

COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 14 May 1993

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)

EXPLANATORY MEMORANDUM

Legal base

1. This proposal is based on Article 118A of the EEC Treaty and is presented in the form of an individual Directive under Article 16 of Council Directive 89/391/EEC "on the introduction of measures to encourage improvements in the health and safety at work" (1).

Justification for this proposal

a) Reason for Community action

2. Exposure to chemical agents occurs in every aspect of daily life. Over 100,000 chemicals are included in the European Inventory of Existing Chemical Substances (EINECS). Many of these chemicals have dangerous properties which can adversely affect the health and safety of workers at work. It has been estimated that accidents and ill health at work account for approximately 7% of all social security expenditure within the EC, affecting 10 million workers every year at an overall cost of 20 billion ECU. It is clear from information in Member States that a significant proportion of the ill-health that is caused by work activities is due to

(1) O.J. N° L183 of 29.06.1989, p. 1

exposure to chemical agents. It is therefore important that suitable precautions should be taken at the workplace to prevent these problems.

3. In Member States the legal provisions concerning protection of workers against the risks related to chemical agents are divergent. In some cases they are rudimentary and in others they are comprehensive; some are more stringent than the present proposal which is designed to ensure that all Member States come up to at least the minimum level considered necessary. In line with Article 118A of the EEC Treaty the proposal is couched in general terms with general principles covering all chemical agents. This is because it is the most cost-effective way of providing a general framework, which will avoid the need for specific Community provisions for many individual chemicals on a case-by-case basis.

b) Subsidiarity.

4. The proposal does not breach the principle of subsidiarity, because it is only by Community action that a minimum level of protection for workers from the risks related to exposure to chemical agents can be assured in all Member States. Such action will also avoid any distortion in the area of competitiveness by preventing the unequal application of minimum standards for worker protection in one or other Member States.

5. Moreover this proposal will encourage more flexibility in cross border employment because workers can be reassured that they will find at least the minimum level of protection of their health and safety in all Member States. Employers will also be reassured that the costs of production will not be unduly distorted as a result of differences in the levels of protection of health and safety at work.

6. The current proposal responds to the above needs. It is also one of the actions aimed at achieving the social dimension of the internal market. The text includes measures relating to information on dangerous chemical agents as specifically referred to in the programme on the Community Charter of Basic Social Rights for workers. Information is one of the pillars on which effective health and safety practices are built; it forms an integral part of this text and aligns requirements for the labelling of containers for chemicals at work with the existing labelling requirements that apply for the purpose of placing chemical agents on the market.

7. The objectives outlined above involve a number of different areas of Community policy. It is unlikely that they can be achieved by Member States acting individually therefore it is necessary that a co-ordinated action is taken at Community level.

c) Proportionality

8. Community provisions have to be framed in such a way that they meet the requirements for acceptable minimum standards of health and safety without imposing an undue burden on employers; in particular they must avoid constraints which would hold back the creation and development of small and medium-sized enterprises. The present proposal is believed to achieve those two requirements.

9. In the first place the proposal is an amplification of the requirements of the Framework Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work rather than a set of new and unrelated measures. Requirements on employers under this proposal are therefore based on an assessment of risks made by the employer in accordance with Article 6 (3) of Directive 89/391/EEC. The measures to be taken are therefore in

proportion to the risks incurred from the chemical agents being used at work. In the same sense that the text is an amplification of Directive 89/391/EEC the more specific requirements of this text in fact render the framework of Directive 89/391/EEC less onerous, by the provision of guidance on its application.

10. The proposal as it stands covers all chemical agents without prejudging whether or not they are hazardous. This is important because even chemical agents that are nominally harmless may interact with others to create or enhance a risk. Chemical agents not normally considered hazardous in daily life may also be hazardous when used in larger quantities at the workplace. For example sand is not hazardous unless it is ground to a fine powder when it can cause lung disease such as has occurred in foundries and potteries. Also hazardous interaction may occur involving chemicals that are nominally harmless on their own. For example water may react violently with other chemicals such as strong acids or metals; it is only when the combination of the water and the other chemical occurs together that a risk exists.

Therefore it is only by taking into account the combined action of all chemical agents that a proper assessment can be made and the correct measures taken to protect workers.

