

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(94) 230 final - SYN 459
Brussels, 09.08.1994

Amended proposal for a

COUNCIL DIRECTIVE

**on the protection of the health and safety of workers
from the risks related to chemical agents at work**

(presented by the Commission pursuant to Article 189 A (2)
of the EC-Treaty)

EXPLANATORY MEMORANDUM

Amended proposal for a Council Directive on the protection of the health and safety of workers from the risks related to chemical agents at work

Following receipt of the Opinion adopted by the European Parliament on the first reading on 20 April 1994, the Commission submits to Council, pursuant to Article 189a(2) of the EC Treaty, an amended proposal for a Directive:

There are two different types of proposed amendments:

- The first type of amendment adds precision to and makes useful clarification of the initial proposal;
- The second type of amendment is of a more general kind with the aim of strengthening the improvement of the health and safety of workers at work from risks related to chemical agents.

The amended proposal of the Commission conserves the structure and objectives of the initial proposal but it clarifies and amplifies certain provisions.

Of 38 amendments adopted by the European Parliament the Commission has not adopted 4 in total and 1 in part.

The Commission has not accepted an enlargement of the scope to include the self-employed. The proposal is an individual Directive under the framework Directive 89/391/EEC where only workers and employers are covered. A lower biological limit value for lead for women workers was not accepted because it is justified only during pregnancy. The Directive concerning measures to protect pregnant workers already provides such protection. A graduation of the risk assessment depending on the undefined term "insignificant" was not accepted because Article 3 of the initial proposal already provides for proportionality between risk and control and prevention measures.

The additional recital concerning the reference method retained from paragraphs B 3 and 4 of Annex IIa of Directive 88/642/EEC is a consequence of the acceptance of the relevant amendments of the European Parliament.

The addition of paragraph 8 of Article 8 is necessary in order to have consistency between biological limit values and limit values. The amendment of the European Parliament only contains the procedure to set biological limit values but not an obligation for Member States to implement such values.

1

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

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, drawn up after
consultation with the Advisory
Committee on Safety, Hygiene and
Health Protection at Work,

In co-operation with the European
Parliament),

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

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;

Whereas, pursuant to that Article,
such Directives must avoid imposing
administrative, financial and legal
constraints which would hold back
the creation and development of
small and medium-sized underta-
kings;

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

Whereas the respect of minimum
requirements on the protection of
the health and safety of workers
from the risks related to chemical
agents ensures not only the pro-
tection of the health and safety of
each individual worker but also
provides a level of minimum
protection of all workers in the
Community which avoids any possible
distortion in the area of

AMENDED TEXT

THE COUNCIL OF THE EUROPEAN UNION

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

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

competitiveness;

Whereas a consistent level of protection from the risks related to chemical agents has to be established for the Community as a whole and 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;

Whereas a work activity involving chemical agents is likely to expose workers to particularly high levels of risk;

Whereas Council Directive 80/1107/EEC of 22 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work as last amended by Council Directive 88/642/EEC, 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), and Council Directive 88/364/EEC of 9 June 1988 on the protection of workers by the banning of certain agents and/or certain work activities (fourth individual Directive within the meaning of Article 8 of Directive 80/1107/EEC) should, for the sake of consistency and clarity as well as for technical reasons, 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;

Whereas this Directive is an individual Directive within the meaning of Article 16 of 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;

Whereas, therefore the provisions of the said Directive, apply in full to workers exposed to chemical agents, without prejudice to more

AMENDED TEXT

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

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

stringent and/or specific provisions contained in this Directive;

Whereas Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, as last amended by Council Directive 92/32/EEC of 30 April 1992, Council Directive of 26 June 1978 on the approximation of the laws of the Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides) and Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations, as last amended by Council Directive 90/492/EEC, define and lay 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 establishes a system for marking containers and pipes used for dangerous substances or preparations at work;

Whereas Council Directive 82/501/EEC of 24 July 1982, on the major-accident hazards of certain industrial activities has as its objective the limitation of the consequences of such accidents to man and the environment and to ensure high levels of protection against such accidents and their consequences throughout the Community;

Whereas, in order to complete the information available to workers so as to ensure an improved level of protection, it is necessary that workers and their representatives be informed about the risks which chemical agents can pose for their

AMENDED TEXT

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

safety and health and about the measures necessary to reduce or eliminate those risks and that they should be in a position to check that the necessary protective measures are taken;

Whereas employers must keep abreast of new developments in technology with a view to improving the protection of worker's safety and health, and assess on a regular basis the implications for the safety and health of workers;

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 chemicals agents will none the less reduce these risks;

Whereas Commission Directive 91/322/EEC of 29 May 1991, establishes indicative limit values as provided for by Council Directive 80/1107/EEC on the protection of workers from the risks relating to chemical, physical and biological agents at work and whereas the former Directive should be maintained as part of the current framework;

