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Proposal for a
COUNCIL DIRECTIVE

ON THE PROTECTION OF WORKERS FROM THE RISKS RELATED
TO EXPOSURE TO BIOLOGICAL AGENTS AT WORK

(presented by the Commission)

**PROPOSAL FOR A COUNCIL DIRECTIVE
ON THE PROTECTION OF WORKERS FROM THE RISKS RELATED
TO EXPOSURE TO BIOLOGICAL AGENTS AT WORK**

EXPLANATORY MEMORANDUM

1. Introduction

The Communication of the Commission of the European Communities on its programme concerning safety, hygiene and health at work (1) stated that it intended to make a proposal for a Directive on biological agents which affect health, such as pathogenic microorganisms, and genetic engineering techniques which may present a risk to health.

A strategy for controlling dangerous agents was adopted under Council Directive 80/1107/EEC covering all chemical, physical and biological agents at the workplace. Several Council Directives have been adopted on chemical agents and one on a physical agent (noise). The Commission has not yet proposed specific measures for biological agents.

It has, however, been proved that many biological agents are harmful to health, and hence that exposure to these agents increases the risk of disease. Workers can become exposed to these agents in a wide variety of activities, such as :

- research and development laboratories,
- hospital isolation units,
- clinical, veterinary and diagnostic laboratories,
- certain branches of industry.

(1) Com (520) final

It is particularly important that workers in the above-mentioned areas of activity are exposed to biological agents as little as possible, if at all, in order to prevent them from developing infections or diseases.

2. Summary of regulations on exposure to biological agents at work in the various Member States

Most Member States recognize the need to protect workers against the risks related to exposure to biological agents. This matter has become more important with the development of biotechnologies in which biological agents that are dangerous for people can be used or produced.

However, this question is dealt with in a different way in the national legislation of each Member State. In some cases, national legislation does not provide for any specific measures. The measures which do exist are mostly of a general nature and provide some legal protection against the effects of biological agents. Other Member States already apply quite detailed legislation, but this often proves to be inadequate in some areas, particularly as regards biotechnologies.

The proposal for a Directive referred to here aims to protect workers against the risks to their health and safety arising from exposure to biological agents and thus to promote the progressive harmonization of existing requirements in the Member States in this field.

The main regulations currently in force in the Member States on exposure to biological agents at work are described below.

BELGIUM

A safety survey must be carried out and safety instructions drawn up before a new process or activity is used at work which is likely to pose a threat to the health of workers due to the presence of biological agents.

Employers are obliged to take measures to eliminate or reduce the danger to workers if there is an obvious risk of exposure to biological agents.

Medical examinations are carried out and workers are given information on protective measures.

Lastly, there are specific provisions for pregnant women, and for workers under the age of 18, as well as for vaccinating workers handling skin and hair of animal origin against smallpox and tetanus.

FEDERAL REPUBLIC OF GERMANY

List of the relevant legal provisions and directives in force in the Federal Republic of Germany concerning biological agents :

Law on the prevention and control of communicable human diseases (Bundes-Seuchengesetz) in its published version of 18 December 1979 (Bundesgesetzblatt I p. 2262, 1980 p. 151), most recently amended by the Law of 27 June 1985 (BGBl I p. 1254) chap. 3, 8, 9, 19-29.

Regulations on pathogens of 21 November 1917 (published in Reichsgesetzblatt p. 1069, BGBl III p. 2126-1-1) chap. 1, 2.

Law reforming the legislation on pharmaceuticals of 24 August 1976 (BGBl I p. 2445), amended by the Law of 24 February 1983 (BGBl I p. 169) chap. 4, 13-20, 32, 35.

Law on livestock epidemics, in its published version of 28 March 1980 (BGBl I p. 386) chap. 10.

Order concerning the importation of live animal pathogens and vaccines containing them (Tierseuchenerreger-Einfuhrverordnung) of 7 December 1971 (BGBl I p. 1960, most recently amended by the amending order of 19 July 1983 BGBl I p. 958).

Order concerning working with animal pathogens (Tierseuchenerreger-Verordnung) of 25 November 1985 (BGBl I p. 2123).

