

COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 15 July 1992

Proposal for a

COUNCIL DIRECTIVE

amending

**Directive 90/679/EEC on the protection
of workers from risks related
to exposure to biological
agents at work**

(presented by the Commission)

EXPLANATORY MEMORANDUM

On 26 November 1990 the Council adopted a Directive on the protection of workers from risks related to exposure to biological agents at work⁽¹⁾, which provides for the classification of biological agents into four infection risk groups on the basis of the following criteria:

- 1) a group 1 biological agent is unlikely to cause human disease;
- 2) a group 2 biological agent 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) a group 3 biological agent 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) a group 4 biological agent 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 18 of the above-mentioned Directive states that, in accordance with the procedure laid down in Article 118a of the Treaty, the Council must adopt by 28.5.1994 a first list of group 2, group 3 and group 4 biological agents to be included in Annex III of the Directive.

(1) OJ L 374 of 31.12.1990, p.1.

The list of biological agents contained in the annex to this proposal for a Directive is as complete as possible given the current state of technical progress. The basic approach in compiling the list was a wish to concentrate on concepts without entering into details, but at the same time to be as exhaustive as possible. In view of the constant development in the taxonomy of biological agents and viruses in particular, the names given in the lists are those receiving the most recent international consensus.

Moreover this list of classified biological agents does not claim to be an explicit list of all agents responsible for disease in man. Since there are a large number of species or even pathogenic strains for some genuses, the list indicates only those most frequently causing illness; but that does not mean that the species or strains not mentioned are harmless. For example, arbitrary choices have sometimes had to be made in order to show only the species or strains most often implicated in pathogenic processes. This means that under the "spp" heading, which refers to other species which are known pathogens in humans, science may identify one or more species in the future which will have to receive a special or different classification from that given to this "spp" heading.

The procedure provided for in Article 19 of Directive 90/679/EEC permits rapid revision of this list of classified biological agents to ensure that it is as complete as possible and is constantly updated from the scientific point of view.

The list given in the Annex contains separate indications for biological agents likely to cause allergic or toxic reactions or for which it is appropriate to keep lists of exposed workers for more than ten years in order to provide the best possible protection.

**Proposal for a Council
Directive amending Directive 90/679/EEC on the
protection of workers from 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⁽²⁾, drawn up after consulting the Advisory Committee on Safety, Hygiene and Health Protection at Work,

In cooperation with the European Parliament⁽³⁾,

Having regard to the Opinion of the Economic and Social Committee⁽⁴⁾,

Whereas Article 18 of Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work⁽⁵⁾ states that, in accordance with the procedure laid down in Article 118a of the Treaty, the Council must adopt by 28.5.1994 a first list of group 2, group 3 and group 4 biological agents for Annex III to that Directive;

Whereas this first list of biological agents must be classified on the basis of the definitions given in Article 2(d) points 2, 3 and 4 (groups 2, 3 and 4) of the Directive;

Whereas, for certain of these biological agents, it is appropriate to keep lists of exposed workers for more than ten years after their last exposure to the said biological agents;

Whereas other biological agents are likely to cause allergic or toxic reactions;

(2) OJ

(3) OJ

(4) OJ

(5) OJ L 374 of 31.12.1990, p.1.

Whereas the first list of biological agents should contain separate information on the above-mentioned properties in order to provide better protection for workers,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/679/EEC shall be amended as follows:

Annex III shall be supplemented by a first list of group 2, group 3 and group 4 biological agents as given in the annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 April 1994. They shall forthwith inform the Commission thereof.
2. Member States shall communicate to the Commission the provisions of national law already adopted or which they adopt in the field governed by this Directive.
3. Such provisions adopted by the Member States shall contain a reference to this Directive, or shall be accompanied by such a reference upon official publication. The Member States shall decide how such reference is made.

Article 3

This Directive is addressed to the Member States.

