



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.03.1998
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Re-examined proposal for a

COUNCIL DIRECTIVE

on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

(presented by the Commission pursuant to Article 189 c (d)
of the EC Treaty)

EXPLANATORY MEMORANDUM

The initial proposal was adopted by the Commission on 14 May 1993 and forwarded to Council on 17 May 1993⁽¹⁾.

The aim of the proposal is to lay down minimum requirements for the protection of workers from risk to their safety and health arising from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents.

Further to the first reading at the European Parliament, the Commission forwarded an amended proposal to the Council on 9 June 1994⁽²⁾.

On account of significant divergences in delegations' positions, work on the amended proposal was suspended in 1994 and only resumed on the basis of a compromise text put forward by the Irish Presidency in October 1996.

On 7 October 1997 a common position⁽³⁾ was adopted by the Council laying down general principles covering all chemical agents. The common position reflected most of the principles proposed by the Commission and was therefore supported. In particular the common position accepted the existence of two kinds of occupational limit values (indicative and binding). It confirmed the Commission's proposal that in conformity with Directive 89/391/EEC, the employer shall assess any risk to the safety and health of workers, but additionally it defined the type of risk assessment to be undertaken for the hazardous chemical agents at work. It also provided more details relating to health surveillance for workers exposed to hazardous chemical agents by introducing in the text requirements mentioned in the Annex of the amended proposal. On the other hand the common position did not include some technical requirements which were included in the Annex of the Commission's amended proposal, e.g. requirements in respect of measuring procedures, and in respect of specific protective measures.

The European Parliament at its second reading proposed 12 amendments to the common position adopted by the Council.

¹ OJ C 165, 16.6.1993, p. 4

² OJ C 191, 14.7.1994, p.7

³ OJ C 375, 10.12.1997, p. 1

The Commission has agreed on 9 amendments (plus one part amendment), which it considers improve the text of the common position. The amendments draw particular attention to the training of and information to workers, to the need to make cross reference to particular Directives such as Directive 89/654/EEC⁽⁴⁾ concerning the minimum safety and health requirements for the workplace, directive 89/656/EEC⁽⁵⁾ on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace, Directive 92/85/EEC⁽⁶⁾ on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding and Directive 94/33/EEC⁽⁷⁾ on the protection of young people at work and to appropriate actions to be taken by the Commission for closer harmonization in the field of occupational exposure limits.

The legal consistency under Article 8 the Commission has also inserted reference to Article 12 of Directive 89/391/EEC to align the text with the title of the Article.

This re-examined proposal contains the amendments accepted by the Commission and is presented by the Commission under the terms of article 189 C(d) of the Treaty.

(4) OJ No L 393, 30.12.1989, p. 1
(5) OJ No L 393, 30.12.1989, p. 18
(6) OJ No L 348, 28.11.1992, p. 1
(7) OJ No L 216, 20.8.1994, p. 12

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on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

(Text with EEA relevance)

PREVIOUS TEXT

AMENDED TEXT

THE COUNCIL OF THE EUROPEAN UNION,

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

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

Having regard to the Opinion of the Economic and Social Committee⁽²⁾,

Acting in accordance with the procedure laid down in Article 189c of the Treaty⁽³⁾,

⁽¹⁾ OJ No C 165, 16.6.1993, p. 4.

⁽²⁾ OJ No C 34, 2.2.1994, p. 42.

⁽³⁾ Opinion of the European Parliament of 20 April 1994 (OJ No C 128, 9.5.1994, p. 167), Council common position of 7 October 1997 (O.J. C 375, 10.12.1997, p. 1) and Decision of the European Parliament of (not yet published in the Official Journal).

(1) Whereas Article 118a of the Treaty provides that the Council shall adopt by means of Directives minimum requirements for encouraging improvements, especially in the working environment, to guarantee a better level of protection of the safety and health of workers;

(2) Whereas, pursuant to that Article, such Directives shall avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings;

(3) Whereas the improvement of workers' safety, hygiene and health at work is an objective which should not be subordinated to purely economic considerations;

(4) Whereas the respect of minimum requirements on the protection of the health and safety of workers from the risks related to chemical agents aims to ensure not only the protection of the health and safety of each individual worker but also to provide a level of minimum protection of all workers in the Community which avoids any possible distortion in the area of competition;

(5) Whereas a consistent level of protection from the risks related to chemical agents has to be established for the Community as a whole; whereas that level of protection has to be set not by detailed prescriptive requirements but by a framework of general principles to enable Member States to apply the minimum requirements consistently;

(6) Whereas a work activity involving chemical agents is likely to expose workers to risk;

(7) 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⁾, Council Directive 82/605/EEC of 28 July 1982 on the protection of workers from the risks related to exposure to metallic lead and its ionic compounds at work (first individual Directive within the meaning of Article 8 of Directive 80/1107/EEC)⁽⁵⁾ and Council Directive 88/364/EEC of 9 June 1988 on the protection of workers by the banning of certain specific agents and/or certain work activities (fourth individual Directive within the meaning of Article 8 of Directive 80/1107/EEC)⁽⁶⁾, for the sake of consistency and clarity as well as for technical reasons, should be revised and included in a single Directive laying down minimum requirements for the protection of the health and safety of workers in work activities involving chemical agents; whereas these Directives can be repealed;

(8) Whereas this Directive is an individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work⁽⁷⁾;

(9) Whereas therefore the provisions of the said Directive apply in full to the exposure of workers to chemical agents, without prejudice to more stringent and/or specific provisions contained in this Directive;

⁽⁴⁾ OJ No L 327, 3.12.1980, p. 8. Directive as last amended by Directive 88/642/EEC (OJ No L 356, 24.12.1988, p. 74).