If it can be shown that for any particular chemical there are no foreseeable risks from the chemical or its interaction then no further action is required once the assessment has been completed.

11. In amplifying the requirements of Directive 89/391/EEC care has been taken to cast the proposals in terms of objectives to be achieved, rather than as detailed and prescriptive requirements. The employer is given maximum flexibility in deciding how best to achieve the objectives for any of the 100,000 or more

industrial chemical agents that may be relevant in his particular circumstances. It is only in cases of particularly dangerous chemical agents e.g. for materials that may be carcinogenic, mutagenic or toxic to reproduction, that this freedom is limited by prescribing which measures shall have priority. Other specific measures should be established e.g. limit values, only when this is shown to be necessary.

12. As further evidence that the measures required by this proposal are reasonable in proportion to the risks from chemical agents it should be noted that they follow closely the Convention on Chemicals adopted by ILO in 1990 and therefore already have a substantial measure of acceptance world-wide.

d) The case for consolidation of existing provisions.

13. The Council Resolution of 21.12.1987 ⁽²⁾ on the Commission's programme concerning safety, hygiene and health at work ⁽³⁾ welcomed the intention to bring forward further proposals concerning dangerous agents. Moreover, at the time of the adoption of the Framework Directive 89/391/EEC the Council, in a Declaration, invited the Commission to examine coherence between the new Directive and Directive 80/1107/EEC on chemical, physical and biological agents ⁽⁴⁾. This is indispensable in order to bring the existing related individual Directives on specific chemical agents into conformity with Directive 89/391/EEC and in particular to remove ambiguities in existing requirements.

14. The further need for consolidation of the requirements relating to chemical agents and to ensure harmony of content and approach in relation to the new Framework Directive 89/391/EEC was emphasised by the Council at the time of the

(2) O.J. N° C28 of 03.02.1988, p. 1

(3) O.J. N° C28 of 03.02.1988, p. 4

(4) O.J. N° L327 of 03.12.1980, p. 8

adoption of Council Directive 90/394/EEC "on the protection of workers from the risks related to exposure to carcinogens at work" (5),

15. The current proposal responds to these various invitations. However, it is proposed that carcinogens should continue to be covered by a separate text. This exception also covers asbestos and vinyl chloride monomer both of which are already classified as human carcinogens (R 45) and which are, therefore, already within the scope of Directive 90/394/EEC on carcinogens. In the case of asbestos and vinyl chloride monomer, the detailed requirements contained in Directives 83/477/EEC as amended by Directive 91/382/EEC and Directive 78/610/EEC will be reviewed separately taking account of the more recent Directive on carcinogens covering all classified R 45 substances.

16. It should also be noted that biological agents, which are included in the coverage of Directive 80/1107/EEC which covers physical, chemical and biological agents are now subject to a specific Directive 90/679/EEC for the protection of workers from the risks related to exposure to biological agents at work (6). Furthermore, a separate proposal is in preparation to deal with physical agents. Thus the adoption of Directives on biological agents and physical agents will render Directive 80/1107/EEC obsolete for these agents. Therefore the present proposal deals only with chemical agents. At the same time as the Directive on chemical agents comes into force, the outdated Directives will be repealed.

17. When Directive 80/1107/EEC was modified in 1988 by Directive 88/642/EEC(7) one of the amendments was to introduce a detailed Annex relating to technical aspects concerning the measurement of exposure to chemical agents. This Annex made reference to the use of CEN standards. Since that time several draft

(5) O.J. N° L196 of 26.07.1990, p. 1

(6) O.J. N° L374 of 31.12.1990, p. 1

(7) O.J. N° L356 of 24.12.1988, p. 74

CEN standards have been developed as part of the standardisation policy of the European Community. Such standards will be of particular relevance to chemical agents. Three standards are in the process of adoption namely:

1. CEN standard on "Guidelines for the assessment of exposure to chemical agents in the air at the workplace for comparison with Limit Values". (Pr EN 689)
2. CEN standard on "General requirements for the performance of procedures for workplace measurements". (Pr EN 482)
3. CEN standard on "Specifications for conventions for measurement of suspended matter in workplace atmospheres". (Pr EN 481)

18. The above-mentioned draft CEN standards will, after their adoption, provide comprehensive guidance on carrying out measurements of exposure. For this reason detailed guidance on measurement methods is not included in the Annex of the current text and some of the detailed requirements from Directive 82/605/EEC on lead are being omitted without reducing the level of protection provided.