Done at Brussels,

For the Council

A N N E X

ANNEX III

INTRODUCTORY NOTES

1. In line with the scope of Directive 90/679/EEC only agents which are known to infect humans are to be included. Where appropriate, indicators are given of the toxic and allergenic potential of these agents. Animal and plant pathogens which are known not to affect man are excluded. In drawing up this first list of classified biological agents consideration has not been given to genetically modified microorganisms.
2. The list of classified biological agents is based on the effect of these agents on healthy workers. No specific account is taken of particular effects on those whose susceptibility may be affected for one or other reasons such as pre-existing disease, medication, compromised immunity, pregnancy or breast feeding. Additional risk to such workers should be considered as part of the risk assessment required by Council Directive 90/679/EEC. In industrial processes, laboratory work or work with animals involving actual or potential exposure to biological agents of Groups 3 or 4, any technical precautions taken must conform to Article 16(c) of Council Directive 90/679/EEC.
3. Biological agents which have not been classified for inclusion in Group 2 to 4 in the list, are therefore not implicitly classified in Group 1. For agents where there are more than one species known to be pathogenic to man, the list of classified biological agents may include the whole genus of a biological agent, together with individual entries for those species which are known to be the most important in terms of human infectivity, allergy and toxicity or are more frequently encountered. When a whole genus is mentioned in the classified list of biological agents, it is implicit that the species and strains known to be non-pathogenic are excluded.

4. Where a strain is attenuated or has lost known virulence genes, then the containment required by the classification of its parent strain need not necessarily apply, subject to assessment appropriate for risk in the workplace. (E.g. when such a strain is to be used as a product or part of a product for prophylactic/therapeutic purposes).
5. The nomenclature of classified agents used to establish this list reflects and is in conformity with the latest international agreements on the taxonomy and nomenclature of agents at the time the list was prepared.
6. This list of classified biological agents reflects the state of knowledge at the time that it was devised.
7. All viruses which have already been isolated in humans and which are not allocated in a group in the list are to be classified in group 2 as a minimum (specific measures for these agents have to be taken according to Directive 90/679/EEC).
8. The classification of parasites and the resulting requirements as to containment apply only to stages in the life cycle of the parasite in which it is liable to be infectious to humans at the workplace.
9. This list also gives a special indication in cases where the biological agents are likely to cause toxic or allergic reactions, where preventive vaccination is available, or where it is advisable to keep a list of exposed workers for more than ten years. These indications are shown by the following letters:

A: Possible allergic effects

D: List of workers exposed to this biological agent to be kept for more than ten years after last known exposure

T: Toxin production

V: Vaccination recommended

Biological agent	Classification	Notes
BACTERIA and similar		
Actinomadura madurae	2	
Actinomadura pelletieri	2	
Actinomyces gerencseriae	2	
Actinomyces israelii	2	
Actinomyces pyogenes	2	
Actinomyces spp*	2	
Arcanobacterium haemolyticum (corynebacterium haemolyticum)	2	
Bacillus anthracis	3	
Bacteroides fragilis	2	
Bartonella bacilliformis	2	
Bordetella bronchiseptica	2	
Bordetella parapertussis	2	
Bordetella pertussis	2	
Borrelia burgdorferi	2	
Borrelia duttonii	2	
Borrelia recurrentis	2	
Borrelia spp*	2	
Brucella abortus	3	
Brucella canis	3	
Brucella melitensis	3	
Brucella suis	3	

* "spp" refers to other species which are known pathogens in humans

Biological agent	Classification	Notes
BACTERIA and similar		
Campylobacter fetus	2	
Campylobacter jejuni	2	
Campylobacter spp*	2	
Cardiobacterium hominis	2	
Chlamydia pneumoniae	2	
Chlamydia trachomatis	2	
Chlamydia psittaci (avian strains)	3	
Chlamydia psittaci (other strains)	2	
Clostridium botulinum	2	T
Clostridium perfringens	2	
Clostridium tetani	2	T, V
Clostridium spp*	2	
Corynebacterium diphtheriae	2	T, V
Corynebacterium minutissimum	2	
Corynebacterium pseudotuberculosis	2	
Corynebacterium spp*	2	
Coxiella burnetii	3	
Edwardsiella tarda	2	
Ehrlichia sennetsu (<i>Rickettsia Sennetsu</i>)	2	
Ehrlichia spp*	2	
Eikenella corrodens	2	
Enterobacter aerogenes	2	
Enterococcus spp*	2	
Erysipelothrix rhusiopathiae	2	