Order concerning dangerous substances (Gefahrstoffverordnung) of 26 August 1986 (BGBl I p. 1470) chap. 14-36.

Law on works doctors, safety engineers and other experts on occupational safety (Arbeitssicherheitsgesetz) of 12 December 1973 (BGBl I p. 1885).

Directives on protection from hazards presented by nucleic acids formed by in vitro recombination (fifth revision), Bundesanzeiger No 109 of 20 June 1986.

Accident prevention regulations :

- Works doctors VBG 123
- Occupational preventive medicine VBG 100 (and implementing orders)
- Health service VBG 103
- Biotechnology VBG 102

DENMARK

There are specific regulations for sewage work, including provisions for certain vaccinations (polio and tetanus), and for genetic engineering, including those specifying containment levels for a prior risk assessment, which also involves classification of the biological agent concerned.

Other areas of work activity in which there is a risk of exposure to biological agents are covered by the general provisions of Danish law on the working environment and the protection of workers. Under these provisions employers must ensure that the working environment is safe and that it does not constitute a risk to health of workers.

The Danish Ministry of Public Health is publishing guidelines and recommendations of the risks of infection with contagious diseases such as hepatitis B and AIDS. Since these guidelines are mainly concerned with the protection of public health, they outline general hygiene measures and do not take the specific conditions of some workers into consideration.

SPAIN

In addition to provisions of a general nature on the health of workers (general health law) and on occupational diseases, regulations have been adopted on medical examinations and the organization of medical services, as well as on industrial medical services.

Preventive measures are included in the general regulation on hygiene and safety at work and in the general law on social security.

Several specific provisions are contained in the general regulations on sanitary measures for foodstuffs (codex alimentarius), medico-therapeutic equipment, preventive medicine and hygiene in hospitals, abattoirs and meat which is intended for export to other Member States. The legislation also includes an obligation to provide notification of some infectious diseases.

Lastly, a law has been passed on toxic and dangerous waste.

FRANCE

General regulations on hygiene and health apply.

These provide specifically for

- all types of pollutants which can be released in work areas to be collected at source;
- the atmosphere of workrooms to be protected from all sources of infection;
- the cleaning of rooms in which organic substances are handled;
- the availability of showers for dirty or unhealthy work.

In addition, every new product which comes onto the market must be studied and appraised by the relevant authorities.

GREECE

There is no specific legislation governing the exposure of workers to biological substances.

However, Chapter 5 of General Law No 1568/85 on the hygiene and safety of workers contains articles on the general principles for preventing occupational diseases, including those resulting from biological agents.

Special legislation is planned for tanneries, abattoirs and meat shops. In addition, commissions on infectious in hospitals are responsible for applying codes of practice.

No data are available on the number of workers concerned and the type of biological substances to which they are exposed.

IRELAND

Under public health legislation, the Director of Community Care (Medical Officer of Health) can make enquiries about the spread in the community of biological agents that can involve a risk. There is also some factory legislation (worker protection) relating specifically to anthrax (wool and hair, hides and skins).

ITALY

Occupational safety legislation in Italy does not include a comprehensive set of preventive or protective measures for workers exposed to risks from biological agents at work. Presidential Decree No 303 of 19 March 1956, entitled "General regulations governing occupational hygiene", provides for periodic preventive medical examinations for workers exposed to the risk of leptospirosis (for those working in sewers, canals and marshland), ankylostomiasis (for those working underground and in brick furnaces), carbuncles and glanders (for those working in veterinary hospitals, slaughterhouses, carcass dumps, tanning factories, rendering plants and for those involved in the collection of animal waste), tuberculosis and syphilis (for those working in non-mechanized glass blowing).

Under Laws No 292 of 5 March 1963 and No 149 of 20 March 1968, as well as the Health Ministry Decrees of 16 and 22 September 1975, farmhands, shepherds, livestock farmers, stablehands, jockeys, people involved in tending racecourse tracks, refuse collectors, platelayers, roadworkers, building workers, asphalters, rag-and-bone men, refuse handlers, paper and board manufacturers and railway, harbour and dock workers are all required to have an anti-tetanus vaccination. Lastly, Law No 1033 of 14 December 1970 on financial measures to combat tuberculosis prescribes vaccination for workers in hospitals, clinics and psychiatric hospitals (and for their families), medical students and soldiers with a negative cutireaction.