Whereas technical implementing measures for the application of this Directive should be entrusted to the Commission in close co-operation with the Member States using the procedure provided in Article 13;

AMENDED TEXT

Whereas the requirements of Directive 88/642/EEC are repealed by the provisions of Article 14 of this Directive, and whereas the reference method in Annex IIa of Directive 88/642/EEC and in particular paragraphs 3 and 4 thereof, identifies a procedure for carrying out measurements of a concentration of a chemical agent in the air at the workplace the two above-mentioned paragraphs are to be retained in this Directive and whereas these methods shall be reviewed within 5 years taking account of modern standards for the general requirements for the performance of measuring procedures and devices for workplace measurements;

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

AMENDED TEXT

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

Subject

1. This Directive, which is the individual Directive within the meaning of Article 16 of Directive 89/391/EEC, lays down minimum requirements for the protection of workers against risks to their health and safety 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 to all chemical agents at work, without prejudice to other Community provisions under Directive 82/501/EEC, as amended, on the major accident hazards of certain industrial activities and 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 Directive 90/394/EEC apply where these are more favourable to the safety and health of workers at work.
4. The provisions of Directive 89/391/EEC shall apply fully to

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

the whole area referred to in paragraph 1, without prejudice to more stringent and/or specific provisions contained in this Directive.

5. The competent authorities shall regularly check if employers have taken the appropriate measures to protect the health and safety of workers at work and review the risk assessment pursuant to Article 3(2).

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 by any work activity, whether or not produced intentionally and whether or not placed on the market;
- (b) "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.
- (c) "Occupational exposure level" means, unless otherwise specified, the concentration of a chemical agent at the workplace in the air within the breathing zone of a worker and includes "limit value" and "occupational guidance value";
- (d) "Biological limit value" means the limit of concentration in the appropriate biological medium, of the relevant agent, its metabolite, or an indicator of effect;
- (e) "Hazard" means the intrinsic

AMENDED TEXT

- (c) "Occupational exposure limit" means, unless otherwise specified in this Directive, the concentration of a chemical agent at the workplace in the air within the breathing zone of a worker and includes "limit value" and "occupational guidance value";

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

property of a chemical agent with the potential to cause harm;

- (f) "Risk" means the likelihood that the potential for harm will be attained under the conditions of use and/or exposure;
- (g) "Competent person" means any person who has the necessary knowledge, experience, practical ability and skills to perform the task in question;
- (h) "Waste" means any chemical agent remaining after a process, or any object or material contaminated by a chemical agent, which is intended for disposal;
- (i) "Health surveillance" means the assessment of an individual worker to determine the state of health of this individual.

SECTION II

PROVISIONS ADDRESSED TO EMPLOYERS

Article 3

General obligations

- 1. To safeguard the safety and health of workers the employer shall take the necessary measures including the assignation of specific duties to a competent person to ensure that for activities involving chemical agents:
 - a) workers can perform the work assigned to them without endangering their safety and health and/or those of other workers;
 - b) the operation of workplaces when workers are present takes place under the responsibility of a person in charge;

AMENDED TEXT

- 1. To safeguard the safety and health of workers the employer shall take the necessary preventive measures set out in Article 6(1) and 6(2) of Directive 89/391/EEC to ensure that for activities involving chemical agents:

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

- c) work involving a special risk is entrusted only to competent staff and carried out in accordance with the instructions given;
- d) effective arrangements are made to deal with accidents and emergencies, including any relevant safety drills which are to be performed at regular intervals;
- e) all safety and health instructions are comprehensible to the workers concerned;
- f) appropriate first aid facilities are provided.

2. The employer shall be in possession of an assessment of the risks concerning safety and health drawn up in a Document, hereinafter referred to as the "safety and health document", which shall be kept up-to-date.

The safety and health document shall identify any risk at work and record in particular:

- an assessment of the risks incurred by the workers in any activity involving chemical agents, and that a competent person has carried out this assessment; where a chemical agent has been subject to a specific evaluation concerning the risks for its users as part of a process of authorization for placing on the market, the risk assessment shall take into

AMENDED TEXT

- c) work is entrusted only to competent staff and carried out in accordance with the instructions given;
- d) effective arrangements are made to deal with incidents, accidents and emergencies, including any relevant safety drills which are to be performed at regular intervals;
- f) appropriate first aid facilities and appropriately trained personnel are provided.

The safety and health document shall identify any risk at work arising from the intrinsic properties of the agents, alone or in combination, the level of exposure and the circumstance of work involving chemical agents and record in particular:

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

account the results of
that evaluation;

- that adequate measures will be taken to attain the aim of the Directive and in particular any precautionary measures to protect the health and safety of workers provided for in other Community legislation;
- that the design, use and maintenance of the workplace and of the equipment involving chemical agents are safe;
- that an up-to-date list has been made of the chemicals used, or intended to be used at work.

The safety and health document must be drawn up prior to the commencement of work and shall be kept up-to-date in particular if there have been major changes which could render it out-of-date.

