</i>	2		93/88/EEC – Art. 1 (2)
<i>Neisseria gonorrhoeae</i>	2		
<i>Neisseria meningitidis</i>	2	V	
<i>Nocardia asteroides</i>	2		
<i>Nocardia brasiliensis</i>	2		
<i>Nocardia farcinica</i>	2		
<i>Nocardia nova</i>	2		
<i>Nocardia otitidiscavium</i>	2		
<i>Pasteurella multocida</i>	2		
<i>Pasteurella</i> spp.	2		
<i>Peptostreptococcus anaerobius</i>	2		

Biological agent	Classification	Notes
<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>	2	
<i>Providencia rettgeri</i>	2	
<i>Providencia</i> spp.	2	
<i>Pseudomonas aeruginosa</i>	2	
<i>Rhodococcus equi</i>	2	
<i>Rickettsia akari</i>	3 (**)	Corrigendum OJ L 217, 23. 8. 1994, p. 18.
<i>Rickettsia canada</i>	3 (**)	Corrigendum OJ L 217, 23. 8. 1994, p. 18.
<i>Rickettsia conorii</i>	3	
<i>Rickettsia montana</i>	3 (**)	Corrigendum OJ L 217, 23. 8. 1994, p. 18.
<i>Rickettsia typhi</i> (<i>Rickettsia mooseri</i>)	3	
<i>Rickettsia prowazekii</i>	3	
<i>Rickettsia rickettsii</i>	3	
<i>Rickettsia tsutsugamushi</i>	3	
<i>Rickettsia</i> spp.	2	
<i>Salmonella arizonae</i>	2	
<i>Salmonella enteritidis</i>	2	
<i>Salmonella typhimurium</i>	2	
<i>Salmonella paratyphi A, B, C</i>	2	V
<i>Salmonella typhi</i>	3 (**)	V Corrigendum OJ L 217, 23. 8. 1994, p. 18.
<i>Salmonella</i> (other serovars)	2	
<i>Serpulina</i> spp.	2	
<i>Shigella boydii</i>	2	
<i>Shigella dysenteriae</i> (Type 1)	3 (**)	T Corrigendum OJ L 217, 23. 8. 1994, p. 18.
<i>Shigella dysenteriae</i> , other than Type 1	2	97/59/EC - Art. 1
<i>Shigella flexneri</i>	2	93/88/EEC - Art. 1 (2)
<i>Shigella sonnei</i>	2	
<i>Staphylococcus aureus</i>	2	
<i>Streptobacillus moniliformis</i>	2	
<i>Streptococcus pneumoniae</i>	2	
<i>Streptococcus pyogenes</i>	2	
<i>Streptococcus</i> spp.	2	
<i>Streptococcus suis</i>	2	95/30/EC - Art. 1
<i>Treponema carateum</i>	2	93/88/EEC - Art. 1 (2)
<i>Treponema pallidum</i>	2	
<i>Treponema pertenue</i>	2	
<i>Treponema</i> spp.	2	
<i>Vibrio cholerae</i> (including El Tor)	2	
<i>Vibrio parahaemolyticus</i>	2	
<i>Vibrio</i> spp.	2	
<i>Yersinia enterocolitica</i>	2	
<i>Yersinia pestis</i>	3	V
<i>Yersinia pseudotuberculosis</i>	2	
<i>Yersinia</i> spp.	2	