* "spp" refers to other species which are known pathogens in humans

Biological agent	Classification	Notes
BACTERIA and similar		
Escherichia coli	2	
Flavobacterium meningosepticum	2	
Fluoribacter bozemanæ (<i>Legionella</i>)	2	
Francisella tularensis (Type A)	3	
Francisella tularensis (Type B)	2	
Gardnerella vaginalis	2	
Haemophilus actinomycetem comitans (<i>Actinobacillus</i>)	2	
Haemophilus ducreyi	2	
Haemophilus influenzae	2	
Haemophilus spp*	2	
Helicobacter pylori	2	
Klebsiella oxytoca	2	
Klebsiella pneumoniae	2	
Klebsiella spp*	2	
Legionella pneumophila	2	
Legionella spp*	2	
Leptospira interrogans (all serovars)	2	
Listeria monocytogenes	2	
Listeria ivanovii	2	
Morganella morganii	2	
Mycobacterium africanum	3	V
Mycobacterium avium intracellulare	2	
Mycobacterium bovis (excluding BCG Strain)	3	V

* "spp" refers to other species which are known pathogens in humans

Biological agent	Classification	Notes
BACTERIA and similar		
<i>Mycobacterium chelonae</i>	2	
<i>Mycobacterium fortuitum</i>	2	
<i>Mycobacterium kansasii</i>	2	
<i>Mycobacterium leprae</i>	3	
<i>Mycobacterium malmoense</i>	2	
<i>Mycobacterium marinum</i>	2	
<i>Mycobacterium microti</i>	3	
<i>Mycobacterium paratuberculosis</i>	2	
<i>Mycobacterium scrofulaceum</i>	2	
<i>Mycobacterium simiae</i>	2	
<i>Mycobacterium szulgai</i>	2	
<i>Mycobacterium tuberculosis</i>	3	V
<i>Mycobacterium ulcerans</i>	3	
<i>Mycobacterium xenopi</i>	2	
<i>Mycoplasma pneumoniae</i>	2	
<i>Neisseria gonorrhoeae</i>	2	
<i>Neisseria meningitidis</i>	2	
<i>Nocardia asteroides</i>	2	
<i>Nocardia brasiliensis</i>	2	
<i>Nocardia farcinica</i>	2	
<i>Nocardia nova</i>	2	
<i>Nocardia otitidis-caviarum</i>	2	
<i>Pasteurella multocida</i>	2	
<i>Pasteurella spp*</i>	2	

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Biological agent	Classification	Notes
BACTERIA and similar		
<i>Plesiomonas shigelloides</i>	2	
<i>Proteus mirabilis</i>	2	
<i>Proteus penneri</i>	2	
<i>Proteus vulgaris</i>	2	
<i>Providencia alcalifaciens</i>	2	
<i>Providencia rettgeri</i>	2	
<i>Providencia spp*</i>	2	
<i>Pseudomonas aeruginosa</i>	2	
<i>Pseudomonas mallei</i>	3	
<i>Pseudomonas pseudomallei</i>	3	
<i>Rhodococcus equi</i>	2	
<i>Rickettsia akari</i>	3	
<i>Rickettsia canada</i>	3	
<i>Rickettsia conorii</i>	3	
<i>Rickettsia montana</i>	3	
<i>Rickettsia typhi</i> (mooseri)	3	
<i>Rickettsia prowazekii</i>	3	
<i>Rickettsia rickettsii</i>	3	
<i>Rickettsia tsutsugamushi</i>	3	
<i>Rochalimaea quintana</i>	2	
<i>Salmonella arizonae</i>	2	
<i>Salmonella enteritidis</i>	2	
<i>Salmonella typhimurium</i>	2	

* "spp" refers to other species which are known pathogens in humans

Biological agent	Classification	Notes
BACTERIA and similar		
Salmonella paratyphi A, B, C	3	V
Salmonella typhi	3	V
Salmonella (other serovars)	2	
Shigella boydii	2	
Shigella dysenteriae (Type 1)	3	T
Shigella flexneri	2	
Shigella sonnei	2	
Staphylococcus aureus	2	
Streptobacillus moniliformis	2	
Streptococcus pneumoniae	2	
Streptococcus pyogenes	2	
Streptococcus spp*	2	
Treponema carateum	2	
Treponema pallidum	2	
Treponema pertenuae	2	
Treponema spp*	2	
Vibrio cholerae (incl El Tor)	2	
Vibrio parahaemolyticus	2	
Vibrio spp*	2	
Yersinia enterocolitica	2	
Yersinia pestis	3	V
Yersinia pseudotuberculosis	2	
Yersinia spp*	2	