Objectives of the Current Proposal

19. This proposal has the following objectives :

- (a) to establish minimum requirements for the protection of workers against risks to their health and safety arising from all chemical agents at work;
- (b) to consolidate, update and adapt existing provisions in relation to chemical agents in the light of current knowledge and to align them with the measures established in Directive 89/391/EEC;

- (c) to incorporate into the new text the individual Directive 82/605/EEC relating to exposure to metallic lead and its compounds and the Directive 88/364/EEC relating to the banning of certain agents and certain work activities;
- (d) to establish additional requirements with respect to improving the protection of workers against the risks arising from activities involving chemical agents;
- (e) to remove ambiguities in the requirements of existing Directives and uncertainty in the extent of their application;
- (f) to clarify the Community provisions relating to the health and safety of workers exposed to chemical agents, and to provide an improved basis for the provision of information to workers;
- (g) to ensure that all precautionary measures at work are based on a proper assessment of risks arising from the way chemical agents are used and that measures to afford protection take account of the features of the workplace, the activity, the circumstances and any specific risk. In this way, the measures taken can properly reflect the scale of risk, the appropriate precautions and the size of the undertaking without unnecessarily imposing burdens on employers;
- (h) to render more explicit the existing alignment of Community provisions with the ILO Convention No. 170 ⁽⁸⁾ and its associated Recommendation No. 177 on Chemical Agents at work;

⁽⁸⁾ Convention No 170 concerning safety in the use of chemicals-at work, adopted by the International Labour Conference at its 77th session, Geneva, 25 June 1990

- (i) to ensure that the Directive on Carcinogens (90/394/EEC) remains in force, and is excluded from this text, as it contains specific additional requirements for carcinogenic chemical agents.

Description of this proposal

20. This proposal comprises a preamble, three parts and an Annex which sets out minimum health and safety requirements:

- a) Contents of the proposal

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

Preamble

Section I : General provisions

Article 1 Subject

Article 2 Definitions

Section II : Provisions addressed to employers

Article 3 General obligations

Article 4 Specific protection and prevention measures

Article 5 Communication, warning and alarm systems

Article 6 Keeping workers informed

Section III : Miscellaneous provisions

Article 7 Prohibitions

Article 8 Occupational exposure levels

Article 9 Health surveillance

Article 10 Consultation and participation of workers

Article 11 Minimum requirements for health and safety

Article 12 Adjustments to the Annex

Article 13 Committee

Article 14 Revocation

Article 15 Final Provisions

Article 16 Address

Annex

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

b) Characteristics of this proposal

1. **Preamble**
2. **Section I : General Provisions**

Article 1

This Article establishes the Directive as an individual Directive under the Framework Directive 89/391/EEC, its requirements therefore being minimum requirements under Article 118A of the Treaty.

Article 2

The definition of 'chemical agent' in this text is very broad, with the aim of bringing within its scope all chemical agents, while ensuring in the text that the requirements imposed are commensurate with the risk. It covers all forms of chemical agents, such as fumes, contaminants and wastes that may arise in the course of work activities as well as chemical agents that are produced or used intentionally.

3. **Section II : Provisions addressed to employers**

Article 3

This Article places an obligation on the employer to ensure that workers can carry out their work without endangering themselves or others at work.

Because an assessment of workplace hazards and risks is an important practical contribution to the actions which an employer must take to protect health and safety, this Directive adapts the requirements laid down in Directive 89/391/EEC so that assessments are made of the risks incurred by the workers in any activity involving chemical agents. The assessment has to cover all the chemical agents that are used or likely to be used.

For chemical agents which have been the subject of specific evaluation within the Community as part of the process of authorisation for placing on the market, e.g. for plant protection products, this evaluation and any related labelling or safety instructions will often provide the basis for a major part of the work assessment under this Directive. What has to be done, in addition, is an assessment of the way in which the hazards of the chemical agents interact with other aspects of the workplace and the methods of use.

