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)

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 speciments 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 biologial 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 tobe 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.