II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive on the protection of workers from the risks related to exposure to biological agents at work

COM(88) 165 final

(Submitted by the Commission on 19 April 1988)

(88/C 150/05)

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, established following consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work,

In cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

Whereas Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work [1], as amended by the Act of Accession of Spain and Portugal, provides for Directives for certain agents;

Whereas, under the terms of the said Directive, such protection should, as far as possible, be ensured by measures to prevent exposure or to keep it at as low a level as is reasonably practicable;

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;

Whereas it is necessary, in order to ensure the highest degree of protection reasonably practicable, that workers and their representatives be informed about the risks which biological agents can pose for their health, and the measures necessary to lessen or eliminate those risks and that they should be in a position to ensure that the necessary protective measures are taken;

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

HAS ADOPTED THIS DIRECTIVE:

Objective

Article 1

1. The purpose of this Directive is to protect workers against risks to their health and safety, and to prevent such risks arising or likely to arise from exposure to biological agents at work.

2. This Directive shall apply to all workers with the exception of workers engaged in sea transport and in air transport.

For the purposes of this Directive 'workers engaged in sea transport and in air transport' means personnel on board.

Definitions

Article 2

For the purposes of this Directive:

(a) 'Biological agents' are micro-organisms including those which have been genetically manipulated, cell cultures and multicellular human endoparasites.

[1] OJ No L 327, 3. 12. 1980, p. 8.

(b) A 'Group 1' biological agent is one that is most unlikely to cause human disease. It does not produce infection and is unlikely to spread in the community. This definition includes any genetically modified biological agent which fulfils the criteria for good microbiological practice as laid down in Annex I.

(c) A 'Group 2' biological agent is one that may cause human disease and might be a hazard to workers. It rarely produces infection. It is unlikely to spread in the community and there is usually effective prophylaxis or treatment available.

(d) A 'Group 3' biological agent is one that may cause severe human disease and presents a serious hazard to workers. It may present a risk of spread in the community but there is usually effective prophylaxis or treatment available.

(e) A 'Group 4' biological agent is one that causes severe human disease and is a serious hazard to workers. It may present a high risk of spread in the community and there is usually no effective prophylaxis or treatment available.

(f) 'Micro-organism' is any microscopic unicellular or subcellular biological entity capable of replication.

(g) 'Genetically modified biological agent' is an organism derived by the techniques of genetic manipulation.

(h) 'Genetic manipulation' is the formation of a new combination of genetic material by the insertion of nucleic acid molecules produced by whatever means outside the cell, into any virus, bacterial plasmid or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.

(i) 'Cell culture' is the *in vitro* growth of cells isolated from multicellular organisms.

(j) 'Incidental exposure to biological agents' is any work activity or sector of activity in which there is no deliberate intention to handle or use biological agents but where the work activity may result in workers being exposed to biological agents, including contact with animals and animal products where there may be a risk of exposure to zoonotic agents, and sewage and health care activities where there may be a risk of exposure to persons or pathological material with infectious disease.

(k) 'Conscious decision to work with biological agents' is any work activity or sector of activity in which the purpose of the work is to handle or use biological agents, including work in research laboratories or industrial processes employing biological agents.

Assessment

Article 3

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

2. In the case of any activity or sector of activity likely to involve a risk of exposure to biological agents the risk must be assessed. Member States shall fix the conditions of this assessment and of any further assessment, if necessary, and shall determine by whom it is to be conducted. The assessment shall be conducted so as to determine the nature and degree of the:

— inherent hazard of a biological agent to health,

— risk of workers' exposure or potential exposure, including a determination of whether this involves either incidental exposure, or a conscious decision to work with biological agents,

— risk of transfer from the workplace to the community;

— risk of further spread within the community.

This assessment shall not apply to genetically modified biological agents which have been notified in accordance with the provisions of Council Directive .../.../EEC [on deliberate release into the environment of genetically modified organisms].

3. The identification of a biological agent as being hazardous to health shall be based on all available information including:

— a disease from which a worker is found to be suffering which has a direct connection with his work activity and/or epidemiology which indicates that a biological agent has been a source of human infection and/or illness,

— guidelines issued by a responsible authority which indicate that a biological agent should be controlled in some way in order to prevent human infection and/or illness when workers are or are potentially exposed to such an agent as a result of their work activity.