⁽⁵⁾ OJ No L 247, 23.8.1982, p. 12.

⁽⁶⁾ OJ No L 179, 9.7.1988, p. 44.

⁽⁷⁾ OJ No L 183, 29.6.1989, p. 1.

(10) Whereas more stringent and/or specific provisions relating to the transport of hazardous chemical agents are contained in binding international agreements and conventions incorporated into Community provisions on transport of dangerous goods by road, rail, water and air;

(11) Whereas in Directive 67/548/EEC⁽⁸⁾ and Directive 88/379/EEC⁽⁹⁾ on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of, respectively, dangerous substances and preparations, the Council laid down a system of criteria for the classification of dangerous substances and preparations;

(12) Whereas the definition of hazardous chemical agent should include any chemical substance which meets these criteria and also any chemical substance which whilst not meeting these criteria may because of its physico-chemical, chemical or toxicological properties, and the way it is used or is present in the workplace, present a risk to the safety and health of workers;

(13) Whereas in Directive 90/492/EEC⁽¹⁰⁾ the Commission defined and laid down a system of specific information on dangerous substances and preparations, in the form of safety data sheets principally intended for industrial users to enable them to take the measures necessary to ensure the protection of the safety and health of workers; whereas Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth

⁽⁸⁾ OJ No 196, 16.8.1967, p. 1. Directive as last amended by Directive 96/56/EC (OJ No L 236, 18.9.1996, p. 35).

⁽⁹⁾ OJ No L 187, 16.7.1988, p. 14. Directive as last amended by Commission Directive 96/65/EC (OJ No L 265, 18.10.1996, p. 15).

⁽¹⁰⁾ OJ No L 275, 5.10.1990, p. 35.

individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC⁽¹¹⁾ establishes a system for marking containers and pipes used for dangerous substances or preparations at work;

(14) Whereas the employer should assess any risk to the safety and health of workers arising from the presence of hazardous chemical agents at the workplace, in order to take the necessary preventive and protective measures set out in this Directive;

(15) Whereas the preventive measures identified by the assessment of risk and taken by the employer should be consistent with the need to protect public health and the environment;

(16) Whereas, to supplement the information available to workers so as to ensure an improved level of protection, it is necessary for workers and their representatives to be informed about the risks which chemical agents can pose for their safety and health and about the measures necessary to reduce or eliminate those risks, and for them to be in a position to check that the necessary protective measures are taken;

(17) Whereas the health surveillance of workers for whom the results of the aforementioned assessment reveal a risk to health, can contribute to the prevention and protection measures to be undertaken by the employer;

(18) Whereas the employer must on a regular basis carry out evaluation and measurements and be aware of new developments in technology with a view to improving the protection of workers' safety and health;

⁽¹¹⁾ OJ No L 245, 26.8.1992, p. 23.

(19) Whereas the latest scientific data should be evaluated by independent scientists to assist the Commission in setting occupational exposure limit values;

(20) Whereas, although in some cases scientific knowledge may not be such that a level of exposure to a chemical agent can be established below which risks to health cease to exist, a reduction in exposure to these chemical agents will nonetheless reduce these risks;

(21) Whereas in Directive 91/322/EEC⁽¹²⁾ and Directive 96/94/EC⁽¹³⁾ the Commission laid down indicative limit values as provided for by Directive 80/1107/EEC; whereas the former Directives should be maintained as part of the current framework;

(22) Whereas necessary technical adjustments to this Directive should be drawn up by the Commission in cooperation with the Committee set up by Directive 89/391/EEC to assist the Commission in making technical adaptations to individual Directives adopted under the framework of that Directive; whereas the Commission, after first seeking the advice of the Advisory Committee on Safety, Hygiene and Health Protection at Work in accordance with Decision 74/325/EEC⁽¹⁴⁾, should also draw up practical guidelines for the application of this Directive;

(23) Whereas the repeal of Directive 80/1107/EEC must not give rise to the lowering of the present standards of worker protection from chemical, physical and biological agents; whereas standards resulting from the existing Directives on

⁽¹²⁾ OJ No L 177, 5. 7.1991, p. 22.

⁽¹³⁾ OJ No L 338, 28.12.1996, p. 86.

⁽¹⁴⁾ OJ No L 185, 9.7.1974, p. 15. Decision as last amended by the 1994 Act of Accession.

biological agents, the proposed Directive on physical agents, this Directive and any amendments to these texts should reflect and at least maintain the standards laid down in the said Directive;

(24) Whereas this Directive is a practical contribution towards creating the social dimension of the internal market.

HAS ADOPTED THIS DIRECTIVE:

**SECTION I
GENERAL PROVISIONS**

Article 1

Objective and scope

1. This Directive, which is the fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC, lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents.