The employer shall ensure that the workers are informed of the contents of the safety and health document whenever a major alteration at the workplace leads to a change in the document.

3. The employer shall ensure that the risk from a chemical agent to the safety and health of workers at work is eliminated or reduced in particular by eliminating the risk at source or by seeking to achieve the maximum degree of reduction of risk by collective protection measures in particular cleaner technologies and the state of art and technology, in preference to individual protection measures.

AMENDED TEXT

- which measures have been taken to attain the aim of this Directive.

- that the work systems deployed the design and maintenance of the workplace and of the equipment involving chemical agents are safe;

3. The employer shall ensure that the risk from a chemical agent to the safety and health of workers at work is eliminated or reduced in particular by eliminating the risk at source or by seeking to achieve the maximum degree of reduction of risk by collective protection measures in particular cleaner technologies and other organisational and technical measures as they become available, in preference to individual protection measures.

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

4. For certain special 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 on safety and health for other reasons, even after all technical measures have been taken, the employer shall determine, after consultation of the workers or their representatives in the undertaking or establishment, the measures necessary to reduce the duration of workers' exposure to the minimum possible and to ensure protection of workers while they are engaged in such activities.

The employer shall ensure that these activities take place only in areas that are clearly demarcated and indicated, or that persons not specifically authorised are prevented by other means from having access to such areas.

5. The measures taken by the employer to meet the requirements of this Directive shall be consistent with the need to protect public health and the environment

Article 4

Specific protection and prevention measures

The employer shall take measures appropriate to the nature of the risk :

- to provide suitable and safe

AMENDED TEXT

The employer shall take measures appropriate to the nature of the risk in the workplace:

- to provide suitable protective equipment and facilities for use by workers;
- to provide training and safe working procedures;

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

plant and process equipment;

- to limit the quantity of a hazardous chemical agent at the workplace and to segregate incompatible chemical agents;
- to avoid, detect and combat the starting and spread of fires and explosions, and
- to prevent the occurrence of explosive and/or hazardous atmospheres.

Article 5

Communication, warning and alarm systems

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 assistance, escape and rescue operations to be launched immediately if the need arises.

Article 6

Keeping workers informed

1. Without prejudice to Article 10 of Directive 89/391/EEC workers and/or their representatives shall be provided with:

- information on chemical agents, as referred to in paragraph 9 of the Annex, in a comprehensible form and adapted to the needs of the individual worker;
- information on appropriate precautions and actions to be taken in order to safeguard himself and other workers at the workplace;

AMENDED TEXT

- to limit and confine the quantity of a hazardous chemical agent at the workplace to that essential to the nature of the process and to segregate incompatible chemical agents whose incompatibility presents a risk to health and safety;

- to avoid, detect and combat the starting and spread of fires and loss of containment, and

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.

- information on appropriate precautions and actions to be taken in order to safeguard him/herself and other workers at the

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

- written information where the assessment carried out pursuant to Article 3.2 shows it to be necessary and which is kept up-to-date.

2. The employer shall ensure that containers used for chemical agents at work are provided with safety signs or are marked with the identity and the nature of the contents and their hazards. Where a safety data sheet has not been provided at the time of supply the employer shall obtain the relevant information from the supplier or other sources, and shall not use the chemical agent until such information has been obtained and made available to workers.

SECTION III

MISCELLANEOUS PROVISIONS

Article 7

Prohibitions

1. The production, manufacture or use at work of chemical agents and work activities set out below are prohibited to the extent specified. 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.

Eines No (*)	CAS No (*)	Name of agent	Concentration limit for exemption
102-080-4	91-59-8	2-naphthylamine and its salts	0,1 % w/w
102-177-1	92-67-1	4-aminodiphenyl and its salts	0,1 % w/w
102-199-1	92-87-5	Benzidine and its salts	0,1 % w/w
102-204-7	92-93-3	4-nitrodiphenyl	0,1 % w/w

AMENDED TEXT

workplace;

- written information where the assessment carried out pursuant to Article 3.2 shows such information to be necessary and which is kept up-to-date.

2. The employer shall ensure that containers used for chemical agents at work are provided with safety signs or are marked with the identity and the nature of the contents and their hazards or else are clearly identifiable with regard to their nature and hazards. Where a safety data sheet has not been provided at the time of supply the employer shall obtain the relevant information from the supplier or other sources, and shall not use the chemical agent until such information has been obtained and made available to workers.

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

- (1) EINECS : European Inventory of Existing Chemical Substances
- (2) CAS : Chemical Abstract Service

2. An application from an employer Member States may grant specific derogations from the requirements of paragraph 1 in the following circumstances:

- for the sole purpose of scientific research and testing, including analysis;
- for work activities intended to eliminate the prohibited chemical agents;
- provided that the production or use is carried out in a closed system and that the chemical agent no longer remains at the end of the process.

