II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE 93/88/EEC

of 12 October 1993

amending Directive 90/679/EEC on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

In cooperation with the European Parliament (2),

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

Whereas Article 18 of Directive 90/679/EEC (4) states that, in accordance with the procedure laid down in Article 118a of the Treaty, the Council must adopt a first list of Group 2, Group 3 and Group 4 biological agents for Annex III to that Directive;

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

Whereas the list does not contain genetically modified biological agents;

Whereas, for a number of biological agents details additional to their classification should be given;

Whereas it is appropriate to include in Directive 90/679/EEC a recommended code of practice, for the purpose of furnishing guidelines only, on vaccination of workers exposed to biological agents for which effective vaccines exist,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/679/EEC is hereby amended as follows:

1. the following subparagraph shall be inserted after the second subparagraph of Article 14 (3):

   'When employers make vaccines available, they should take account of the recommended code of practice set out in Annex VII.';

2. Annex III shall be replaced by the text in Annex I to this Directive;

3. Annex VII appearing in Annex II to this Directive shall be added.

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.

However, in the case of the Portuguese Republic, the date referred to in the first subparagraph shall be 31 December 1995.

(1) OJ No C 217, 24. 8. 1992, p. 32.
(2) OJ No C 72, 19. 3. 1993, p. 74 and OJ No C 255, 20. 9. 1993.
(3) OJ No C 19, 25. 1. 1993, p. 16.
(4) OJ No L 374, 31. 12. 1990, p. 1.

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. When Member States adopt such provisions, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such a reference shall be laid down by the Member States.

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 12 October 1993.

For the Council

The President

M. SMET

ANNEX I

'ANNEX III

COMMUNITY CLASSIFICATION

(Article 18 and Article 2 (d))

Introductory notes

1. In line with the scope of the Directive, only agents which are known to infect humans are to be included in the classified list.

   Where appropriate, indicators are given of the toxic and allergic 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 micro-organisms.

2. The list of classified agents is based on the effect of those agents on healthy workers.

   No specific account is taken of particular effects on those whose susceptibility may be affected for one or other reason 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 the Directive.

   In certain industrial processes, certain laboratory work or certain work with animals involving actual or potential exposure to biological agents of Groups 3 or 4, any technical precautions taken must comply with Article 16 of the Directive.

3. Biological agents which have not been classified for inclusion in Groups 2 to 4 of the list are not implicitly classified in Group 1.

   For agents where more than one species is known to be pathogenic to man, the list will include those species which are known to be the most frequently responsible for diseases, together with a more general reference to the fact that other species of the same genus may affect health.

   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.

   For example, when such a strain is to be used as a product or part of a product for prophylactic or therapeutic purposes.

5. The nomenclature of classified agents used to establish this list reflects and is in conformity with the latest international agreements of the taxonomy and nomenclature of agents at the time the list was prepared.

6. The list or classified biological agents reflects the state of knowledge at the time that it was devised.

   It will be updated as soon as it no longer reflects the latest state of knowledge.

7. Member States are to ensure that all viruses which have already been isolated in humans and which have not been assessed and allocated in this Annex are classified in Group 2 as a minimum, except where Member States have proof that they are unlikely to cause disease in humans.

8. Certain biologocial agents classified in Group 3 which are indicated in the appended list by an asterisk (*), may present a limited risk of infection for workers because they are not normally infectious by the air-borne route.

   Member States shall assess the containment measures to be applied to such agents, taking account of the nature of specific activities in question and of the quantity of the agent involved, with a view to determining whether, in particular circumstances, some of these measures may be dispensed with.

9. The requirements as to containment consequent upon the classification of parasites apply only to stages in the life cycle of the parasite in which it is liable to be infectious to humans at the workplace.

10. This list also gives a separate indication in cases where the biological agents are likely to cause allergic or toxic reactions, where an effective vaccine is available, or where it is advisable to keep a list of exposed workers for more than 10 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 10 years after the end of last known exposure

T: Toxin production

V: Effective vaccine available

The application of preventive vaccination should take account of the Code of Practice given in Annex VII.

BACTERIA

and similar organisms

NB: For biological agents appearing on this list, "spp." refers to other species which are known pathogens in humans.

Biological agent	Classification	Notes
Actinobacillus actinomycetemcomitans	2	
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	V
Borrelia burgdorferi	2	
Borrelia duttonii	2	
Borrelia recurrentis	2	
Borrelia spp.	2	
Brucella abortus	3	
Brucella canis	3	
Brucella melitensis	3	
Brucella suis	3	
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	

Biological agent	Classification	Notes
Corynebacterium diphtheriae	2	T, V
Corynebacterium minutissimum	2	
Corynebacterium pseudotuberculosis	2	
Corynebacterium spp.	2	
Coxiella burnetii	3	
Edwardsiella tarda	2	
Ehrlichia sennetsu (Rickettsia sennetsu)	2	
Ehrlichia spp.	2	
Eikenella corrodens	2	
Enterobacter aerogenes/cloacae	2	
Enterobacter spp.	2	
Enterococcus spp.	2	
Erysipelothrix rhusiopathiae	2	
Escherichia coli (with the exception of non-pathogenic strains)	2	
Flavobacterium meningosepticum	2	
Fluoribacter bozemanae (Legionella)	2	
Francisella tularensis (Type A)	3	
Francisella tularensis (Type B)	2	
Fusobacterium necrophorum	2	
Gardnerella vaginalis	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 (except BCG strain)	3	V
Mycobacterium chelonae	2	
Mycobacterium fortuitum	2	
Mycobacterium kansasii	2	
Mycobacterium leprae	3	
Mycobacterium malmoense	2	
Mycobacterium marinum	2	
Mycobacterium microti	3 (*)	
Mycobacterium paratuberculosis	2	
Mycobacterium scrofulaceum	2	
Mycobacterium simiae	2	
Mycobacterium szulgai	2	
Mycobacterium tuberculosis	3	V
Mycobacterium ulcerans	3 (*)	
Mycobacterium xenopi	2	
Mycoplasma pneumoniae	2	
Neisseria gonorrhoeae	2	
Neisseria meningitidis	2	V
Nocardia asteroides	2	
Nocardia brasiliensis	2	
Nocardia farcinica	2	
Nocardia nova	2	
Nocardia otitidiscaviarum	2	