2. The requirements of this Directive apply where hazardous chemical agents are present or may be present at the workplace, without prejudice to the provisions for chemical agents to which measures for radiation protection apply pursuant to Directives adopted under the Treaty establishing the European Atomic Energy Community.

3. For carcinogens at work the provisions of this Directive shall apply without prejudice to more stringent and/or specific provisions contained in Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens (sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)⁽¹⁵⁾.

4. The provisions of Directive 89/391/EEC shall apply fully to the whole field referred to in this Article, without prejudice to more stringent and/or specific provisions contained in this Directive.

4. The provisions of Directive 89/391/EEC and subsequent individual directives, in particular Directive 89/654/EEC⁽¹⁶⁾ concerning the minimum safety and health requirements for the workplace, Directive 89/656/EEC⁽¹⁷⁾ on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace, Directive 92/85/EEC⁽¹⁸⁾ on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding and Directive 94/33/EEC⁽¹⁹⁾ on the protection of young people at work, shall apply fully to the whole field referred to in this Article, without prejudice to more stringent and/or specific provisions contained in this Directive.

5. As far as the transport of hazardous chemical agents is concerned, the provisions of this Directive shall apply without prejudice to more stringent and/or specific provisions contained in Directive 94/55/EC⁽²⁰⁾, in Directive 96/49/EC⁽²¹⁾, in

⁽¹⁵⁾ OJ No L 196, 26.7.1990, p. 1.

⁽¹⁶⁾ OJ No L 393, 30.12.1989, p. 1

⁽¹⁷⁾ OJ No L 393, 30.12.1989, p. 18

⁽¹⁸⁾ OJ No L 348, 28.11.1992, p. 1

⁽¹⁹⁾ OJ No L 216, 20.8.1994, p. 12

⁽²⁰⁾ Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road (OJ No L 319, 12.12.1994, p. 7). Directive as amended by Commission Directive 96/86/EC (OJ No L 335, 24.12.1996, p. 43).

the provisions of the IMDG Code, IBC Code and IGC Code as defined in Article 2 of Directive 93/75/EEC⁽²²⁾, in the provisions of the European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterway and of the Regulation for the Carriage of Dangerous Substances on the Rhine as incorporated in Community law and in the technical instructions for the safe transport of dangerous goods issued, at the date of entry into force of this Directive, by the International Civil Aviation Organization.

Article 2

Definitions

For the purpose of this Directive, the terms used shall have the following meanings:

- (a) "Chemical agent" means any chemical element or compound, on its own or admixed, as it occurs in the natural state or as produced, used or released, including release as waste, by any work activity, whether or not produced intentionally and whether or not placed on the market;
- (b) "Hazardous chemical agent" means:
 - (i) any chemical agent which meets the criteria for classification as a dangerous substance according to the criteria in Annex VI to Directive 67/548/EEC, whether or not that substance is classified under that Directive, other than

⁽²¹⁾ Council Directive 96/49/EC of 23 July 1996 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail (OJ L No 235, 17.9.1996, p. 25). Directive as amended by Commission Directive 96/87/EC (OJ No L 335, 24.12.1996, p. 45).

⁽²²⁾ Council Directive 93/75/EEC of 13 September 1993 concerning minimum requirements for vessels bound for or leaving Community ports and carrying dangerous or polluting goods (OJ No L 247, 5.10.1993, p. 19). Directive as last amended by Commission Directive 97/34/EC (OJ No L 158, 17.6.1997, p. 40).

those substances which only meet the criteria for classification as dangerous for the environment;

- (ii) any chemical agent which meets the criteria for classification as a dangerous preparation within the meaning of Directive 88/379/EEC, whether or not that preparation is classified under that Directive, other than those preparations which only meet the criteria for classification as dangerous for the environment;
 - (iii) any chemical agent which, whilst not meeting the criteria for classification as dangerous in accordance with (i) and (ii), may, because of its physico-chemical, chemical or toxicological properties and the way it is used or is present in the workplace, present a risk to the safety and health of workers, including any chemical agent assigned an occupational exposure limit value under Article 3.
- (c) "Activity involving chemical agents" means any work in which chemical agents are used, or are intended to be used, in any process, including production, handling, storage, transport or disposal and treatment, or which result from such work;
- (d) "Occupational exposure limit value" means, unless otherwise specified, the limit of the time-weighted average of the concentration of a chemical agent in the air within the breathing zone of a worker in relation to a specified reference period;

- (c) "Biological limit value" means the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect;
- (f) "Health surveillance" means the assessment of an individual worker to determine the state of health of that individual, as related to exposure to specific chemical agents at work;
- (g) "Hazard" means the intrinsic property of a chemical agent with the potential to cause harm;
- (h) "Risk" means the likelihood that the potential for harm will be attained under the conditions of use and/or exposure.

Article 3

Occupational exposure limit values and biological limit values

1. The Commission shall evaluate the relationship between the health effects of hazardous chemical agents and the level of occupational exposure by means of an independent scientific assessment of the latest available scientific data.
2. On the basis of the evaluation described in paragraph 1, the Commission, after first consulting the Advisory Committee on Safety, Hygiene and Health Protection at Work, shall propose European objectives in the form of indicative occupational exposure limit values for the protection of workers from chemical risks, to be set at Community level.