3. Amendments required with regard to the chemical agents and work activities already covered by this Article shall be determined and adopted, in accordance with the procedure referred to in Article 13.

Article 8

Occupational exposure levels

1. Occupational exposure levels shall be drawn up taking account of available information, including scientific and technical data in accordance with the procedure referred to in Article 13.

AMENDED TEXT

Occupational exposure limits and biological limit values

1. Occupational exposure limits, drawn up at Community level after an evaluation of the latest available scientific data relevant to occupational health effects and on measuring aspects, shall be established or revised after consultation of the Advisory Committee on

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

2. For any chemical agent for which a limit value is listed in the Annex (paragraph 10), Member States shall establish a corresponding occupational exposure level which shall not be exceeded.
3. Occupational exposure levels established as indicative limit values by Directive 91/322/EEC shall be considered as occupational guidance values for the purpose of this Directive.
4. Member States shall take into account occupational guidance values when setting occupational exposure levels on their own territories.

AMENDED TEXT

Safety, Hygiene and Health Protection at Work, in accordance with the procedure laid down in Article 13. For the purpose of this Directive these occupational exposure limits shall be referred to as "occupational guidance values".

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2. Occupational exposure limits established as indicative limit values by Directive 91/322/EEC shall be considered as occupational guidance values for the purpose of this Directive.
3. Member States shall take into account occupational guidance values when setting national occupational exposure limits. They shall inform workers' and employers' organisations of occupational guidance values. In cooperation with these organisations Member States shall establish the time scale required to bring national occupational exposure limits into line with occupational guidance values.
4. Occupational exposure limits, drawn up at Community level after an evaluation of the latest available scientific data relevant to occupational health effects and on measuring aspects and taking account of technical and feasibility factors whilst maintaining the aims of ensuring the health and safety of workers at work, shall be established or revised after consultation of the Advisory Committee on Safety, Hygiene and Health Protection at Work, in accordance with the procedure laid down in Article 118A of the Treaty. For the purpose of this Directive, these occupational exposure limits shall be referred to as "limit values".

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

5. When a Member State introduces or revises an occupational exposure level for a chemical agent, on the basis of new data, it shall inform the Commission and the other Member States thereof together with the relevant scientific and technical data.

Article 9

Health Surveillance

Member States shall establish arrangements to ensure that workers receive health surveillance appropriate to the safety and health risks they incur at work, in accordance with Article 14 of

AMENDED TEXT

5. For any chemical agent for which a limit value is established, Member States shall set up a corresponding national occupational exposure limit based on, but not exceeding, the Community minimum requirement.
6. The Commission shall review each occupational guidance value within a period of 5 years from the date of its adoption with a view either to proposing a limit value or to maintaining its status.
7. Biological limit values shall take account of available information including scientific and technical data and shall be established after consultation of the Advisory Committee on Safety, Hygiene and Health Protection at Work, in accordance with the procedure laid down in Article 118A of the Treaty.
8. For any chemical agent for which a biological limit value is established, Member States shall set up a corresponding national biological limit value based on, but not exceeding, the Community minimum requirement.
9. Where a Member State introduces or revises a national occupational exposure limit or a 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.

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

Directive 89/391/EEC.

Article 10

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. In
particular the employer shall make
arrangements to facilitate the
participation of workers and/or
their representatives in appraising
their workplace and in the
establishment of the precautions to
be adopted when it is found that an
occupational exposure level or
biological limit value is exceeded.

Article 11

Minimum requirements for health and
safety

1. A new activity involving
chemical agents for the first
time after the date on which
this Directive is brought into
effect as referred to in
Article 15, must satisfy the
minimum safety and health
requirements laid down in the
Annex.
2. An activity involving chemical
agents existing on the date on
which this Directive is brought
into effect as referred to in
Article 15, must satisfy the
minimum safety and health
requirements laid down in the
Annex as soon as possible and at
the latest five years after
that date.

Article 12

Adjustments to the Annex

1. Technical adjustments to the

AMENDED TEXT

2. An existing activity involving
chemical agents on the date on
which this Directive is brought
into effect as referred to in
Article 15, must satisfy the
minimum safety and health
requirements laid down in the
Annex as soon as possible and at
the latest five years after
that date.

Adjustments to the Annex and
practical implementation

PREVIOUS TEXT

Anne in line with :

- the adoption of Directives in the field of technical harmonisation and standardisation concerning chemical agents,

and/or

- technical progress, changes in international regulations or specifications and new findings concerning chemical agents,

shall be adopted in accordance with the procedure laid down in Article 13.

2. Detailed rules on technical guidance for the implementation of the provisions contained in this Directive shall be adopted in accordance with the procedure referred to in Article 13.

Article 13

Committee

1. The Commission shall be assisted by the committee created in Article 17(1) of Directive 89/391/EEC.
2. Where reference is made to the procedure laid down in this Article the matter shall be referred to the Committee by the chairman either on his own initiative or at the request of the representative of a Member State.