LUXEMBOURG

General provisions are contained in the basic Law of 28 August 1924 on the health and safety of workers in factories, industrial and commercial enterprises, and of those employed in construction, development, repair or excavation work. More specific decrees have been issued on the basis of this law.

Moreover, the Law of 16 April 1979 on dangerous, unhealthy or unpleasant working premises provides for operating licences to be granted for such premises on a case-by-case basis.

NETHERLANDS

The Law on the working environment includes general provisions on occupational health care and the safety of workers.

There are no specific national provisions on the protection of workers against biological agents, but preparatory work is being carried out in this area.

PORTUGAL

A Statutory Order on the production, import, marketing and use of biological products intended for veterinary usage was published in 1987.

Provision has been made for compulsory vaccinations against tetanus under certain circumstances.

Lastly, there is compulsory notification in the case of some occupational diseases resulting from exposure to certain microbiological agents.

UNITED KINGDOM

The Health and Safety at Work Act (HSW) provides a general framework for health and safety at work. The Dangerous Pathogens and Genetic Manipulation Regulations impose only notification requirements. At the moment, detailed guidance on the assessment and control of hazards from biological agents is produced by the Health and Safety Executive (HSE) in the form of notes and codes of practice drawn up under the aegis of advisory committees (the Advisory Committee on Dangerous Pathogens and the Advisory Committee on Genetic Manipulation).

The requirements of the HSW Act of 1974 apply to biological agents, in particular Sections 2 (under which it is the duty of every employer to ensure, as far as is reasonably practicable, the health and safety of all his or her employees) and 3 thereof (which stipulates that employers and the self-employed must conduct their undertakings so as to ensure, as far as is reasonably practicable, that persons not in their employment, who may be affected thereby, are not exposed to risks to their health and safety).

The Health and Safety (Genetic Manipulation) Regulations of 1978, made under the HSW Act, require that the HSE be notified of any intention to carry out genetic manipulation as defined in the Regulations, and that details of individual experiments be provided. A consultative document will be issued by the Health and Safety Commission on revisions of these Regulations, which will include proposals for the statutory obligation to notify the HSE of the "use" of genetically manipulated organisms and the planned release of such organisms into the environment. Both these activities are at present broadly covered by voluntary notification schemes.

There is no specific requirement to provide notification of the fermentation of non-manipulated organisms on an industrial scale or of their release into the environment. However, the Control of Pesticides Regulations of 1986, made under the Food and Environment Protection Act of 1985, provide for statutory powers to approve pesticides (including microorganisms) and make it an offence to sell, supply, store or use an unapproved pesticide. The use of non-indigenous plant pest organisms in a fermentation process requires a licence under the Plant Pests (Great Britain) Order of 1980.

The HSE must be notified of any intention to work with or transport certain of the most dangerous pathogens under the Health and Safety (Dangerous Pathogens) Regulations of 1981. These Regulations are also under review.

3. General principles of the proposal

Experience to date in some Member States has shown that the risks arising from exposure to biological agents at work must be assessed before workers can be given adequate protection against them.

The assessment should enable the nature and level of the following to be determined :

- the intrinsic danger of the agents,
- exposure or potential exposure of workers to these agents,
- the probability/risk of propagation in the community.

Before a biological agent is designated a health hazard, various factors must be considered, such as existing epidemiological data and the guidelines issued by the appropriate authorities on the way in which some agents should be controlled.

The Member States will then have to classify biological agents according to their level of danger, using the definitions proposed in this Directive. The classification will cover research and development laboratories, animal and industrial processes.

The proposal for a Directive includes a very clear distinction between a conscious decision to work with biological agents (voluntary exposure) and incidental exposure to agents. Different provisions have been made for the two groups.

Biological agents for use in biotechnologies are included in the proposal for a Directive in such a way as to cover the agents which have already been designated dangerous and are used for genetic manipulation, as well as those which can become dangerous as a result of such manipulation.

The proposal for a Directive aims to provide guidelines for drawing up measures to protect workers against agents which are known to be dangerous and those which are suspected of being dangerous.

