

**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)**

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),

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty(2),

Whereas:

(1) 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)(3) has been substantially amended on a number of occasions(4). For the sake of clarity and rationality Directive 90/679/EEC should be codified.

(2) 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 essential to ensure the safety and health of workers.

(3) 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(5). 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.

(4) More precise knowledge of the risks involved in exposure to biological agents can be obtained through the keeping of records.

(5) The list and classification of the biological agents must be examined regularly and revised on the basis of new scientific data.

(6) For a number of biological agents details additional to their classification should be given.

(7) Employers must keep abreast of new developments in technology with a view to improving the protection of workers' health and safety.

(8) Preventive measures should be taken for the protection of the health and safety of workers exposed to biological agent.

(9) This Directive constitutes a practical aspect of the realisation of the social dimension of the internal market.

(10) Pursuant to Council Decision 74/325/EEC(6) 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. It was so consulted over the formulation of proposals for the Council directives embodied in this Directive.

(11) 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:

## 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(7) and of Council Directive 90/220/EEC(8).

#### 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:
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.

### 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.

## 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.

## 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 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.

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 minimise 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;

(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.

## 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.

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.

## 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

### 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

### 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 recrudescence 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.

## 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.

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.

## 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 minimise 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 minimise 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.

(b) 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 which they adopt in the field governed by this Directive.

## 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 its publication in the Official Journal of the European Communities.

## Article 23

### Addresses

This Directive is addressed to the Member States.

Done at Brussels, 18 September 2000.

For the European Parliament

(4) See Annex VIII, part A.

(5) OJ L 183, 29.6.1989, p. 1.

(6) OJ L 185, 9.7.1974, p. 15; Decision as last amended by the 1994 Act of Accession.

(7) 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).

(8) 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).

## 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 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.

Article 2, second paragraph, and Article 18

## INTRODUCTORY NOTES

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

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

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

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

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

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

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

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

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

For 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 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 when it is advisable to keep a list of exposed workers for more than 10 years.