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Biological agent	Classification	Notes
VIRUSES*		
Adenoviridae	2	
Arenaviridae		
Junin Virus	4	
Lassa fever virus	4	
Lymphocytic choriomeningitis virus (neurotropic strains)	3	
Lymphocytic choriomeningitis virus (other strains)	2	
Machupo virus	4	
Mopeia virus and other Tacaribe viruses	2	
Astroviridae	2	
Bunyaviridae Bunyamwera viruses:		
Bunyamwera virus	2	
Oropouche virus	3	
California encephalitis virus	2	
Hantaviruses:		
Hantaan (Korean haemorrhagic fever)	3	
Other hantaviruses	3	
Nairoviruses:		
Congo/Crimean haemorrhagic fever	4	
Hazara virus	2	

* See Introductory Note No. 7

Biological agent	Classification	Notes
VIRUSES		
Phleboviruses:		
Rift Valley fever	3	V
Sandfly fever virus	2	
Toscana virus	2	
Other bunyaviridae known to be pathogenic	2	
Caliciviridae	2	
Coronaviridae	2	
Filoviridae		
Ebola virus	4	
Marburg virus	4	
Flaviviridae:		
Australia encephalitis (Murray Valley encephalitis)	3	
Central European tick-borne encephalitis virus	3	
Absettarov	3	V
Hanzalova	3	V
Hypr	3	V
Kumlinge	3	V
Dengue virus Type 1-4	3	
Hepatitis C virus	3	D
Japanese B encephalitis	3	V
Kyasanur Forest	3	V
Louping ill	3	
Omsk	3	V(TBE)
Powassan	3	
Rocio	3	

Biological agent	Classification	Notes
VIRUSES		
Russian spring-summer encephalitis (TBE)	3	V
St Louis encephalitis	3	
Wesselsbron virus	3	
West Nile virus	3	
Yellow fever	3	V
Other known flaviviruses known to be pathogenic	2	
Hepadnaviridae		
Hepatitis B virus	3	V, D
Hepatitis D virus (Delta)**	3	V, D
Herpesviridae		
Cytomegalovirus	2	
Epstein-Barr virus	2	
<i>Herpesvirus simiae</i> (B virus)	3	
<i>Herpes simplex viruses types 1 and 2</i>	2	
<i>Herpesvirus varicella-zoster</i>	2	
Human B-lymphotropic virus (HBLV - HHV6)	2	
Orthomyxoviridae		
Influenza viruses types A, B, & C	2	V
Tick-borne orthomyxoviridae: Dhoru & Thogoto viruses	2	
Papovaviridae		
BK and JC viruses	2	D*
Human papillomaviruses	2	D*

* For work involving direct contact with these agents.

** Hepatitis D virus is only pathogenic in workers in the presence of simultaneous or secondary infection caused by Hepatitis B virus.

Biological agent	Classification	Notes
VIRUSES		
Paramyxoviridae		
Measles virus	2	V
Mumps virus	2	V
Newcastle disease virus	2	
Parainfluenza viruses types 1 to 4	2	
Respiratory syncytial virus	2	
Parvoviridae		
Human parvovirus (B 19)	2	
Picornaviridae		
Acute haemorrhagic conjunctivitis virus (AHC)	2	
Coxsackieviruses	2	
Echoviruses	2	
Hepatitis A virus (human enterovirus type 72)	2	
Polioviruses	2	V
Rhinoviruses	2	
Poxviridae		
Buffalopox virus (1)	2	
Cowpox virus	2	
Elephantpox virus (2)	2	
Milkers' node virus	2	
Molluscum contagiosum virus	2	
Monkeypox virus	3	V
Orf virus	2	

(1) Two viruses are identified : one a buffalopox type and the other a variant of the vaccinia virus

(2) Variant of cowpox virus

Biological agent	Classification	Notes
VIRUSES		
Rabbitpox virus (3)	2	
Vaccinia virus	2	
Variola (major & minor) virus	4	V
White pox virus ("variola virus")	4	
Yatapox virus (Tana & Yaba)	2	
Reoviridae		
Coltiviruses	2	
Human rotaviruses	2	
Orbiviruses	2	
Reoviruses	2	
Retroviridae*		
Human immunodeficiency viruses (AIDS)	3	D
Human T-cell lymphotropic viruses (HTLV) types 1 and 2	3	D
Rhabdoviridae		
Rabies virus	3	V
Vesicular stomatitis virus	2	
Togaviridae		
Alphaviruses:		
Eastern equine encephalomyelitis	3	V
Bebaru virus	2	
Chikungunya virus	2	
Everglade virus	2	

(3) Variant of "vaccinia"

* At present there is no evidence of infection of humans with retroviruses of simian origin. As a precaution containment level 3 is recommended for work with them.