The employer is also required to ensure supervision of the workplace, that competent staff are employed for important tasks such as the assessments and work involving special risks, that arrangements, including first-aid facilities, are made to deal with emergencies, and that clear instructions are given to workers.

The Article also establishes the principle that priority is given to collective protection measures in preference to individual protection measures.

Article 4

This Article sets out general requirements for the arrangements of plant and equipment so as to reduce risks to the health and safety of workers at work.

Article 5

This Article places an obligation on the employer to make arrangements to provide warning if there is an increased risk to health and safety.

Article 6

This Article is concerned with making information available to workers about the chemical agents and precautions to be taken.

4. Section III : Miscellaneous provisions

Article 7

The prohibitions at present contained in Directive 88/364/EEC on the banning of certain specific agents and/or work activities are included in this Article without material change. Provision is made for new bans to be added by Council based on Article 118 A of the Treaty, whereas technical amendments to existing provisions are to be carried out by the Commission in accordance with the procedure referred to in Article 13.

Article 8

Co-operation already exists between Member States in the scientific process leading to the establishment of occupational exposure levels. The text lays down a Community framework so that in the future this co-operation can be developed in a systematic way at Community level.

The concept of having two different types of occupational exposure levels, of different status, is retained.

'Limit values' under this proposal incorporate the 'binding limit values' under Directive 88/642/EEC and the existing limit value for lead under Directive 82/605/EEC. Member States will be required to set a national occupational exposure level once a Community limit value has been established which shall not be exceeded.

For 'occupational guidance values', Member States are to be required to take them into account if they set or revise a national limit for a particular chemical agent.

During the five year period before an occupational guidance value is reviewed, all interested parties will have the opportunity to submit information arising from experience gained in its practical application.

Article 9

This Article sets out general arrangements for the provision of health surveillance, with particular reference to activities involving chemical agents.

Article 10

This Article adapts the general arrangements for consultation and participation of workers set out in Article 11 of Directive 89/391/EEC to activities involving chemical agents.

Employers are obliged to involve workers in appraising the workplace and on the precautions to be adopted when it is found that an occupational exposure level or biological limit value is exceeded.

Article 11

This Article establishes the time scale in which employers shall meet the minimum requirements for health and safety which are set out in the Annex. For new activities, the employer shall comply at the time this Directive comes into force; for existing activities there is a transition period of five years.

Article 12

This Article sets out arrangements for technical adjustments to be made to the Annex and provides for the establishment of technical guidance.

Article 14

The Directives listed will become redundant on the adoption of this Directive and are therefore to be repealed. It is to be noted that Directive 80/1107/EEC covers chemical, physical and biological agents. Of these, biological agents are already covered by Directive 90/679/EEC and physical agents are the subject of a separate proposal already under discussion.

The three individual Directives under Directive 80/1107/EEC can, in principle, stand alone even if 80/1107/EEC is repealed. However the first individual Directive on lead (82/605/EEC) is already assimilated into the present proposal and can be repealed also. The second, on asbestos (83/477/EEC as amended by 91/382/EEC) will be the subject of a separate review to be carried out by 31 December 1995 pursuant to Article 9(1) of Directive 83/477/EEC as amended. The third, on noise (86/188/EEC) will be consolidated into the proposal relating to physical agents referred to above. The fourth on banning certain specified agents and/or work activities (88/364/EEC) is already assimilated into the current proposal and can therefore be repealed.

ANNEX**1. Preliminary note**

The Annex sets out minimum safety and health requirements which apply whenever appropriate taking account of the features at the workplace, the activity, the circumstances or a specific risk.

2. Supervisory obligations

The text sets out the requirements for competence of the person in charge of the workplace and those supervising workers. It explains that the employer may personally fill these roles so long as he meets the requirements for competence.

3. Protective measures

This paragraph is concerned with the concentration in air of chemical agents which might present a risk to the health and safety of workers.

The employer is obliged to ensure that the exposure of workers to a chemical agent for which a limit value has been set does not exceed the occupational exposure limit. Arrangements are summarised for assessing and measuring the exposure of workers.