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

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VIRUS (*)			93/88/EEC - Art. 1 (2)
Biological agent	Classification	Notes	
<i>Adenoviridae</i>	2		
<i>Arenaviridae</i>			
LCM-Lassa-Virus Complex (Old World arena viruses):			97/59/EC - Art. 1
Lassa virus	4		
Lymphocytic choriomeningitis virus (neurotropic strains)	3		
Lymphocytic choriomeningitis virus (other strains)	2		
Mopeia virus	2		
Other LCM-Lassa complex viruses	2		
Tacaribe-Virus-Complex (New World arena viruses):			
Guanarito virus	4		
Junin virus	4		
Sabia virus	4		
Machupo virus	4		
Flexal virus	3		
Other Tacaribe complex viruses	2		
<i>Astroviridae</i>	2		93/88/EEC - Art. 1 (2)
<i>Bunyaviridae</i>			
Belgrade (also known as Dobrava)	3		97/59/EC - Art. 1
Bhanja	2		
Bunyamwera virus	2		93/88/EEC - Art. 1 (2)
Germiston	2		97/59/EC - Art. 1
Oropouche virus	3		93/88/EEC - Art. 1 (2)
Sin Nombre (formerly Muerto Canyon)	3		97/59/EC - Art. 1
California encephalitis virus	2		93/88/EEC - Art. 1 (2)
Hantaviruses:			
Hantaan (Korean haemorrhagic fever)	3		
Seoul virus	3		
Puumala virus	2		
Prospect Hill virus	2		
Other hantaviruses	2		
Nairoviruses:			
Crimean-Congo haemorrhagic fever	4		
Hazara virus	2		
Phleboviruses:			
Rift Valley fever	3	V	
Sandfly fever	2		
Toscana virus	2		
Other <i>bunyaviridae</i> known to be pathogenic	2		
<i>Caliciviridae</i>			
Hepatitis E virus	3 (**)		97/59/EC - Art. 1
Norwalk virus	2		93/88/EEC - Art. 1 (2)
Other <i>Caliciviridae</i>	2		
<i>Coronaviridae</i>	2		
<i>Filoviridae</i>			
Ebola virus	4		
Marburg virus	4		

Biological agent	Classification	Notes	
<i>Flaviviridae</i>			
Australia encephalitis (Murray Valley encephalitis)	3		
Central European tick-borne encephalitis virus	3 (**)	V	
Absettarov	3		
Hanzalova	3		
Hypr	3		
Kumlinge	3		
Dengue virus type 1-4	3		
Hepatitis C virus	3 (**)	D	
Hepatitis G virus	3 (**)	D	97/59/EC - Art. 1 (adapted)
Japanese B encephalitis	3	V	93/88/EEC - Art. 1 (2)
Kyasanur Forest	3	V	
Louping ill	3 (**)		
Omsk (a)	3	V	
Powassan	3		
Rocio	3		
Russian spring-summer encephalitis (TBE) (a)	3	V	
St Louis encephalitis	3		
Wesselsbron virus	3 (**)		
West Nile fever virus	3		
Yellow fever	3	V	
Other flaviviruses known to be pathogenic	2		
<i>Hepadnaviridae</i>			
Hepatitis B virus	3 (**)	V, D	
Hepatitis D virus (Delta) (b)	3 (**)	V, D	
<i>Herpesviridae</i>			
Cytomegalovirus	2		
Epstein-Barr virus	2		
Herpesvirus simiae (B virus)	3		
Herpes simplex virus types 1 and 2	2		
Herpesvirus varicella-zoster	2		
Human B-lymphotropic virus (HBLV-HHV6)	2		
<i>Human herpes virus 7</i>	2		97/59/EC - Art. 1
<i>Human herpes virus 8</i>	2	D	
<i>Orthomyxoviridae</i>			
Influenza viruses types A, B and C	2	V (c)	93/88/EEC - Art. 1 (2)
Tick-borne <i>orthomyxoviridae</i> : Dhori and Thogoto viruses	2		
<i>Papovaviridae</i>			
BK and JC viruses	2	D (d)	
Human papillomaviruses	2	D (d)	
<i>Paramyxoviridae</i>			
Measles virus	2	V	
Mumps virus	2	V	
Newcastle disease virus	2		
Parainfluenza viruses types 1 to 4	2		
Respiratory syncytial virus	2		
<i>Parvoviridae</i>			
Human parvovirus (B 19)	2		
<i>Picornaviridae</i>			
Acute haemorrhagic conjunctivitis virus (AHC)	2		
Coxsackie viruses	2		
Echo viruses	2		

