II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

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)

(90/679/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 118a thereof,

Having regard to the proposal from the Commission (1), drawn up after consulting the Advisory Committee on Safety, Hygiene and Health Protection at Work,

In cooperation with the European Parliament (2)

Having regard to the Opinion of the Economic and Social Committee (3),

Whereas Article 118a of the Treaty provides that the Council shall adopt, by means of Directives, minimum requirements in order to encourage improvements, especially in the working environment, so as to guarantee better protection of the health and safety of workers;

Whereas that Article provides that such Directives shall avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings;

Whereas the Council Resolution of 27 February 1984 on a second action programme of the European Communities on safety and health at work (4) provides for the development of protective measures for workers exposed to dangerous agents;

Whereas the communication from the Commission on its programme concerning safety, hygiene and health at work (5) provides for the adoption of Directives to guarantee the safety and health of workers;

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 essential to ensure the safety and health of workers;

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 (6); 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 the present Directive;

Whereas more precise knowledge of the risks involved in exposure to biological agents at work can be obtained through the keeping of records;

Whereas employers must keep abreast of new developments in technology with a view to improving the protection of workers' health and safety;

(1) OJ No C 150, 8. 6. 1988, p. 6.
(2) OJ No C 158, 26. 6. 1989, p. 92.
(3) OJ No C 56, 6. 3. 1989, p. 38.
(4) OJ No C 67, 8. 3. 1984, p. 2.
(5) OJ No C 28, 3. 2. 1988, p. 1.
(6) OJ No L 183, 29. 6. 1989, p. 1.

Whereas preventive measures should be taken for the protection of the health and safety of workers exposed to biological agents;

Whereas this Directive constitutes a practical aspect of the realization of the social dimension of the internal market;

Whereas, pursuant to Decision 74/325/EEC (1), the Advisory Committee on Safety, Hygiene and Health Protection at Work is consulted by the Commission on the drafting of proposals in this field,

HAS ADOPTED THIS DIRECTIVE:

SECTION I

GENERAL PROVISIONS

Article 1

Objective

1. This Directive, which is the seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC, 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 of 23 April 1990 on the contained use of genetically modified micro-organisms (2) and of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (3).

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;

(d) '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. (a) 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.

(b) 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.

(1) OJ No L 185, 9. 7. 1974, p. 15.
(2) OJ No L 117, 8. 5. 1990, p. 1.
(3) OJ No L 117, 8. 5. 1990, p. 15.

(c) 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.

(d) 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:

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

— 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;

— information on diseases which may be contracted as a result of the work of the workers;

— potential allergenic or toxigenic effects as a result of the work of the workers;

— 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, Aricles 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.

SECTION 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 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 a risk to workers' health or safety, employers shall, when requested, make available to the competent authority appropriate information on:

— the results of the assessment;

— the activities in which workers have been exposed or may have been exposed to biological agents;

— the number of workers exposed;

— the name and capabilities of the person responsible for safety and health at work;

— the protective and preventive measures taken, including working procedures and methods;

— an emergency plan for the protection of workers from exposure to a 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. (a) 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 subparagraph (b), kept separately from other clothing.

(b) 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:

— given at the beginning of work involving contact with biological agents,

— adapted to take account of new or changed risks, and

— 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 serious accident or incident involving the handling of a biological agent;

— 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:

— with biological agents known to be capable of establishing persistent or latent infections,

— that, in the light of present knowledge, are undiagnosable until illness develops many years later,

— that have particularly long incubation periods before illness develops,

— that result in illnesses which recrudesce at times over a long period despite treatment, or

— 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 including the Annexes 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:

— group 2 biological agents,