4. Protection from abnormal risks

This paragraph requires the employer to give special consideration to activities, such as maintenance, where the risks may be increased because the normal process controls cannot be applied. It also covers situations such as an emergency and where remedial action has to be taken after an accident or incident and requires the employer to make arrangements as to how to deal with such events, if they occur.

5. Derogation information

This paragraph states the information to be provided to competent authorities where derogations is sought from the prohibitions.

6. Safety equipment maintenance

General requirements are set out.

7. Health surveillance measures

For some chemical agents the Commission believes that specific provisions on health surveillance are necessary. These agents fall into two categories:

- sensitisers;
- other specified dangerous chemicals as referred to in this paragraph of the Annex.

For these agents, health surveillance is to be provided.

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

8. Record keeping

The paragraph sets out arrangements to be made by an employer to maintain a record of the safety and health document. It also provides for Member States to arrange for individual health records.

9. Information on chemical agents

This paragraph requires the employer to provide the worker with the information that is necessary to ensure safe working practices. Where appropriate and in line with other Community Directives, the information is to be provided by signs, labels and safety sheets.

An obligation is placed on the employer to ensure that containers and pipes used for chemical agents at the workplace are labelled or marked in line with Directive 92/58/EEC. In many cases the products bought by the employer will already be clearly marked with their identity and hazards according to other legislation. Where the original labelling is not available e.g. when the chemical is transferred in-plant to another container, the employer must make other arrangements. At the time of the adoption of the 7th amendment to Directive 67/548/EEC the Council specifically invited the Commission to make proposals in this matter with respect to intermediates.

There are also obligations to make available to workers the Safety Data Sheets from the supplier and where these are not available to prepare an equivalent data sheet.

10. Limit Values and Biological Limit Values

This paragraph sets out the limit values and biological limit values that have been established. At present there are the limit value for lead in air at the workplace, and the biological limit value (which indicates absorption of lead by the worker). The list of values may be extended in due course.

When Directive 82/605/EEC on risks related to exposure to lead was adopted there was a requirement to review the exposure limit value for lead and the biological limit values with a view to reducing them. The current proposal confirms the biological limit value in blood of $70\mu\text{g}/100\text{ ml}$ as a minimum requirement; however it removes the latitude set out in Directive 82/605/EEC which permitted a lead in blood level of between 70 and $80\mu\text{g Pb}/100\text{ ml}$ under certain circumstances.

11. Special measures for lead.

This paragraph sets out other means of biological monitoring for lead.

OPINION OF THE ADVISORY COMMITTEE

The opinion of the Advisory Committee on Safety, Hygiene, and Health Protection at Work has been obtained on the proposal. The Commission has taken due note of the Committee's opinion in preparing the text now submitted to the Council, in particular in relation to the procedure for setting limit values, the requirements for the assessment and for record keeping, the strengthening of the provisions relating to safety, and the limit value for lead in air, which remains unchanged from the limit value in Directive 82/605/EEC on lead.

IMPACT ASSESSMENT

An impact study has been carried out and a copy of the summary assessment is attached as Annex A to this explanatory note. It should be noted that as a result of this impact study the list of chemical agents for which health surveillance is required, under Article 9, has been reduced by more than half from the draft on which the study was based.

**PROPOSAL FOR A COUNCIL DIRECTIVE ON THE PROTECTION OF
THE HEALTH AND SAFETY OF WORKERS FROM THE RISKS
RELATED TO CHEMICAL AGENTS AT WORK**

THE COUNCIL OF THE EUROPEAN COMMUNITIES

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

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

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

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

Whereas 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 undertakings;

(1) O.J. No. ...

(2) O.J. No. ...

(3) O.J. No. ...