Biological agent	Classification	Notes	93/88/EEC - Art. 1 (2)
Hepatitis A virus (human enterovirus type 72)	2	V	
Polioviruses	2	V	
Rhinoviruses	2		
<i>Poxviridae</i>			
Buffalopox virus (e)	2		
Cowpox virus	2		
Elephantpox virus (f)	2		
Milkers' node virus	2		
<i>Molluscum contagiosum</i> virus	2		
Monkeypox virus	3	V	
Orf virus	2		
Rabbitpox virus (g)	2		
Vaccinia virus	2		
Variola (major and minor) virus	4	V	
Whitepox virus (" <i>Variola virus</i> ")	4	V	
Yatapox virus (Tana & Yaba)	2		
<i>Reoviridae</i>			
Coltivirus	2		
Human rotaviruses	2		
Orbiviruses	2		
Reoviruses	2		
<i>Retroviridae</i>			
Human immunodeficiency viruses	3 (**)	D	95/30/EC - Art. 1
Human T-cell lymphotropic viruses (HTLV) types 1 and 2	3 (**)	D	95/30/EC - Art. 1
SIV (h)	3 (**)		95/30/EC - Art. 1
<i>Rhabdoviridae</i>			
Rabies virus	3 (**)	V	93/88/EEC - Art. 1 (2)
Visicular stomatitis virus	2		
<i>Togaviridae</i>			
Alfaviruses:			
Eastern equine encephalomyelitis	3	V	
Behar 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	3	V	
Western equine encephalomyelitis	3	V	
Other known alphaviruses	2		
Rubivirus (rubella)	2	V	
<i>Toroviridae</i>			
Unclassified viruses	2		
Equine morbillivirus	4		97/59/EC - Art. 1
<u>Hepatitis viruses not yet identified</u>			93/88/EEC - Art. 1 (2)
	3 (**)	D	97/59/EC - Art. 1

Biological agent	Classification	Notes
93/88/EEC – Art. 1 (2)		
<u>Unconventional agents associated with the transmissible spongiform encephalopathies (TSEs)</u>		
Creutzfeldt-Jakob disease	3 (**)	D
Variant Creutzfeldt-Jakob disease	3 (**)	D (d)
Bovine spongiform encephalopathy (BSE) and other related animal TSEs (i)	3 (**)	D (d)
Gerstmann-Sträussler-Scheinker syndrome	3 (**)	D (d)
Kuru	3 (**)	D (d)
97/65/EC – Art. 1		
97/65/EC – Art. 1		
93/88/EEC – Art. 1 (2)		
<p>(*) See paragraph 7 of the introductory notes.</p> <p>(**) See paragraph 8 of the introductory notes.</p> <p>(a) Tick-borne encephalitis.</p> <p>(b) Hepatitis D 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 D virus (Delta).</p> <p>(c) Only for types A and B.</p> <p>(d) Recommended for work involving direct contact with these agents.</p> <p>(e) Two viruses are identified: one a buffalopox type and the other a variant of the Vaccinia virus.</p> <p>(f) Variant of cowpox virus.</p> <p>(g) Variant of Vaccinia.</p>		
95/30/EC – Art. 1		
<p>(h) At the present there is no evidence of disease in humans caused by retroviruses of simian origin. As a precaution containment level 3 is recommended for work with them.</p>		
97/65/EC – Art. 1		
<p>(i) There is no evidence in humans of infections caused by the agents responsible for other animal TSEs. Nevertheless, the containment measures for agents categorised in risk group 3 (**) are recommended as a precaution for laboratory work, except for laboratory work relating to an identified agent of scrapie where containment level 2 is sufficient.</p>		

PARASITES

93/88/EEC - Art. 1 (2)