4. Presentation of the proposal

Article 1 covers measures of a general nature and states that "the purpose (of this Directive) is to protect workers against risks, including the prevention of such risks, arising from exposure to biological agents at work".

Article 2 contains definitions of "biological agents", "Groups 1-4 of biological agents", "microorganisms", "cell cultures", "genetically modified biological agents", "genetic manipulation", "incidental exposure to biological agents" and a "conscious decision to work with biological agents (voluntary exposure)".

One of the key parts of the proposal is Article 3, which lays down the scope of the Directive. The risk must be assessed for each activity and may also be further assessed. This article also lays down which types of information must be used in the classification of biological agents. Point 5 states that the proposal for a Directive will not apply to some agents, and point 6 specifies which provisions will not apply to activities involving incidental exposure to biological agents.

Articles 4 and 5 are of a general nature and apply to incidental exposure and to activities which involve a conscious decision to work with biological agents.

Article 4 lays down the measures for avoiding the exposure of workers to biological agents or, where this is not reasonably practicable, for reducing the exposure to as low a level as is necessary in order to adequately protect the health and safety of the workers concerned. Other measures provide for the limitation of the number of workers exposed, the design of work processes, collective and personal protection, adequate and information training for workers, the use of bio-hazard signs and emergency procedures.

Article 5 deals with the obligation of employers to provide information and adequate instruction to workers, e.g. on serious incidents and accidents.

Articles 6-12 inclusive contain provisions applicable only to activities which involve a conscious decision to work with biological agents.

Article 6 lays down the measures to be taken for working clothes, personal protective equipment and the provision of areas where workers can eat and drink. They must be provided with skin and eye antiseptics and, if appropriate, showers and must not be charged for the cost of these measures.

Under Article 7, employers must keep a record of the workers involved in the activities involving Group 3 and/or Group 4 biological agents, as well as of accidents and incidents.

Doctors and workers will also have access to these records.

Article 8 provides for the replacement, as far as possible, of a hazardous agent by a less hazardous or non-hazardous one. In addition, importers and suppliers must ensure that the agents are not dangerous and that they are suitably described, packed and transported.

Under Article 9, employers must make available to the responsible authorities information on the results of assessments, the number of workers exposed, protective and preventive measures, etc.

Under Article 10, employers must give prior notification of genetic manipulation or work with a genetically modified biological agent, work with a Group 4 biological agent or the intention to introduce substantial changes to a procedure of which notification has already been provided. The content of this notification is also laid down.

Employers must inform the responsible authority forthwith of any incident that may have resulted in the release of any biological agent which could be a hazard to the health of workers.

Article 11 obliges employers to draw up written instructions which include the procedure to be used in the case of a serious incident. Furthermore, workers or their representatives must be informed as quickly as possible when a serious accident or incident occurs.

Article 12 lays down the requirements for the health surveillance of workers, which include, when appropriate, the use of effective vaccines and the keeping of individual health records.

Article 13 covers specific measures for health care facilities and diagnostic laboratories. Following the above-mentioned assessment appropriate measures will be taken as laid down in Annex 3 of the proposal for a Directive.

Article 14 deals with the physical containment levels set out in Annex 3 which are to be observed for the manipulation of biological agents in laboratories (other than diagnostic laboratories), animal rooms and industrial processes.

Once the hazard has been assessed, one of three physical containment levels with different requirements will be chosen.

Certain measures listed in annex 3 shall be applied in an industrial process, only when appropriate.

A minimum physical containment level will be used for biological agents in respect of which it has not yet been possible to reach a conclusive assessment. Moreover, when the volume of biological agents handled has reached a certain figure, the physical containment level will be increased.

Additional measures are listed in annex 4 for laboratories and animal rooms.

Under Article 15, in the section of final provisions, the annexes to this Directive may be adapted to technical progress.

Under Article 16, the Member States must ensure that workers are consulted on the provisions contained in this Directive.

Under Article 17, Member States must keep statistics of recognized cases of serious illness or death due to exposure to biological agents, and publish up-to-date information on occupational diseases caused by biological agents.