Biological agent	Classification	Notes
VIRUSES		
Mayaro virus	3	
Mucambo virus	3	
Ndumu virus	3	
O'nyong-nyong virus	2	
Ross River virus	2	
Semliki Forest virus	2	
Sindbis virus	2	
Tonate virus	3	
Venezuelan equine encephalomyelitis	3	V
Western equine encephalomyelitis	3	V
Other known alphaviruses	2	
Rubivirus (rubella)	2	V
Toroviridae	2	
Unclassified viruses		
Blood-borne hepatitis viruses not yet identified	3	D
Hepatitis E virus	3	
Norwalk virus	2	
Unconventional agents associated with (1):		
Creutzfeld-Jakob disease	3	* D
Gerstmann-Sträussler-Scheinker syndrome	3	* D
Kuru	3	* D

(1) There is no evidence in humans of infections caused by the agents responsible for bovine spongiform encephalitis and "scrapie". Nevertheless, containment level 2 is recommended as a precaution for work involving contact with these agents or with tissues infected by these agents.

* For work involving direct contact with these agents.

Biological agents	Classification	Notes
PARASITES		
<i>Acanthamoeba castellani</i>	2	
<i>Ancylostoma duodenale</i>	2	
<i>Angiostrongylus cantonensis</i>	2	
<i>Angiostrongylus costaricensis</i>	2	
<i>Ascaris lumbricoides</i>	2	A
<i>Ascaris suum</i>	2	A
<i>Babesia divergens</i>	2	
<i>Babesia microti</i>	2	
<i>Balantidium coli</i>	2	
<i>Brugia malayi</i>	2	
<i>Brugia pahangi</i>	2	
<i>Capillaria philippinensis</i>	2	
<i>Capillaria spp*</i>	2	
<i>Clonorchis sinensis</i>	2	
<i>Clonorchis viverrini</i>	2	
<i>Cryptosporidium parvum</i>	2	
<i>Cryptosporidium spp*</i>	2	
<i>Dipetalonema streptocerca</i>	2	
<i>Diphyllobothrium latum</i>	2	
<i>Dracunculus medinensis</i>	2	
<i>Echinococcus granulosus</i>	3	

* "spp" refers to other species which are known pathogens in humans

Biological agents	Classification	Notes
PARASITES		
Echinococcus multilocularis	3	
Echinococcus vogeli	3	
Entamoeba histolytica	2	
Fasciola gigantica	2	
Fasciola hepatica	2	
Fasciolopsis buski	2	
Giardia lamblia (<i>Giardia intestinalis</i>)	2	
Hymenolepis diminuta	2	
Hymenolepis nana	2	
Leishmania brasiliensis	3	
Leishmania donovani	3	
Leishmania ethiopia	2	
Leishmania mexicana	2	
Leishmania peruviana	2	
Leishmania tropica	2	
Leishmania major	2	
Leishmania spp*	2	
Loa loa	2	
Mansonella ozzardi	2	
Mansonella perstans	2	
Naegleria fowleri	3	
Necator americanus	2	
Onchocerca volvulus	2	

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Biological agents	Classification	Notes
PARASITES		
Opisthorchis felineus	2	
Opisthorchis spp*	2	
Paragonimus westermani	2	
Plasmodium falciparum	3	
Plasmodium spp* (human & simian)	2	
Sarcocystis sui hominis	2	
Schistosoma haematobium	2	
Schistosoma intercalatum	2	
Schistosoma japonicum	2	
Schistosoma mansoni	2	
Schistosoma mekongi	2	
Strongyloides stercoralis	2	
Strongyloides spp*	2	
Taenia saginata	3	
Taenia solium	3	
Toxocara canis	2	
Toxoplasma gondii	2	
Trichinella spiralis	2	
Trichuris trichiura	2	
Trypanosoma brucei brucei	2	
Trypanosoma brucei gambiense	3	
Trypanosoma brucei rhodesiense	3	
Trypanosoma cruzi	3	
Wuchereria bancroftii	2	