These limit values shall be established or revised, taking into account the availability of measurement techniques, in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC. Member States shall keep workers' and employers' organizations informed of occupational exposure limit values set at Community level.

These limit values shall be established or revised, taking into account the availability of validated measurement techniques, in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC. Member States shall keep workers' and employers' organizations informed of indicative occupational exposure limit values set at Community level.

3. For any chemical agent for which an indicative occupational exposure limit value is established at Community level, Member States shall establish a national occupational exposure limit value, taking into account the Community limit value, determining its nature in accordance with national legislation and practice.

4. Binding occupational exposure limit values may be drawn up at Community level and, in addition to the factors considered when establishing indicative occupational exposure limit values, shall reflect feasibility factors while maintaining the aim of ensuring the health of workers at work. Such limit values shall be established in accordance with Article 118a of the Treaty and laid down in Annex I to this Directive.

5. For any chemical agent for which a binding occupational exposure limit value is established, Member States shall establish a corresponding national binding occupational exposure limit value based on, but not exceeding, the Community limit value.

6. Binding biological limit values may be drawn up at Community level on the basis of the evaluation described in paragraph 1 and of the availability of measurement techniques, and shall reflect feasibility factors while maintaining the aim of ensuring the health of workers at work.

Such limit values shall be established in accordance with the procedure laid down in Article 118a of the Treaty and laid down in Annex II to this Directive, together with other relevant health surveillance information.

7. For any chemical agent for which a binding biological limit value is established, Member States shall establish a corresponding national binding biological limit value based on, but not exceeding, the Community limit value.

8. Where a Member State introduces or revises a national occupational exposure limit value or a national biological limit value for a chemical agent on the basis of new data, it shall inform the Commission and other Member States thereof together with the relevant scientific and technical data. The Commission shall undertake the appropriate action.

8. Where a Member State introduces or, on the basis of new data, revises a national occupational exposure limit value or a national biological limit value for a chemical agent, it shall inform the Commission and other Member States thereof together with the relevant scientific and technical data. The Commission shall undertake the appropriate action.

8a. On the basis of the reports provided by the Member States under Article 15 the Commission shall carry out an assessment of the way in which Member States have taken account of Community indicative limit values when establishing the corresponding national occupational exposure limit values. If this assessment reveals wide differences in standards the Commission shall undertake appropriate action with a view to closer harmonization in this area.

9. Standardized methods for the measurement and evaluation of workplace air concentrations in relation to occupational exposure limit values shall be developed in accordance with Article 12(2).

SECTION II EMPLOYERS' OBLIGATIONS

Article 4

Determination and assessment of risk of hazardous chemical agents

1. In carrying out the obligations laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer shall first determine whether any hazardous chemical agents are present at the workplace. If so, he shall then assess any risk to the safety and health of workers arising from the presence of those chemical agents, taking into consideration the following:

- their hazardous properties;
- information on safety and health that shall be provided by the supplier, (e.g. the relevant safety data sheet in accordance with the provisions of Directive 67/548/EEC or Directive 88/379/EEC);
- the level, type and duration of exposure;
- the circumstances of work involving such agents, including their amount;
- any occupational exposure limit values or biological limit values established on the territory of the Member State in question;
- the effect of preventive measures taken or to be taken;
- where available, the conclusions to be drawn from any health surveillance already undertaken.

The employer shall obtain additional information which is needed for the risk assessment from the supplier or from other readily available sources. Where appropriate, this information shall comprise the specific assessment concerning the risk to users established on the basis of Community legislation on chemical agents.

2. The employer must be in possession of an assessment of the risk in accordance with Article 9 of Directive 89/391/EEC, and shall identify which measures have been taken in accordance with Articles 5 and 6 of this Directive. The risk assessment shall be documented in a suitable form according to national law and practice, and may include a justification by the employer that the nature and extent of the risks related to chemical agents make a further detailed risk assessment unnecessary. The risk assessment shall be kept up-to-date, particularly if there have been significant changes which could render it out-of-date, or when the results of health surveillance show it to be necessary.

3. Certain activities within the undertaking or establishment, such as maintenance, in respect of which it is foreseeable that there is a potential for significant exposure, or which may result in deleterious effects to safety and health for other reasons, even after all technical measures have been taken, shall be included in the risk assessment.

4. In the case of activities involving exposure to several hazardous chemical agents, the risk shall be assessed on the basis of the risk presented by all such chemical agents in combination.

2. The employer must be in possession of an assessment of the risk in accordance with Article 9 of Directive 89/391/EEC, and shall identify which measures have been taken in accordance with Articles 5 and 6 of this Directive. The risk assessment shall be recorded in a suitable form according to national law and practice, and may include a justification by the employer that the nature and extent of the risks related to chemical agents make a further detailed risk assessment unnecessary. The risk assessment shall be kept up-to-date, particularly if there have been significant changes which could render it out-of-date, or when the results of health surveillance show it to be necessary.

5. In the case of a new activity involving hazardous chemical agents, work shall only commence after an assessment of the risk of that activity has been made and any preventive measures identified have been implemented.

6. Practical guidelines for the determination and assessment of risk, and for their review and, if necessary, adjustment, shall be developed in accordance with Article 12(2).