4. Biological agents shall be assessed on the basis of the maximum degree of hazard, unless there is evidence, in individual cases, that the degree of hazard is lower.

The assessment of a genetically modified biological agent shall be made, when appropriate, on the same basis.

5. This Directive shall apply without prejudice to the provisions of Council Directive .../.../EEC on the contained use of genetically modified micro-organisms.

6. Articles 4 to 17, with the exception of the first indent of Article 9, shall not apply if the assessment referred to in paragraph 2 shows that the exposure and/or potential exposure is to a Group 1 biological agent or to a biological agent which causes disease only in animals and/or in plants and that there is no identifiable health risk to workers.

7. Articles 6 to 14 shall not apply if the assessment referred to in paragraph 2 shows that the work activities involve only incidental exposure to biological agents.

General provisions applicable to work activities which involve both incidental exposure to biological agents and a conscious decision to work with biological agents

Article 4

The risk of workers' exposure must be avoided. Where this is not reasonably practicable, having regard to the work activity and the risk assessment referred to in Article 3 (2) exposure shall be reduced to as low a level as is 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 when appropriate:

(a) the limitation of the number of workers exposed or potentially exposed;

(b) the prevention of exposure or its adequate control by the appropriate design of work processes and/or the use of engineering control measures;

(c) collective protection measures including the use and maintenance of adequate equipment;

(d) personal protection measures, where exposure cannot reasonably be avoided by other means;

(e) hygiene measures designed to prevent the accidental transfer or release of a biological agent from the workplace;

(f) the provision of up-to-date information on biological agents which are or may be present at the workplace together with a continuing programme of adequate training for workers;

(g) use of a biohazard sign (Annex II) and other warning signs;

(h) emergency procedures designed to minimize workers' exposure resulting from a serious accident or incident.

Article 5

1. At the beginning of employment and at regular intervals thereafter, the workers shall receive up-to-date information together with adequate instruction, so that they are made aware of all the requirements laid down in Article 4.

2. Appropriate measures shall be taken to ensure that workers and/or any workers' representatives in the undertaking or establishment receive explanations on the potential risks to health from exposure to biological agents, the hygiene requirements, and the emergency procedures designed to minimize workers' exposure resulting from a serious accident or incident.

Additional provisions applicable to work activities which involve a conscious decision to work with biological agents

Article 6

1. Appropriate measures shall be taken so far as is reasonably practical for the protection of the health and safety of workers by providing that:

(a) areas are set aside where workers can eat and drink without risking contamination by biological agents;

(b) workers are provided with appropriate protective clothing or other appropriate special clothing;

(c) separate storage places are provided for working or protective clothing and for street clothes;

(d) protective respiratory equipment is placed in a well-defined place and is checked, if possible before, and in any case after each use; defective equipment shall be repaired or replaced before further use.

2. Working clothes and personal protective equipment, including protective clothing which may be contaminated by biological agents, must be removed on leaving the working area and stored separately from other clothing. The employer must ensure that such clothing and personal protective equipment are disinfected, cleaned or, if necessary, destroyed.

3. Workers who handle biological agents must be provided with skin and eye antiseptics, suitable washing facilities and, if appropriate, showers.

4. Workers may not be charged for the cost of measures taken pursuant to paragraphs 1, 2 and 3.

Article 7

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

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

3. The doctor and/or the authority responsible for health and safety at work shall have access to the records referred to in paragraph 1.

4. Each worker shall have access to information in the records which relates to him personally.

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

Article 8

1. The use of a Group 3 or 4 biological agent shall be avoided, as far as is reasonably practicable, by its replacement by a less hazardous or non-hazardous agent.

2. Suppliers or importers of a Group 3 or 4 biological agent for use at work shall ensure that they are adequately described, packed and transported.

Article 9

Employers shall on request make available to the responsible authorities appropriate information on:

— the results of the assessment referred to in Article 3 (2),

— the activities in which workers have been exposed or potentially exposed to biological agents,

— the number of workers exposed,

— the name 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 4 biological agent which might result from a loss of physical containment.