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>Ascaris lumbricoides</i>	2	A
<i>Ascaris suum</i>	2	A
<i>Babesia divergens</i>	2	
<i>Babesia microti</i>	2	
<i>Balantidium coli</i>	2	
<i>Brugia malayi</i>	2	
<i>Brugia pahangi</i>	2	
<i>Capillaria philippinensis</i>	2	
<i>Capillaria</i> spp.	2	
<i>Clonorchis sinensis</i>	2	
<i>Clonorchis viverrini</i>	2	
<i>Cryptosporidium parvum</i>	2	
<i>Cryptosporidium</i> spp.	2	
<i>Cyclospora cayetanensis</i>	2	95/30/EC - Art. 1
<i>Dipetalonema streptocera</i>	2	93/88/EEC - Art. 1 (2)
<i>Diphyllobothrium latum</i>	2	
<i>Dracunculus medinensis</i>	2	
<i>Echinococcus granulosus</i>	3 (**)	95/30/EC - Art. 1
<i>Echinococcus multilocularis</i>	3 (**)	95/30/EC - Art. 1
<i>Echinococcus vogeli</i>	3 (**)	95/30/EC - Art. 1
<i>Entamoeba histolytica</i>	2	
<i>Fasciola gigantica</i>	2	
<i>Fasciola hepatica</i>	2	
<i>Fasciolopsis buski</i>	2	
<i>Giardia lamblia</i> (<i>Giardia intestinalis</i>)	2	
<i>Hymenolepis diminuta</i>	2	
<i>Hymenolepis nana</i>	2	
<i>Leishmania brasiliensis</i>	3 (**)	95/30/EC - Art. 1
<i>Leishmania donovani</i>	3 (**)	95/30/EC - Art. 1
<i>Leishmania ethiopica</i>	2	
<i>Leishmania mexicana</i>	2	
<i>Leishmania peruviana</i>	2	
<i>Leishmania tropica</i>	2	
<i>Leishmania major</i>	2	
<i>Leishmania</i> spp.	2	
<i>Loa loa</i>	2	
<i>Mansonella ozzardi</i>	2	
<i>Mansonella perstans</i>	2	
<i>Naegleria fowleri</i>	3	
<i>Necator americanus</i>	2	
<i>Onchocerca volvulus</i>	2	
<i>Opisthorchis felinus</i>	2	
<i>Opisthorchis</i> spp.	2	
<i>Paragonimus westernani</i>	2	
<i>Plasmodium falciparum</i>	3 (**)	95/30/EC - Art. 1
<i>Plasmodium</i> spp. (human and simian)	2	
<i>Sarcocystis suihominis</i>	2	
<i>Schistosoma haematobium</i>	2	
<i>Schistosoma intercalatum</i>	2	
<i>Schistosoma japonicum</i>	2	

Biological agent	Classification	Notes	
<i>Schistosoma mansoni</i>	2	93/88/EEC - Art. 1 (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 (**)		95/30/EC - Art. 1
<i>Toxocara canis</i>	2		
<i>Toxoplasma gondii</i>	2		
<i>Trichinella spiralis</i>	2		
<i>Trichuris trichiura</i>	2		
<i>Trypanosoma brucei brucei</i>	2		
<i>Trypanosoma brucei gambiense</i>	2		
<i>Trypanosoma brucei rhodesiense</i>	3 (**)		95/30/EC - Art. 1
<i>Trypanosoma cruzi</i>	3		
<i>Wuchereria bancrofti</i>	2		

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

95/30/EC - Art. 1

FUNGI

93/88/EEC - Art. 1 (2)