Article 5

General principles for prevention of risks associated with hazardous chemical agents and application of this Directive in relation to assessment of risks

1. In carrying out his obligation to ensure the health and safety of workers in any activity involving hazardous chemical agents the employer shall take the necessary preventive measures set out in Article 6(1) and (2) of Directive 89/391/EEC and include the measures set out in this Directive.

2. Risks to the health and safety of workers at work involving hazardous chemical agents shall be eliminated or reduced to a minimum by:

- the design and organization of systems of work at the workplace;
- the provision of suitable equipment for work with chemical agents and maintenance procedures which ensure the health and safety of workers at work;

- reducing to a minimum the number of workers exposed or likely to be exposed;
- reducing to a minimum the duration and intensity of exposure;
- appropriate hygiene measures;
- reducing the quantity of chemical agents present at the workplace to the minimum required for the type of work concerned;

suitable working procedures including arrangements for the safe handling, storage and transport within the workplace of hazardous chemical agents and waste containing such chemical agents.

Practical guidelines for preventive measures to control risk shall be developed in accordance with Article 12(2).

3. Where the results of the assessment referred to in Article 4(1) reveal a risk to the safety and health of workers, the specific protection, prevention, monitoring and information measures laid down in Articles 6, 7, 8 and 10 shall be applied.

4. Where the results of the risk assessment referred to in Article 4(1) show that, because of the quantities of a hazardous chemical agent present in the workplace, there is only a slight risk to the safety and health of workers, and the measures taken in accordance with paragraphs 1 and 2 of this Article are sufficient to reduce that risk, the provisions of Articles 6, 7 and 10 shall not apply.

3. Where the results of the assessment referred to in Article 4(1) reveal a risk to the safety and health of workers, the specific protection, prevention and monitoring measures laid down in Articles 6, 7 and 10 shall be applied.

Article 6

Specific protection and prevention measures

1. The employer shall ensure that the risk from a hazardous chemical agent to the safety and health of workers at work is eliminated or reduced to a minimum.

2. In applying paragraph 1, substitution shall by preference be undertaken, whereby the employer shall avoid the use of a hazardous chemical agent by replacing it with a chemical agent or process which, under its condition of use, is not hazardous or is less hazardous to workers' safety and health, as the case may be.

Where the nature of the activity does not permit risk to be eliminated by substitution, having regard to the activity and risk assessment referred to in Article 4, the employer shall ensure that the risk is reduced to a minimum by application of protection and prevention measures, consistent with the assessment of the risk made pursuant to Article 4. These will include, in order of priority:

- (a) design of appropriate work processes and engineering controls and use of adequate equipment and materials, so as to avoid or minimize the release of hazardous chemical agents which may present a risk to workers' safety and health at the place of work;
- (b) application of collective protection measures at the source of the risk, such as adequate ventilation and appropriate organizational measures;

- (c) where exposure cannot be prevented by other means, application of individual protection measures including personal protective equipment.

Practical guidelines for protection and prevention measures to control risk shall be developed in accordance with Article 12(2).

3. The measures referred to in paragraph 2 of this Article shall be accompanied by health surveillance in accordance with Article 10 if it is appropriate to the nature of the risk.

4. Unless the employer clearly demonstrates by other means of evaluation that, in accordance with paragraph 2, adequate prevention and protection have been achieved, the employer shall carry out on a regular basis, and when any change occurs in the conditions which may affect workers' exposure to chemical agents, such measurements of chemical agents which may present a risk to workers' health at the workplace as are necessary, in particular in relation to the occupational exposure limit values.

5. The employer shall take into account the results of the procedures referred to in paragraph 4 of this Article in carrying out the obligations laid down in or resulting as a consequence of Article 4.

In any event, where an occupational exposure limit value effectively established on the territory of a Member State has been exceeded, the employer shall immediately take steps, taking into account the nature of that limit, to remedy the situation by carrying out preventive and protective measures.

6. On the basis of the overall assessment of and general principles for the prevention of risks in Articles 4 and 5, the employer shall take technical and/or organizational measures appropriate to the nature of the operation, including storage and handling, providing protection of workers against hazards arising from the physico-chemical properties of chemical agents. In particular he shall take measures, in order of priority, to:

- (a) prevent the presence at the workplace of hazardous concentrations of inflammable substances or hazardous quantities of chemically unstable substances or, where the nature of the work does not allow that,
- (b) avoid the presence of ignition sources which could give rise to fires and explosions, or adverse conditions which could cause chemically unstable substances or mixtures of substances to give rise to harmful physical effects, and
- (c) mitigate the detrimental effects to the health and safety of workers in the event of fire or explosion due to the ignition of inflammable substances, or harmful physical effects arising from chemically unstable substances or mixtures of substances.

Work equipment and protective systems provided by the employer for the protection of workers shall comply with the relevant Community provisions on design, manufacture and supply with respect to health and safety. Technical and/or organizational measures taken by the employer shall take account of and be consistent with the equipment group

6. On the basis of the overall assessment of and general principles for the prevention of risks in Articles 4 and 5, the employer shall take technical and/or organizational measures appropriate to the nature of the operation, including storage, handling and segregation of incompatible chemical agents, providing protection of workers against hazards arising from the physico-chemical properties of chemical agents. In particular he shall take measures, in order of priority, to:

categorization in Annex I to Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres ⁽²³⁾.