Article 10

1. Without prejudice to Directive .../.../EEC on the deliberate release of genetically modified organisms, employers shall give a prior notification to the responsible authority, at least 60 days before:

— an intention to carry out genetic manipulation work or to work with a genetically modified biological agent in Group 2, 3 or 4,

— an intention to introduce substantial changes to a procedure which has already been notified,

— work with a Group 4 biological agent, or if there is an intention to handle, store or transport such an agent.

2. In the case of genetic manipulation work, or work with a genetically modified biological agent, prior notification shall include the name and address of the undertaking and/or establishment and the name of the person responsible for safety and health at work.

In the case of a Group 4 biological agent prior notification shall include:

— the result of the assessment referred to in Article 3 (2),

— the name of the biological agent,

— the protection and preventive measures that are envisaged,

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

3. Employers shall inform forthwith the responsible authority of any accident or incident that may have resulted in the release of any biological agent such that it could cause severe human infection and/or illness.

Article 11

1. Employers shall display written instructions at the workplace which shall include the procedure to be used in the case of:

— a serious accident or incident,

— work with a Group 4 biological agent.

2. A serious accident or incident shall be reported immediately to and recorded by the person responsible for the work.

3. Workers and/or any workers' representatives in the undertaking or establishment shall be informed 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.

Article 12

1. The specific rules for the health surveillance of workers shall be established by Member States in accordance with national law and practice.

2. Members States shall make arrangements to ensure that, where relevant, each worker can undergo an assessment of his state of health prior to potential exposure. This assessment should be such that it is directly possible to implement individual and hygiene measures.

3. Where relevant, the assessment referred to in paragraph 2 should identify those workers for whom special protective measures may be required. When appropriate, 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 potentially exposed.

4. If a worker is found to be suffering from an infection and/or illness which is suspected of being the result of exposure, the doctor or authorities responsible for health surveillance may decide that other workers similarly exposed shall undergo assessments of their state of health, and may require a reassessment of the risk of exposure as referred to in Article 3 (2).

5. When the assessments referred to in this Article have been made, an individual health record shall be kept for at least 10 years following the end of exposure, in accordance with national laws and practice.

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

6. The worker concerned or the employer may request a review of the assessments referred to in this Article, in accordance with national laws and practice.

Special measures for health care facilities and diagnostic laboratories

Article 13

1. Specific measures shall be taken for health care facilities, in particular isolation and *post-mortem* units, and clinical, veterinary and diagnostic laboratories.

2. For the purposes of the assessment referred to in Article 3 (2), particular attention shall be paid to:

— uncertainties about the presence of biological agents in the materials and specimens being investigated,

— the hazard of biological agents known or suspected to be present in the materials or specimens,

— the risk posed by the nature of the work activity.

3. The specific measures listed in Annex III for the physical containment of biological agents shall be applied, when appropriate.

Special measures for industrial processes, laboratories and animal rooms

Article 14

1. Specific measures shall be taken for industrial processes, animal rooms and laboratories, excluding clinical, veterinary and diagnostic laboratories in order to ensure the physical containment of a Group 2, 3 or 4 biological agent.

For this purpose Member States shall classify biological agents using the definitions in Article 2 (c), (d) and (e) relating respectively to a Group 2, 3 or 4 biological agent.

2. Following the assessment referred to in Article 3 (2), special measures shall be taken as laid down in Annex III after matching the physical containment level for biological agents with the degree of risk.

For this purpose work activities involving:

— a Group 2 biological agent may be carried out only in working areas corresponding to at least the physical containment level 2,

— a Group 3 biological agent may be carried out only in working areas corresponding to at least the physical containment level 3,

— a Group 4 biological agent may be carried out only in working areas corresponding to the physical containment level 4.

3. When the volume of the biological agents which are being handled in Groups 2 and/or 3 justifies it, the physical containment level shall be increased, when appropriate, to at least the level 3 or 4 respectively, in order to ensure that the health and safety risks are minimized.

4. In an industrial process in which there is adequate physical containment of biological agents by means of a closed system, the specific measures listed in points 1 and 2 of Annex III shall be applied only when appropriate.

5. In the case of a biological agent in respect of which a conclusive assessment has not yet been possible as referred to in Article 3 (2), but the indications are that a risk to health might arise from the proposed use, then work activities may be carried out only in working areas corresponding to at least the physical containment level 3.