Biological agent	Classification	Notes
<i>Aspergillus fumigatus</i>	2	A
<i>Blastomyces dermatitidis</i> (<i>Ajellomyces dermatitidis</i>)	3	
<i>Candida albicans</i>	2	A
<i>Candida tropicalis</i>	2	97/59/EC - Art. 1
<i>Cladophialophora bantiana</i> (formerly: <i>Xylohypha bantiana</i> , <i>Cladosporium bantianum</i> or <i>trichoides</i>)	3	
<i>Coccidioides immitis</i>	3	A
<i>Cryptococcus neoformans</i> var. <i>neoformans</i> (<i>Filobasidiella neoformans</i> var. <i>neoformans</i>)	2	A
<i>Cryptococcus neoformans</i> var. <i>gattii</i> (<i>Filobasidiella bacillispora</i>)	2	A
<i>Emmonsia parva</i> var. <i>parva</i>	2	
<i>Emmonsia parva</i> var. <i>crecens</i>	2	
<i>Epidermophyton floccosum</i>	2	A
<i>Fonsecaea compacta</i>	2	
<i>Fonsecaea pedrosoi</i>	2	
<i>Histoplasma capsulatum</i> var. <i>capsulatum</i> (<i>Ajellomyces capsulatus</i>)	3	
<i>Histoplasma capsulatum duboisii</i>	3	
<i>Madurella grisea</i>	2	
<i>Madurella mycetomatis</i>	2	
<i>Microsporium</i> spp.	2	A
<i>Neotestudina rosatii</i>	2	
<i>Paracoccidioides brasiliensis</i>	3	
<i>Penicillium mameffeii</i>	2	A
<i>Scedosporium apiospermum</i> (<i>Pseudallescheria boydii</i>)	2	97/59/EC - Art. 1
<i>Scedosporium prolificans</i> (<i>inflatum</i>)	2	
<i>Sporothrix schenckii</i>	2	93/88/EEC - Art. 1 (2)
<i>Trichophyton rubrum</i>	2	
<i>Trichophyton</i> 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 personalized 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 upon for each worker when he is the subject of health surveillance, in the light of the most recent knowledge available to occupational medicine.

90/679/EEC

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.

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A. Containment measures	B. Containment levels		
	2	3	4
1. The workplace is to be separated from any other activities in the same building	No	Recommended	Yes
2. 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
3. Access is to be restricted to nominated workers only	Recommended	Yes	Yes, via airlock
4. The workplace is to be sealable to permit disinfection	No	Recommended	Yes
5. Specified disinfection procedures	Yes	Yes	Yes
6. The workplace is to be maintained at an air pressure negative to atmosphere	No	Recommended	Yes
7. Efficient vector control e.g. rodents and insects	Recommended	Yes	Yes
8. Surfaces impervious to water and easy to clean	Yes, for bench	Yes, for bench and floor	Yes, for bench, walls, floor and ceiling
9. Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
10. Safe storage of a biological agent	Yes	Yes	Yes, secure storage
11. An observation window, or, alternative, is to be present, so that occupants can be seen	Recommended	Recommended	Yes
12. A laboratory is to contain own equipment	No	Recommended	Yes
13. Infected material including any animal is to be handled in a safety cabinet or isolator or other suitable containment	Where appropriate	Yes where infection is by airborne route	Yes
14. Incinerator for disposal of animal carcasses	Recommended	Yes (available)	Yes, on site

ANNEX VI

CONTAINMENT FOR INDUSTRIAL PROCESSES

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

Group 1 biological agents

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

Group 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.

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Containment measures	Containment levels		
	2	3	4
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:	Minimize 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:	Minimize 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 means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means
5. Seals should be designed so as to:	Minimize release	Prevent release	Prevent release
6. Closed systems should be located within a controlled area	Optional	Optional	Yes, and purpose-built
(a) Biohazard signs should be posted	Optional	Yes	Yes
(b) Access should be restricted to nominated personnel only	Optional	Yes	Yes, via an airlock
(c) Personnel should wear protective clothing	Yes, work clothing	Yes	A complete change
(d) Decontamination and washing facilities should be provided for personnel	Yes	Yes	Yes
(e) Personnel should shower before leaving the controlled area	No	Optional	Yes
(f) Effluent from sinks and showers should be collected and inactivated before release	No	Optional	Yes
(g) The controlled area should be adequately ventilated to minimize air contamination	Optional	Optional	Yes