The employer shall take measures to provide sufficient control of plant, equipment and machinery or provision of explosion suppression equipment or explosion pressure relief arrangements.

Article 7

Arrangements to deal with accidents, incidents and emergencies

1. Without prejudice to the obligations laid down in Article 8 of Directive 89/391/EEC, the employer shall, in order to protect the safety and health of workers from an accident, incident or emergency related to the presence of hazardous chemical agents at the workplace, establish procedures (action plans) which can be put into effect when any such event occurs, so that appropriate action is taken. These arrangements shall include any relevant safety drills which are to be performed at regular intervals, and the provision of appropriate first aid facilities.

2. In the case of the occurrence of an event such as is mentioned in paragraph 1, the employer shall immediately take steps to mitigate the effects of the event and to inform the workers concerned thereof.

In order to restore the situation to normal:

- the employer shall implement appropriate measures to remedy the situation as soon as possible;

⁽²³⁾ OJ No L 100, 19.4.1994, p. 1.

- only those workers who are essential to the carrying out of repairs and other necessary work shall be permitted to work in the affected area.

3. The workers who are permitted to work in the affected area shall be provided with appropriate protective clothing, personal protective equipment, specialized safety equipment and plant which they must use as long as the situation persists; that situation shall not be permanent.

Unprotected persons shall not be permitted to remain in the affected area.

4. Without prejudice to Article 8 of Directive 89/391/EEC the employer shall take the measures necessary to provide the warning and other communication systems required to signal an increased risk to safety and health, to enable an appropriate response and to launch remedial actions, assistance, escape and rescue operations immediately if the need arises.

5. The employer shall ensure that information on emergency arrangements involving hazardous chemical agents is available. The relevant internal and external accident and emergency services shall have access to this information. It shall include the following:

- advance notice of relevant work hazards, hazard identification arrangements, precautions and procedures, so that the emergency services can prepare their own response procedures and precautionary measures; and

any available information concerning specific hazards arising, or likely to arise, at the time of an accident or emergency, including information on procedures prepared pursuant to this Article.

Article 8

Information for workers

1. Without prejudice to Article 10 of Directive 89/391/EEC the employer shall ensure that workers and/or their representatives are provided with:

- the data obtained pursuant to Article 4 of this Directive, and further informed whenever a major alteration at the workplace leads to a change in these data;

information on hazardous chemical agents, such as the identity of such agents, the risks to safety and health, relevant occupational exposure limit values and other legislative provisions;

- information on appropriate precautions and actions to be taken in order to safeguard themselves and other workers at the workplace;

access to any safety data sheet provided by the supplier in accordance with Article 10 of Directive 88/379/EEC and Article 27 of Directive 92/32/EEC⁽²⁴⁾;

And that the information is:

Information and training for workers

1. Without prejudice to Articles 10 and 12 of Directive 89/391/EEC the employer shall ensure that workers and/or their representatives are provided with:

information on the hazardous chemical agents in the workplace and hazardous chemical agents identified in the risk assessment made pursuant to Article 4(1) such as the identity of these agents, the risks to safety and health, relevant occupational exposure limit values and other legislative provisions;

- training and information on appropriate precautions and actions to be taken in order to safeguard themselves and other workers at the workplace;

⁽²⁴⁾ OJ No L 154, 5.6.1992, p. 1.

- provided in a manner appropriate to the outcome of the risk assessment pursuant to Article 4 of this Directive. This may vary from oral communication to individual instruction and training supported by information in writing, depending on the nature and degree of the risk revealed by the assessment required by the said Article;
- updated to take account of changing circumstances.

2. Where containers and pipes for hazardous chemical agents used at work are not marked in accordance with the relevant Community legislation on the labelling of chemical agents and on safety signs at the workplace, the employer shall, without prejudice to the derogations provided for in the above mentioned legislation, ensure that the contents of the containers and pipes, together with the nature of those contents and any associated hazards, are clearly identifiable.

3. Member States may take measures necessary to ensure that employers may, preferably from the producer or supplier, obtain on request all information on hazardous chemical agents needed to apply Article 4(1) of this Directive, insofar as Directives 67/548/EEC and 88/379/EEC do not include any obligation to provide information.

**SECTION III
MISCELLANEOUS PROVISIONS**

Article 9

Prohibitions

1. To prevent the exposure of workers to health risks from certain chemical agents and/or certain activities involving chemical agents, the production, manufacture or use at work of the chemical agents and the activities set out in Annex III shall be prohibited to the extent specified therein.

2. Member States may permit derogations from the requirements of paragraph 1 in the following circumstances:

- for the sole purpose of scientific research and testing, including analysis;
- for activities intended to eliminate chemical agents that are present in the form of by-products or waste products;
- for the production of the chemical agents referred to in paragraph 1 for use as intermediates, and for such use.

The exposure of workers to chemical agents referred to in paragraph 1 must be prevented, in particular by providing that the production and earliest possible use of such chemical agents as intermediates must take place in a single closed system, from which the aforesaid chemical agents may be removed only to the extent necessary to monitor the process or service the system.

Member States may provide for systems of individual authorizations.