The representative of the Commission shall submit to the

AMENDED TEXT

2. Detailed rules on technical guidance for practical aspects of the implementation of the provisions contained in this Directive shall be adopted, after consultation of the social partners, in accordance with the procedure referred to in Article 13.
3. The provisions in point 12 of the Annex shall be reviewed in the light of technical progress within five years of adoption of this Directive.

PREVIOUS TEXT

committee a draft of the measures to be taken. The committee shall deliver its opinion on the draft within a time limit which the chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged if they are in accordance with the opinion of the committee.

If the measures envisaged are not in accordance with the opinion of the committee, or if no opinion is delivered, the Commission shall, without delay, submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of three months from the date of the referral to the Council, the Council has not acted, the proposed measures shall be adopted by the Commission.

Article 14

Revocation

1. The following Directives shall be repealed on the date this Directive comes into force :

- Directive 80/1107/EEC, as amended by Directive 88/642/EEC, on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work;

AMENDED TEXT

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

AMENDED TEXT

- Directive 82/605/EEC on the protection of workers from the risks related to exposure to metallic lead and its ionic compounds at work;
- Directive 88/364/EEC on the protection of workers by the banning of certain specified agents and/or certain work activities.

2. The reference in :

- Article 15(1) of Directive 83/477/EEC and Article 1(5) of Directive 91/382/EEC amending Directive 83/477/EEC on the protection of workers from the risks related to exposure to asbestos at work;
- Article 12(2) of Directive 86/188/EEC on the protection of workers from the risks related to exposure to noise at work;

to the procedure set out in Article 10 of Directive 80/1107/EEC shall be construed as a reference to the procedure laid down in Article 13.

3. Any other reference in :

- Directive 83/477/EEC, as amended by Directive 91/382/EEC, on the protection of workers from the risks related to exposure to asbestos at work;
- Directive 86/188/EEC on the protection of workers from the risks related to exposure to noise at work;
- Directive 91/322/EEC on establishing indicative limit values by implementing Council Directive

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

80/1107/EEC on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work;

to Directive 80/1107/EEC, as amended by Directive 88/642/EEC, is obsolete.

Article 15

Final provisions

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30th June 1996. They shall forthwith inform the Commission thereof.
2. When Member States adopt the provisions referred to in paragraph 1, these shall contain a reference to this Directive or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be adopted by Member States.
3. The 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.
4. 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.

AMENDED TEXT

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

AMENDED TEXT

Article 16

This Directive is addressed to the
Member States.

ANNEX

Minimum Safety and Health
Requirements as referred to in
Article 11 of the Directive

1. Preliminary note :

The obligations laid down in
this Annex apply whenever
required by the features of
the workplace, the activity,
the circumstances or a
specific risk.

2. Supervisory obligations

2.1 Person in charge

A responsible and competent
person who has been appointed
by the employer in accordance
with the national laws and/or
practices must at all times
be in charge of every
workplace where chemical
agents and workers are
present.

The employer may personally
assume responsibility for the
workplace referred to in the
first paragraph, if he has
the skills and competence
required for the purpose in
accordance with national laws
and/or practices.

2.2 Supervision

To ensure workers' health and
safety protection during all
operations undertaken, the
necessary supervision must be
provided by competent persons
having the necessary knowl-
edge, experience and skills
for the purpose, in accord-

PREVIOUS TEXT

ance with national laws and/or practices, having been appointed by the employer and acting on his behalf.

The employer may personally undertake the supervision referred to in the first paragraph if he has the skills and competence required for the purpose, in accordance with national laws and/or practices.

3. Protective measures

- 3.1 Measures must be taken for assessing the presence of harmful and/or potentially explosive substances in the atmosphere and for measuring the concentration of such substances.

Where required by the safety and health document monitoring devices measuring gas concentrations at specified places automatically and continuously, automatic alarms and devices to cut off power automatically from electrical installations and internal combustion engines must be provided.

Where automatic measurements are provided for, the values measured must be recorded and kept as stipulated in the health and safety document.

- 3.2 The employer shall ensure that any chemical agent which meets the requirements to be classified, according to the criteria in Annex VI of Directive 67/548/EEC, as a category 1 or 2 carcinogen, mutagen or chemical agent toxic to reproduction, is as far as is technically possible, eliminated or replaced by a chemical agent or process which under its conditions of use is not dangerous, or is less dangerous, to workers' health and safety, as the case may

AMENDED TEXT

- 3.1 Measures must be taken for assessing the presence of harmful and/or potentially explosive substances in the atmosphere and for measuring and recording the concentration of such substances.

Where required by the safety and health document appropriate monitoring and safety devices capable when necessary of shutting down production must be provided.

PREVIOUS TEXT

be. Where it is not technically possible to replace the chemical agent by an agent or a process which is not dangerous or is less dangerous to workers' health and safety the employer shall reduce risk, giving preference to the manufacture and use of the chemical agent in a closed system.