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Biological agent	Classification	Notes
FUNGI		
<i>Aspergillus fumigatus</i>	2	A
<i>Blastomyces dermatitidis</i> (<i>Ajellomyces dermatitidis</i>)	3	
<i>Candida albicans</i>	2	A
<i>Coccidioides immitis</i>	3	A
<i>Cryptococcus neoformans</i> (<i>Filobasidella neoformans</i> var <i>neoformans</i> and <i>F. neoformans</i> var <i>garrii</i>)	2	A
<i>Emmonsia parvum</i> var. <i>parva</i>	2	
<i>Emmonsia parvum</i> var. <i>crescens</i>	2	
<i>Epidermophyton floccosum</i>	2	A
<i>Fonsecaea compacta</i>	2	
<i>Fonsecaea pedrosoi</i>	2	
<i>Histoplasma capsulatum</i> var <i>capsulatum</i> (<i>Ajellomyces capsulata</i>)	3	
<i>Histoplasma duboisii</i>	3	
<i>Madurella grisea</i>	2	
<i>Madurella mycetomatis</i>	2	
<i>Microsporium</i> spp*	2	A
<i>Neotestudina rosatii</i>	2	
<i>Paracoccidioides brasiliensis</i>	3	
<i>Penicillium marneffeii</i>	2	A
<i>Sporothrix schenckii</i>	2	
<i>Trichophyton rubrum</i>	2	
<i>Trichophyton</i> spp*	2	

* "spp" refers to other species which are known pathogens in humans

**IMPACT note: Impact on competitiveness and employment of
the proposal for a Council Directive amending Directive
90/679/EEC on the protection of workers from risks
related to exposure to biological agents at work**

I. Main justification for the measure:

On 26 November 1990 the Council adopted a Directive on the protection of workers from risks related to exposure to biological agents at work (1) (Directive 90/679/EEC). This Directive classifies biological agents into four groups according to the degree of risk of infection, and Article 18 lays down that the Council, in accordance with the procedure laid down in Article 118a of the Treaty, shall adopt a first list of classified biological agents for the Annex of that Directive.

In response to these provisions, the Commission is presenting this proposed text to the Council.

II. Obligations imposed directly on undertakings:

This proposal for a Directive is only an implementation of Directive 90/679/EEC and as such imposes no additional obligation compared with the Directive from which it derives for the undertakings concerned.

III. Characteristics of the undertakings concerned:

These characteristics are identical to those for undertakings covered by Directive 90/679/EEC, namely:

- research and development laboratories;
- some hospital departments (resuscitation, infectious diseases, etc.);
- diagnostic, clinical and veterinary laboratories;

(1) OJ L 374, 31.12.1990, p. 1

- industries using biological agents (medical industries, vaccines);
- public hygiene services (sewerage);
- breweries.

The majority of undertakings concerned are medium and large in size, with relatively few small undertakings.

IV. Obligations which may be imposed indirectly on undertakings through local authorities:

Compared with Directive 90/679/EEC, this proposal contains no supplementary measures which can be indirectly imposed on undertakings via local authorities.

V. Special measures for the SMEs:

No specific exemption or incentive for the SMEs is contained in this proposal.

VI. Effects on the competitiveness of undertakings:

1. Advantages for undertakings:

Article 18 of Directive 90/679/EEC lays down that, pending Community classification, Member States shall classify biological agents on the basis of the definition in Article 2.

Disparities in classification between Member States which could result from this provision will be removed when this proposal for an amending Directive enters into force. This will allow the undertakings concerned to compete on equal terms within the Community, subject to the same health, hygiene and safety standards.

2. Disadvantages for undertakings:

Similarly, when this proposal for an amending Directive enters into force, some biological agents may benefit from stricter classification within the Member States. This could result in additional costs arising from additional adaptation of workplaces and from the purchase of personal protective equipment.

VII. Consultation with the two sides of industry:

At its plenary meeting of 26 and 27 November 1991, the Advisory Committee on Safety, Hygiene and Health Protection at Work recommended that the Commission should consult the national experts once again in order to refine the document and rectify a number of omissions.

National experts were consulted on two occasions, 14 January 1992 and 11-12 February 1992, enabling outstanding problems to be resolved and the text to be finalised as requested by the Advisory Committee.

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