3. When derogations are permitted pursuant to paragraph 2, the competent authority shall request the employer to submit the following information:

- the reason for requesting the derogation;
- the quantity of the chemical agent to be used annually;
- the activities and/or reactions or processes involved;
- the number of workers liable to be involved;
- the precautions envisaged to protect the safety and health of workers concerned;
- the technical and organizational measures taken to prevent the exposure of workers.

4. The Council, in accordance with the procedure laid down in Article 118a of the Treaty, may amend the list of prohibitions under paragraph 1 of this Article, to include further chemical agents or activities.

Article 10

Health Surveillance

1. Without prejudice to Article 14 of Directive 89/391/EEC, Member States shall introduce arrangements for carrying out appropriate health surveillance of workers for whom the results of the assessment referred to in Article 4 of this Directive reveal a risk to health. These arrangements, including the requirements specified for health and exposure records and their availability, shall be introduced in accordance with national laws and/or practice.

Health surveillance, the results of which shall be taken into account in applying preventive measures in the specific workplace, shall be appropriate where:

- the exposure of the worker to a hazardous chemical agent is such that an identifiable disease or adverse health effect may be related to the exposure; and
- there is a likelihood that the disease or effect may occur under the particular conditions of the worker's work; and
- the technique of investigation is of low risk to workers.

Health surveillance procedures shall be agreed with the worker concerned.

Furthermore, there shall be valid techniques for detecting indications of the disease or effect.

Where a binding biological limit value has been set as indicated in Annex II, health surveillance shall be a compulsory requirement for work with the hazardous chemical agent in question, in accordance with the procedures in that Annex. Workers shall be informed of this requirement before being assigned to the task involving risk of exposure to the hazardous chemical agent indicated.

2. Member States shall establish arrangements to ensure that for each worker who undergoes health surveillance in accordance with the requirements of paragraph 1, individual health and exposure records are made and kept up-to-date.

3. Health and exposure records shall contain a summary of the results of health surveillance carried out and of any monitoring data representative of the exposure of the individual. Biological monitoring and related requirements may form part of health surveillance.

Health and exposure records shall be kept in a suitable form so as to permit consultation at a later date, taking into account any confidentiality.

Copies of the appropriate records shall be supplied to the competent authority on request. The individual worker shall, at his request, have access to the health and exposure records relating to him personally.

Where an undertaking ceases to trade, the health and exposure records shall be made available to the competent authority.

4. Where, as a result of health surveillance:

- a worker is found to have an identifiable disease or adverse health effect which is considered by a doctor or occupational health-care professional to be the result of exposure at work to a hazardous chemical agent; or
- a binding biological limit value is found to have been exceeded,

the worker shall be informed of the result which relates to him personally, including information and advice regarding any health surveillance which he should undergo following the end of the exposure, and

the worker shall be informed by the doctor or other suitably qualified person of the result which relates to him personally, including information and advice regarding any health surveillance which he should undergo following the end of the exposure, and

the employer shall:

- review the risk assessment made pursuant to Article 4(1);
- review the measures provided to eliminate or reduce risks pursuant to Articles 5 and 6;

take into account the advice of the occupational health-care professional or other suitably qualified person or the competent authority in implementing any measures required to eliminate or reduce risk in accordance with Article 6, including the possibility of assigning the worker to alternative work where there is no risk of further exposure, and

- arrange continued health surveillance and provide for a review of the health status of any other worker who has been similarly exposed. In such cases the competent doctor or occupational health-care professional or the competent authority may propose that exposed persons undergo a medical examination.

Article 11

Consultation and participation of workers

Consultation and participation of workers and/or their representatives shall take place in accordance with Article 11 of Directive 89/391/EEC on the matters covered by this Directive, including the Annexes hereto.

Consultation and participation of workers and/or their representatives shall take place in accordance with Article 11 of Directive 89/391/EEC on the matters covered by this Directive, including the Annexes hereto. Workers and/or their representatives shall in particular be consulted in relation to the outcome of the risk assessment referred to in Article 4(1) and the protection and prevention measures referred to in Articles 5 and 6.

Article 12

Adaptation of the Annexes, preparation and adoption of technical guidance

1. Adjustments of a strictly technical nature to the Annexes in line with:

- the adoption of Directives in the field of technical harmonization and standardisation concerning chemical agents, and/or
- technical progress, changes in international standards or specifications and new findings concerning chemical agents,

shall be adopted in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC.

2. The Commission shall draw up practical guidelines of a non-binding nature. These guidelines shall address the topics referred to in Articles 3, 4, 5 and 6, and Annex II, section 1.

The Commission shall first consult the Advisory Committee on Safety, Hygiene and Health Protection at Work in accordance with Decision 74/325/EEC.

In the context of the application of this Directive, Member States shall take account as far as possible of these guidelines in drawing up their national policies for the protection of the health and safety of workers.

Article 13

Repeal and amendment of earlier Directives

1. Directives 80/1107/EEC, 82/605/EEC and 88/364/EEC shall be repealed on the date referred to in Article 14(1).

2. Council Directive 83/477/EEC of 19 September 1983 on the protection of workers from the risks related to exposure to asbestos at work (second individual Directive within the meaning of Article 8 of Directive 80/1107/EEC)⁽²⁵⁾, is amended as follows:

⁽²⁵⁾ OJ No L 263, 24.9.1983, p. 25. Directive as amended by Directive 91/382/EEC (OJ No L 206, 29.7.1991, p. 16).