3.3 The employer shall ensure that exposure of workers to a chemical agent at work does not exceed the limit value set for that chemical agent using the procedure referred to in Article 8.

3.4 In cases where exposure occurs simultaneously to more than one chemical agent for which limit values have been set, the effects of exposure shall be considered as additive, unless a more precise evaluation of their combined effect is known.

3.5 The employer shall carry out such periodic measurements of chemical agents at the workplace as are necessary in particular in relation to limit values, unless by other means the employer clearly demonstrates that adequate protection has been achieved. Any measurements shall be made by a competent person, using a valid technique.

3.6 The measurements shall be carried out in such a way as to ensure that the result is representative of the exposure of the worker to the agent or agents in question.

4. Protection from abnormal risks

4.1 In order to protect the health and safety of workers from an incident, accident or emergency which is likely to result in abnormal conditions

AMENDED TEXT

3.4 In cases where exposure occurs simultaneously to more than one chemical agent for which occupational exposure limits have been set, the effects of exposure shall be considered as additive, unless a more precise evaluation of their combined effect is known.

PREVIOUS TEXT

AMENDED TEXT

detrimental to the health and safety of workers, the employer shall establish procedures (action plans) which can be put into effect when any such event occurs, so that appropriate action is taken.

4.2 In case of the occurrence of such an event the employer shall immediately inform the workers thereof. Until the situation has been restored to normal and the cause of the abnormal conditions have been eliminated:

- the employer shall identify the cause without delay and implement appropriate measures to remedy the situation as soon as possible;
- 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.

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

4.4.1 Where harmful substances accumulate or may accumulate in the atmosphere appropriate measures must be taken to ensure their collection at source and removal.

Without prejudice to provisions for the protection of public health and the environment the system must be capable of

PREVIOUS TEXT

dispersing such hazardous atmospheres in such a way that workers are not at risk.

- 4.4.2 Without prejudice to Directive 89/656/EEC, an appropriate and sufficient breathing and resuscitation equipment must be available in areas where workers may be exposed to atmospheres which are harmful to health.

In such cases, a sufficient number of workers trained to use such equipment must be present at the workplace.

The equipment must be suitably stored and maintained.

- 4.4.3 Where toxic gases are or may be present in the atmosphere, a protection plan detailing the protective equipment available and the preventive measures taken must be kept and made available to the competent authorities.

- 4.5 The employer shall ensure that information on emergency arrangements involving chemical agents is made available on request to the relevant internal and external accident and emergency services. 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

AMENDED TEXT

- 4.4.3 Where toxic chemical agents are or may be present in the atmosphere and the risk assessment indicates it to be necessary a protection plan detailing the protective equipment available and the preventive measures taken must be kept and made available to the competent authorities.

PREVIOUS TEXT

concerning specific hazards arising, or likely to arise, at the time of an accident or emergency, including information on procedures prepared pursuant to paragraph 4.1 above.

5. Derogation information

5.1 When making an application for a derogation from a prohibition or restriction pursuant to Article 7(2), an employer shall submit the following information to the competent authority :

- the quantities to be used annually;
- the activities or reactions or processes to be carried out;
- the number of workers liable to be exposed;
- the precautions envisaged to protect the health and safety of workers concerned.
- the technical and organisational measures to be taken to prevent the exposure of workers.

6. Safety equipment maintenance

Adequate safety equipment must be maintained ready for use and in good working order at all times.

Maintenance must be undertaken with due regard to operations.

AMENDED TEXT

- the reason for requesting the derogation.

Staff required to use safety

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

7. Special health surveillance
measures

The employer shall ensure
that any worker exposed to :

- a chemical known to cause
sensitisation;
- the following chemical
agents:

Arsenic and its compounds;
Beryllium;
Cadmium and its compounds;
Carbon disulphide;
Chromates (Cr6+);
Cobalt;
Lead and its compounds;
Mercury and its compounds;
Organophosphoric esters;
Tetrachloroethane;

shall, if he so wishes,
undergo health surveillance.

Where biological monitoring
is carried out it shall form
part of health surveillance.
Where indicated by the nature
of the risk, biological moni-
toring shall be used to
reveal pre-clinical effects
on the health status of
workers in order to permit
intervention to prevent
clinical deterioration. The
result of biological
monitoring shall not be used
to discriminate against the
worker.

Biological limit values and
related requirements are to
be observed as part of health
surveillance.

AMENDED TEXT

equipment must be trained and
drilled in its use.

Where the assessment carried
out pursuant to Article 3.2.
indicates a serious risk for
the worker health
surveillance shall be
mandatory. Workers shall be
informed of this requirement
before being assigned to the
task involving such a risk.

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

AMENDED TEXT

Where, as a result of health surveillance, a worker is found to be suffering from an abnormality which is considered to be the result of exposure to a chemical agent, the employer shall:

- review the safety and health document, prepared pursuant to Article 3;
- take into account the advice of the doctor or medical authority and implement specific measures to eliminate or reduce exposure, including the possibility of assigning the worker to alternative work with a lesser risk of exposure;
- 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 medical authority may propose that exposed persons undergo a medical examination.