6. The additional measures required for laboratories and animal rooms are listed in Annex IV.

Final provisions

Article 15

The Annexes to this Directive may be adapted to technical progress in accordance with the procedure set out in Article 10 of Directive 80/1107/EEC.

Article 16

Member States shall ensure that workers and/or workers' representatives where they exist in an undertaking or establishment are consulted on the provisions referred to in this Directive and that they can be involved in their application.

Article 17

1. Member States shall keep national statistics of recognized cases of serious illness or death due to exposure to biological agents at work.

2. Member States shall publish up-to-date and appropriate information on occupational diseases caused by biological agents.

Article 18

1. Member States shall adopt the laws, regulations and administrative provisions necessary to comply with this Directive before 1 January 1992. They shall immediately inform the Commission thereof.

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

Article 19

This Directive is addressed to the Member States.

ANNEX I

For genetically modified micro-organisms the criteria have to be established which permit a comparison of such micro-organisms with natural micro-organisms, in order to be able to determine to which group they belong and therefore which level of physical confinement should be applied.

In this Annex the following definitions are given:

— 'Host organism' is the organism into which donor DNA is inserted in rDNA constructions; it provides the major portion of the genome of the rDNA organism; same as recipient.

— 'Vector' is an agent of transmission; for example a DNA vector is a self-replicating molecule of DNA that transmits genetic information from one cell or organism to another. Plasmids (and some viruses) are used as 'vectors' for DNA in bacterial cloning.

The genetically modified micro-organism will have essentially the properties of the host, the genetic material of which is most often found integrated in the genetically modified micro-organism with only one foreign fragment more.

The following table sets out the criteria for good microbiological practice (GMP) as referred to in Article 2 (b) for a genetically modified biological agent:

Host organism	rDNA engineered organism	Vector/insert
Non-pathogenic	Non-pathogenic	Well characterized and free from known harmful sequences
No adventitious agents	As safe in industrial setting as host organism, but with limited survival without adverse consequences for human health	Limited in size as much as possible to the DNA required to perform the intended function; should not increase the stability of the construct (unless that is a requirement of the intended function)
Extended history of safe industrial use; or		Should be poorly mobilizable
Built-in limitations permitting optimal growth in industrial setting but limited survival without adverse consequences outside the industrial setting		Should not transfer any resistance markers to micro-organisms not known to acquire them naturally (if such acquisition could compromise use of drug to control disease agents)

There are two clear examples of other classes of organisms that warrant the GMP designation unless they are pathogenic:

(i) those constructed entirely from a single prokaryotic host (including its indigenous plasmids and viruses) or from a single eukaryotic host (including its choroplasts, mitochondria or plasmids — but excluding viruses —); and

(ii) those consisting entirely of DNA segments from different species that exchange DNA by known physiological processes.

For the purpose of this table, 'non-pathogenic' means an agent which does not cause human disease.

ANNEX II

Biohazard sign as referred to in Article 4 (g)

ANNEX III

The specific measures required at each of the three physical containment levels, as referred to in Articles 13 (3) and 14 (2), (3), (4) and (5)

Specific measures	Containment levels		
	1	2	3
1. The workplace is to be in an isolated part of a building and separated by an anteroom with two doors	Recommended	Yes	Yes
2. Input air and extract air to the workplace are to be filtered using HEPA or similar	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 an 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. Collection and treatment of effluents	No	Recommended	Yes
9. Surfaces impervious to water	Yes, for bench	Yes, for bench and floor	Yes, for bench, floor and ceilings
10. Surfaces resistant to acids, alkalis, solvents, disinfectants	Recommended	Yes	Yes
11. Safe storage of a biological agent	Recommended	Yes	Yes, secure storage

ANNEX IV

The additional measures required at each of the three physical containment levels for laboratories and animal rooms, as referred to in Article 14 (6)

Specific measures	Containment levels		
	1	2	3
1. An observation window, or alternative, is to be present, so that occupants can be seen	Recommended	Recommended	Yes
2. A laboratory is to contain own equipment	No	Recommended	Yes
3. A microbiological safety cabinet is to be used	Recommended	Yes	Yes, with glove ports
4. Infected material including any animal is to be handled in a safety cabinet or isolator	Recommended	Yes	Yes
5. Autoclave or incinerator for animals	Recommended	Yes	Yes