Article 18 lays down the time scale and procedures for applying this Directive in the Member States.

Article 19 states that the Directive is addressed to the Member States.

Annex 1 sets out the criteria to be used for designating a genetically modified biological agent "non-hazardous".

Annex 2 shows the biohazard sign provided for in Article 4 (g).

Annex 3 sets out the specific measures required at each of the three physical containment levels referred to in Articles 13 and 14.

Annex 4 sets out additional measures required at each of the three physical containment levels for laboratories and animal rooms referred to in Art. 14.6.

5. Consultation

Pursuant to Article 118A of the Treaty establishing the European Economic Community, the Council shall cooperate with the European Parliament and consult the Economic and Social Committee.

PROPOSAL FOR A
COUNCIL DIRECTIVE

of

on the protection of workers from the risks
related to exposure to biological agents at work

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), established following consultation with the Advisory Committee on safety, hygiene and health protection at work,

In co-operation with the European Parliament (2),

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

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 (4), 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;

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- 1 OJ No
- 2 OJ No
- 3 OJ No
- 4 OJ No L 327, 3.12.1980, p. 8

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.
- (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 1.
- (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) "Microorganism" 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 they 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 7 (1)

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.

1) OJ

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 on the contained use of genetically-modified microorganisms.

6. Articles 4 to 17, with the exception of Article 9, first indent, 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, paragraph 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 2) 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 Group 3 and/or Group 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. Member 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 3 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, and 4 biological agent.

2. Following the assessment referred to in Article 3(2), special measures shall be taken as laid down in Annex 3 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 at 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 3 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 4.

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.

Done at Brussels,

For the Council

The President

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 r-DNA constructions; provides the major portion of the genome of the r-DNA organism; same as recipient.

Vector : 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 mobilisable;
- 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 chloroplasts, 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

BIO-HAZARD SIGN AS REFERRED
TO IN ARTICLE 4.g.



ANNEX 3

THE SPECIFIC MEASURES REQUIRED AT EACH OF THE THREE PHYSICAL CONTAINMENT LEVELS AS REFERRED TO IN ARTICLES 13, PARAGRAPH 3 AND 14 PARAGRAPHS 2, 3, 4 AND 5

Specific measures	Containment levels		
	2	3	4
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 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 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 4

**THE ADDITIONAL MEASURES REQUIRED AT EACH OF THE THREE PHYSICAL
CONTAINMENT LEVELS FOR LABORATORIES AND ANIMAL ROOMS
AS REFERRED TO IN ARTICLE 14, PARAGRAPH 6**

Specific measures	Containment Levels		
	2	3	4
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

FINANCIAL SHEET

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

1. Budget item concerned

B 6482 : Health protection, hygiene and safety at work
A 2510 : Compulsory consultation

2. Legal basis

- a) Article 118A of the EEC Treaty added by the Single European Act
- b) Commission communication on its programme concerning safety, hygiene and health at work (SEC(87)1216).

3. Proposal for classification as compulsory or non-compulsory expenditure

Non compulsory

4. Description and grounds for the action

4.1. Description

4.1.1. Aims of the proposal for a Directive

The aim of the proposal is to protect workers from risks to their health and safety which arise or could arise from exposure to biological agents at work, especially the prevention of such risks.

4.1.2. Features of the proposal for a Directive (especially those with financial implications)

Harmonization of national legislation in the field of the protection of workers from biological agents, by means of adequate monitoring, training and information of workers and the provision of physical protection measures.

4.2. Grounds

The action is justified on the legal ground indicated under point 2. The financial implications are inherent in the application of the Directive.

5. Nature of expenditure and method of calculation

5.1. Nature of additional activities to be undertaken after adoption of the Directive

- a) monitoring the application of the Directive at Member State level ;
- b) consultation of experts ;
- c) operation of the Committee.

5.2. Types of activities deriving from point 5.1. and their financial implications

It involves :

- study contracts to examine problems related to the operation of the Directive in practice,
- costs for consultation meetings with experts,
- operating costs of committees.

5.3. Calculation of expenditure

In view of the nature of the activities, it is impossible to estimate the expenditure precisely. The amounts under point 6.1 are overall estimates.