The doctor or medical authority shall inform the worker of the results of health surveillance which relate to him personally, including information and advice regarding any health surveillance which the worker should undergo following the end of exposure.

8. Record keeping

- 8.1 The employer shall ensure that the safety and health document prepared pursuant to Article 3 contains sufficient detail about the information on which it is based and the risk assessment methods used for the competent authority to evaluate the assessment and the measures taken to eliminate or reduce any risk.

PREVIOUS TEXT

The safety and health document shall be kept for at least 5 years from the date on which it is made or revised and shall be made available to workers or their representatives and to the competent authority on request.

- 8.2 Member States shall establish arrangements to ensure that for each worker who undergoes health surveillance in accordance with the requirements of Article 9 an individual health record is made and kept up-to-date. The health record shall contain a summary of the results of health surveillance carried out and of any monitoring data representative of the exposure of the individual. It shall be kept, taking into account medical confidentiality, in accordance with national laws and practice.

The health records shall be retained for at least 40 years from the date of the last entry. A copy shall be supplied to the competent medical authority on request. In accordance with national laws and practice the individual worker shall, at his request, have access to the health record relating to him personally.

In the case where an undertaking ceases to trade, the health records shall be made available to the competent authority, in accordance with national laws and practice.

9. Information on chemical agents

- 9.1 The information on chemical agents to be provided to the worker shall include the following :

AMENDED TEXT

- 8.2 Member States shall establish arrangements to ensure that for each worker who undergoes health surveillance in accordance with the requirements of Article 9 an individual health and exposure record is made and kept up to date. The health and exposure record shall contain a summary of the results of health surveillance, carried out and of any monitoring data representative of the exposure of the individual. It shall be kept, taking into account medical confidentiality, in accordance with national laws and practice.

The health and exposure records shall be retained for at least 40 years from the date of the last entry. A copy shall be supplied to the competent medical authority on request. In accordance with national laws and practice the individual worker shall, at his request, have access to the health and exposure record relating to him personally.

In the case where an undertaking ceases to trade, the health and exposure records shall be made available to the competent authority, in accordance with national laws and practice.

99

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

AMENDED TEXT

- the identity of the agent or agents to which exposure may occur;
- risks to health and safety arising from the work activity or process or arising from possible exposure at the workplace;
- the precautions which the employer has undertaken in order to reduce risks, including information on containment facilities, safe storage and handling, transport and waste disposal within the enterprise;
- the precautions which the worker must take in order to reduce exposure, including use of personal protective equipment;
- relevant occupational exposure levels;
- the consequence of any foreseeable abnormal situation including over-exposure and action to be taken;
- prepared action plans;
- first aid measures;
- fire fighting methods;
- action taken, or to be taken, in the case of a spillage or an incident, accident or emergency involving a chemical agent;
- any restrictions on use of agents or limitation of access to designated areas, including indications on how such areas may be recognised;
- up-to-date information giving the results of measurements of exposure.

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

9.2 The employer shall ensure that containers and pipes for chemical agents at work are :

- in the case of chemical agents covered by the definition of dangerous substances or preparations in accordance with Directives 67/548/EEC and 88/379/EEC as amended, provided with safety signs in accordance with Directive 92/58/EEC. Information shall also be provided either by labelling on the container, or by other suitable means, on the contents and their hazards, the identity, and the risk and safety phrases in accordance with the criteria laid down in Annex VI of Directive 67/548/EEC and in Directive 88/379/EEC;
- in the case of other chemical agents, marked or otherwise provided with an indication of the nature of the contents.

9.3 The employer shall ensure that containers used for chemical agents which are labelled at the time of supply to the employer shall retain the label at the workplace while any hazard from the chemical agent remains.

9.4 The employer shall make available to workers, or workers' representatives, on request, any safety data sheet provided by the supplier in accordance with

AMENDED TEXT

Where a chemical agent is sufficiently identifiable at the workplace under its generic or proprietary name, the use of this latter name shall be allowed.

Smaller containers containing chemical agents transferred from a bulk supply also bear the necessary labels.

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

Article 10 of Directive 88/379/EEC and Article 27 of Directive 92/32/EEC or, where these Directives do not apply, with a data sheet of similar format and content containing relevant data.

9.5 The competent authority shall ensure that employers may obtain information on chemical agents in order to protect the safety and health of workers at work.