Containment measures	Containment levels		
	2	3	4
(h) The controlled area should be maintained at an air pressure negative to atmosphere	No	Optional	Yes
(i) Input air and extract air to the controlled area should be HEPA filtered	No	Optional	Yes
(j) The controlled area should be designed to contain spillage of the entire contents of the closed system	No	Optional	Yes
(k) The controlled area should be sealable to permit fumigation	No	Optional	Yes
(l) Effluent treatment before final discharge	Inactivated by validated means	Inactivated by validated chemical or physical means	Inactivated by validated chemical or physical means

ANNEX VII

93/88/EEC - Art. 1 (3)

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.
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ANNEX VIII

PART A

**Repealed Directive with with its successive amendments
(referred to by 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)

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, 1 st paragraph, point (a)
Article 2, point (b)	Article 2, 1 st paragraph, point (b)
Article 2, point (c)	Article 2, 1 st paragraph, point (c)
Article 2, point (d)	Article 2, 2 nd paragraph
Article 3 (1)	Article 3 (1)
Article 3 (2) (a)	Article 3 (2), 1st subparagraph
Article 3 (2) (b)	Article 3 (2), 2nd subparagraph
Article 3 (2) (c)	Article 3 (2), 3rd subparagraph
Article 3 (2) (d)	Article 3 (2), 4th subparagraph
Article 3 (3), 1st indent	Article 3 (3) (a)
Article 3 (3), 2nd indent	Article 3 (3) (b)
Article 3 (3), 3rd indent	Article 3 (3) (c)
Article 3 (3), 4th indent	Article 3 (3) (d)
Article 3 (3), 5th indent	Article 3 (3) (e)
Article 4	Article 4
Article 5	Article 5
Article 6	Article 6
Article 7 (1), 1st indent	Article 7 (1) (a)
Article 7 (1), 2nd indent	Article 7 (1) (b)
Article 7 (1), 3rd indent	Article 7 (1) (c)
Article 7 (1), 4th indent	Article 7 (1) (d)
Article 7 (1), 5th indent	Article 7 (1) (e)
Article 7 (1), 6th 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), 1st subparagraph
Article 8 (2) (b)	Article 8 (2), 2nd subparagraph
Article 8 (3)	Article 8 (3)
Article 9 (1) (a) to (c)	Article 9 (1) (a) to (c)
Article 9 (2), 1st indent	Article 9 (2) (a)
Article 9 (2), 2nd indent	Article 9 (2) (b)
Article 9 (2), 3rd indent	Article 9 (2) (c)
Article 10 (1), 1st indent	Article 10 (1) (a)
Article 10 (1), 2nd indent	Article 10 (1) (b)
Article 10 (2) to (6)	Article 10 (2) to (6)
Article 11 (1)	Article 11 (1)
Article 11 (2), 2nd subparagraph, 1st indent	Article 11 (2), 2nd subparagraph, (a)
Article 11 (2), 2nd subparagraph, 2nd indent	Article 11 (2), 2nd subparagraph, (b)
Article 11 (2), 2nd subparagraph, 3rd indent	Article 11 (2), 2nd subparagraph, (c)

Directive 90/679/EEC	This Directive
Article 11 (2), 2nd subparagraph, 4th indent	Article 11 (2), 2nd subparagraph, (d)
Article 11 (2), 2nd subparagraph, 5th indent	Article 11 (2), 2nd subparagraph, (e)
Article 11 (3)	Article 11 (3)
Article 12	Article 12
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Article 14 (9)	Article 14 (9)
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Article 16 (2) (b)	Article 16 (2) (b)
Article 16 (2) (c)	Article 16 (3)
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ISSN 0254-1475

COM(1999) 432 final

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04 05 15 11

Catalogue number : CB-CO-99-440-EN-C

Office for Official Publications of the European Communities
L-2985 Luxembourg