- (a) in the first sentence of Article 1(1), the following words shall be deleted: "which is the second individual Directive within the meaning of Article 8 of Directive 80/1107/EEC";
- (b) Article 9(2) shall be replaced by the following:

"2. The amendments necessary to adapt the Annexes to this Directive to technical progress shall be adopted in accordance with the procedure laid down in Article 17 of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at the workplace.
- (c) in the second subparagraph of Article 15(1) the words "in accordance with the procedure set out in Article 10 of Directive 80/1107/EEC" shall be replaced by "in accordance with the procedure laid down in Article 17 of Directive 89/391/EEC".

3. Council Directive 86/188/EEC of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work ⁽²⁶⁾ is amended as follows:

- (a) in Article 1(1), the following words shall be deleted: "which is the third individual Directive within the meaning of Directive 80/1107/EEC";
- (b) in Article 12(2), the second subparagraph shall be replaced by the following:

⁽²⁶⁾ OJ No L 137, 24.5.1986, p. 28.

"Annexes I and II shall be adapted to technical progress in accordance with the procedure laid down in Article 17 of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at the workplace.

4. Any other reference in Directive 83/477/EEC and Directive 86/188/EEC to Directive 80/1107/EEC shall be obsolete from the date of repeal of the said Directive.

5. Directives 91/322/EEC and 96/94/EC remain in force.

SECTION IV **Final provisions**

Article 14

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than []^(*). They shall forthwith inform the Commission thereof.

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

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

^(*) Three years after publication of this Directive in the Official Journal of the European Communities.

Article 15

Member States shall report to the Commission every five years on the practical implementation of this Directive, indicating the views of employers and workers.

The Commission shall inform the European Parliament, the Council and the Economic and Social Committee thereof.

Article 16

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Communities.

Article 17

This Directive is addressed to the Member States.

Done at

For the Council

The President

ANNEX I**List of binding occupational exposure limit values**

Name of agent	EINECS (¹) No	CAS (²) No	Occupational exposure limit value 8 h (³)		Occupational exposure limit value Short-term (⁴)	
			mg/m ³ (⁵)	ppm (⁶)	mg/m ³	ppm
Inorganic lead and its compounds			0,15			

(¹) EINECS: European Inventory of Existing Commercial Chemical Substances

(²) CAS: Chemical Abstracts Service

(³) Measured or calculated in relation to a reference period of 8 hours, time-weighted average

(⁴) A limit value above which exposure should not occur, and which is related to a 15 minute period unless otherwise specified

(⁵) mg/m³ = milligrams per cubic metre of air at 20° C and 101,3 KPa

(⁶) ppm = parts per million by volume in air (ml/m³)

ANNEX II

Binding biological limit values and health surveillance measures

1. Lead and its ionic compounds
 - 1.1. Biological monitoring must include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is:

70 µg Pb/100 ml blood
 - 1.2. Medical surveillance is carried out if:
 - exposure to a concentration of lead in air is greater than 0,075 mg/m³, calculated as a time-weighted average over 40 hours per week, or
 - a blood-lead level greater than 40 µg Pb/100 ml blood is measured in individual workers.
 - 1.3. Practical guidelines for biological monitoring and medical surveillance must be developed in accordance with Article 12(2). These must include recommendations of biological indicators (e.g. ALAU, ZPP, ALAD) and biological monitoring strategies.

ANNEX III**Prohibitions**

The production, manufacture or use at work of the chemical agents and activities involving chemical agents set out below are prohibited. The prohibition does not apply if the chemical agent is present in another chemical agent, or as a constituent of waste, provided that its individual concentration therein is less than the limit specified.

(a) Chemical Agents

EINECS ⁽¹⁾ No	CAS ⁽²⁾ No	Name of agent	Concentration Limit for exemption
202-080-4	91-59-8	2-naphthylamine and its salts	0,1% w/w
201-177-1	92-67-1	4- aminodiphenyl and its salts	0,1% w/w
202-199-1	92-87-5	Benzidine and its salts	0,1% w/w
202-204-7	92-93-3	4-nitrodiphenyl	0,1% w/w

⁽¹⁾ EINECS: European Inventory of Existing Commercial Chemical Substances

⁽²⁾ CAS: Chemical Abstracts Service

(b) Work Activities

None.

The Commission is unable to accept the following amendments proposed by the European Parliament

1. part of Amendment N° 5 (concerning Article 4.2)

This part of the amendment requires employers to record the risk assessment in a suitable form taking into account national law and practice. This would certainly weaken the common position which requires the records to be made according to national law and practice, that is with full respect of the national law.

2. Amendment N° 8 (concerning Article 6.5)

The amendment requires the employers always to adhere to the occupational exposure limit value, irrespective of the nature of the national provision. The Commission considers that this amendment would undermine the distinction between indicative and binding limit value.

3. Amendment N° 14 (concerning Article 12, 1, second indent)

This amendment requires deletion of "new findings" among situations requiring technical adjustments of Annexes. The Commission believes that "new findings" are indeed one of the main reasons behind a need for technical changes. The procedure presented in the common position gives the Community the possibility to react rapidly with technical solutions to "new findings"; the use of this procedure is limited to strictly technical adjustments.

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