10. Limit Values and Biological Limit Values

10.1 Limit Values (3) for occupational exposure

Limit No (1)	CAS No (2)	Name of agent	Limit value (3)	Unit (3)
		Metallic lead and its ionic compounds	0,15	—

- (1) EINECS: European Inventory of Existing Chemical Substances.
- (2) CAS: Chemical Abstract Service Number.
- (3) Measured or calculated in relation to a reference period of eight hours unless otherwise stated.
- (4) mg/m³ milligrams per cubic metre
- (5) ppm parts per million by volume in air (ml/m³)
- (6) at 20 C and 101,3 KPa (760 mm Mercury pressure)

10.2 Biological Limit Values

a) Lead

Biological monitoring shall, apart from the exception mentioned in point 11 b), include measuring the blood-lead level (PbB); the biological limit value is:

70 µg Pb/100 ml blood

AMENDED TEXT

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

The method to be used for the analysis is atomic absorption spectroscopy.

11. Special Measures for Lead

a) The biological monitoring may also include one or more of the following biological indicators:

- delta aminolaevulinic acid in urine (ALAU);
- zinc protoporphyrin (ZPP);
- delta aminolaevulinic acid dehydratase in blood (ALAD).

The related methods to be used for the analysis of samples are:

- ALAU: Davis or equivalent method
- ZPP: Haematofluorimetry or equivalent method
- ALAD: European standardised method or equivalent method

b) The lead in blood (PbB) measurement may be replaced by that of ALAU when dealing with workers who have been subjected for a period of less than one month to risks of high exposure. In this case the following limit values shall be applied for ALAU:

20 mg/g creatinine

c) Biological monitoring shall be carried out at least every six months; this frequency may be reduced to once a year where at the same time:

- the results of the measurements for individuals or for groups of workers have shown, on the previous two consecutive occasions on which monitoring was carried out, a lead-in-air concentration higher

AMENDED TEXT

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

than 0,075 mg/m³ and
lower than 0,1 mg/m³.

- the PbB level of any individual worker does not exceed 50 ug Pb/100 ml blood.

AMENDED TEXT

12. Requirements for measuring procedures

- (a) The measuring procedure must give results representative of worker exposure.
- (b) To ascertain the exposure of the worker at the workplace, where possible personal sampling devices should be used, attached to workers' bodies.

Where a group of workers is performing identical or similar tasks at the same place and has similar exposure, sampling such as to be representative of the group may be carried out within that group.

Fixed-point measuring systems may be used if the results make it possible to assess exposure of the worker at the workplace.

Samples should as far as possible be taken at breathing height and in the immediate vicinity of workers.

If in doubt, the point of greatest risk is to be taken as the measuring point.

- (c) The measuring procedure used must be appropriate to the agent to be measured, its limit value and the workplace atmosphere.

The result must show the concentration of the agent exactly and in the same terms as the limit value.

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

AMENDED TEXT

- (d) If the measuring procedure is not specific to the agent to be measured, the full value recorded must be counted as applying to the agent to be measured.
- (e) The limits of detection, sensitivity and precision of the measuring procedure must be appropriate to the limit value.
- (f) The accuracy of the measuring procedure should be ensured.
- (g) The measuring procedure must have been tested under practical conditions of use.
- (h) If the European Committee for Standardization (CEN) publishes general requirements for the performance of measuring procedures and devices for workplace measurements together with provisions on testing, they should be referred to when selecting appropriate measuring procedures.

Measurement specifications for detecting representative particle populations in the air at the workplace

- (a) Suspended matter concentration should be measured in relation to effect; therefore, when sampling, either the inspirable fraction or the respirable fraction should be measured.

This requires particle separation according to aerodynamic diameter equivalent to the deposition occurring in breathing.

Since, appropriate equipment for workplace sampling is not yet available, practical specifications for uniform measurement are needed.

PREVIOUS TEXT

AMENDED TEXT

(b) The fraction of suspended matter which can be breathed in by a worker through the mouth and/or the nose is deemed to be inspirable.

By way of example, in measurement practice, devices with an inspiration rate of 1,25 m/s +/- 10% or devices in conformity with ISO/TR 7708 1983 (=e) are used for sampling.

In the first of these two cases, cited by way of example:

- with sampling devices attached to the person, the inlet should be directed parallel to the worker's face throughout sampling,

- with fixed-point sampling, the position and shape of the inlet should enable samples representative of workers' exposure covering various directions of flow to be taken,

- The position of the sampling device inlet is of little significance where there are very low flow rates for the surrounding air,

- with surrounding flow rates of 1m/s and above, omnidirectional sampling in the horizontal plane is recommended,

(c) The respirable fraction of suspended matter comprises a population passed through a separation system equivalent in its effect to the theoretical separation function of a sedimentation separator giving 50% separation of particles with

Proposal of the Commission
(OJ C 165 of 16.6.93)

PREVIOUS TEXT

AMENDED TEXT

an aerodynamic diameter
of 5 μ m (Johannesburg
Convention, 1979).

- (d) If the CEN establishes
specifications for the
collection of suspended
material at the work-
place, they should be
applied, by way of
preference.

Other methods may be
used provided that they
yield the same conclu-
sions or a stricter
conclusion in relation
to compliance with the
limit values'.

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