6. Financial impact of the action on appropriations

6.1. Schedule of commitment and payment appropriations

	<u>B 6482</u>	<u>A 2510 *</u>	<u>B 6482</u>	<u>A 2510</u>
	CA (ECU)	CA (ECU)	PA (ECU)	PA (ECU)
1989	80.000	30.000	80.000	30.000
1990	80.000	60.000	80.000	60.000
1991	90.000	60.000	90.000	60.000
1992	100.000	60.000	100.000	60.000
1993	110.000	60.000	110.000	60.000
Total	<u>460.000</u>	<u>270.000</u>	<u>460.000</u>	<u>270.000</u>

6.2. Share of Community financing (in %) in the overall cost of the action : 100 %

7. Comments

None.

* As concerns the post A 2510, the credits foreseen can only be used within the limits of the available budgetary provisions

8. Financial impact on staff appropriations

8.1. Staff needed solely for the execution of the action

From 1989 one full-time category A official, one half-time category B official and one full-time category C official.

The necessary staff will be obtained through internal redeployment or in the framework of the annual budgetary procedure.

8.2. Staff appropriations needed

From 1989 an estimated 158.000 ECU per year will be required.

ASSESSMENT OF IMPACT ON COMPETITIVENESS AND EMPLOYMENT

(Directive on biological agents)

I. The proposed Council Directive is designed to protect workers from the risks related to exposure to biological agents at work.

II. The main activities to which the Directive applies are:

research and development laboratories
hospital isolation departments
clinical and veterinary diagnostic laboratories
industries using biological agents [medical industries - vaccines]
the sewage industry
breweries.

As regards the relative numbers of small and medium-sized undertakings involved in each of these activities, medium-sized undertakings are concentrated mainly in the brewing and medical industries, whereas there are very few small undertakings in these two branches.

III. From the cost angle, the most important articles concern :

- the reduction of worker exposure,
- the introduction of specific measures appropriate to the intrinsic risk of the organisms,
- medical surveillance.

The Directive is structured in such a way that different measures are laid down for activities which may involve incidental exposure to biological agents (the degree of risk is smaller and the measures are therefore less stringent - in particular, they do not require the drawing up or keeping of registers) and for activities involving a conscious decision to work with biological agents (the degree of risk is higher and the measures laid down are therefore stricter).

The heaviest direct costs have been identified as those relating to medical surveillance. However, these will vary from one Member State to another, since some Member States already have such surveillance systems, while in others they have not been required until now.

- IV. It should be pointed out that other indirect costs may be incurred in the application of the Directive, since the individual Member States may lay down more stringent protective measures for workers than those provided for in the Directive. Clearly, the level of such costs cannot be estimated, since it depends on the political and legislative approach chosen by each Member State and the stage reached in existing legislation and scientific development in each country.
- V. The Directive avoids imposing administrative, financial or legal constraints likely to hamper the creation and development of small and medium-sized undertakings. As has already been pointed out, only a very few small and medium-sized undertakings are involved in activities connected with the handling of biological agents.

However, large undertakings may have an advantage over small and medium-sized undertakings, since the higher the number of workers subject to medical surveillance the lower the average cost for each assessment. In order to keep these costs to a minimum, the obligations relating to medical surveillance have been adapted so as to fit in as far as possible with existing systems.

- VI. The information given above is based on the conclusions of a study of the impact of the proposed Directive on small and medium-sized undertakings carried out by the National Institute of Occupational Health (Denmark). However, the conclusions, not sufficiently representative of well-founded in that some Member States, such as France, the United Kingdom and the Federal Republic of Germany, did not supply data.
- VII. The advantages anticipated from the improvement in working conditions will stem from a better awareness of the health problems related to work with biological agents and a consequent reduction in the health risks which such work might pose. These improvements will benefit not only society as a whole but also individual undertakings. In the latter case, undertakings will certainly benefit from the reduction in the number of days lost through sickness.
- VIII. The Advisory Committee for Safety, Hygiene and Health Protection at Work gave an opinion on 2 and 3 July 1987 on the necessary content of a proposal for a Directive in this field. The Committee members confined themselves to technical questions only, and the proposed Directive has been adapted to take account of their opinion.