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 protection 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 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⁽⁴⁾ as last amended by Council Directive 88/642/EEC⁽⁵⁾, 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)⁽⁶⁾, 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

⁽⁴⁾ O.J. No. L327 of 03.12.1980, p. 8

⁽⁵⁾ O.J. No. L356 of 24.12.1988, p. 74

⁽⁶⁾ O.J. No. L247 of 23.08.1982, p. 12

within the meaning of Article 8 of Directive 80/1107/EEC⁽⁷⁾ 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(1) 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 ⁽⁸⁾ ;

Whereas, therefore the provisions of the said Directive, apply in full to workers exposed to chemical agents, without prejudice to more 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⁽⁹⁾, as last amended by Council Directive 92/32/EEC of 30 April 1992⁽¹⁰⁾, 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) ⁽¹¹⁾ 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⁽¹²⁾, as last amended by Council Directive 90/492/EEC⁽¹³⁾, define and lay down a system of specific information on dangerous substances and preparations, in the form of safety data sheets, principally

⁽⁷⁾ O.J. No. L179 of 09.07.1988, p. 44

⁽⁸⁾ O.J. No. L183 of 26.09.1989, p. 1

⁽⁹⁾ O.J. No. L196 of 16.08.1967, p. 1

⁽¹⁰⁾ O.J. No. L154 of 05.06.1992, p. 1

⁽¹¹⁾ O. J. No. L206 of 29.07.1978, P. 13

⁽¹²⁾ O.J. No. L187 of 16.07.1988, p. 14

⁽¹³⁾ O.J. No. L275 of 05.10.1990, p. 35

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⁽¹⁴⁾ 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⁽¹⁵⁾ 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 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

⁽¹⁴⁾ O.J. No. L245 of 26.08.1992, p. 23

⁽¹⁵⁾ O.J. No L 230 of 05.08.1982, p.1

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;

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

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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).

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 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;
 - 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 authorisation for placing on the market, the risk assessment shall take into 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.
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 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;
 - 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.

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
202-177-1	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 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.
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.
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 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 14, 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 14, 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 Annex 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 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;
 - 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 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.

Article 16

This Directive is addressed to the Member States.

Done at

For the Council

The President

**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

2.2 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.

2.3 Supervision

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

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

4.4.2 Without prejudice to Directive 89/656/EEC ⁽¹⁶⁾, 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.

(16) OJ No. L393, 30. 12. 1989, p. 18

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 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.

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;

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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 monitoring 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.

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.

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 :

- 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.

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 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

EINECS No. (1)	CAS No. (2)	Name of Agent	Limit Value (6)	
			mg/m ³ (4)	ppm (5)
-	-	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

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 than $0,075 \text{ mg/m}^3$ and lower than $0,1 \text{ mg/m}^3$.
- the PbB level of any individual worker does not exceed $50 \mu\text{g Pb/100 ml}$ blood.

IMPACT ASSESSMENT

THE IMPACT OF THE PROPOSAL ON BUSINESS with special reference to small and medium sized enterprises (SMEs)

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

Document reference number: HK/seh/consoli/100:6

The proposal

1. *Taking account of the principle of subsidiarity, why is Community legislation necessary in this area and what are its main aims?*

a) Reason for Community action

Exposure to chemical agents occurs in every aspect of daily life. Over 100,000 chemicals are included in the European Inventory of Existing Chemical Substances (EINECS). Many of these chemicals have dangerous properties which can adversely affect the health and safety of workers at work. It has been estimated that accidents and ill health at work account for approximately 7% of all social security expenditure within the EC, affecting 10 million workers every year at an overall cost of 20 billion ECU. It is clear from information in Member States that a significant proportion of the ill-health that is caused by work activities is due to exposure to chemical agents. It is therefore important that suitable precautions should be taken at the workplace to prevent these problems.

The proposal does not breach the principle of subsidiarity, because it is only by Community action pursuant to Article 118A of the Treaty that a minimum level of protection for workers from the risks related to exposure to chemical agents can be assured in all Member States. Such action will also avoid any distortion in the area of competitiveness by preventing the unequal application of minimum standards for worker protection in one or other Member States.

Moreover this proposal will encourage more flexibility in cross border employment because workers can be reassured that they will find at least the minimum level of protection of their health and safety in all Member States. Employers will also be reassured that the costs of production will not be unduely distorted as a result of differences in the levels of protection of health and safety at work.

b) Objectives of the proposal

- (a) to establish minimum requirements for the protection of workers against risks to their health and safety arising from all chemical agents at work;
- (b) to consolidate, update and adapt existing provisions in relation to chemical agents in the light of current knowledge and to align them with the measures established in Directive 89/391/EEC;
- (c) to incorporate into the new text the individual Directive 82/605/EEC relating to exposure to metallic lead and its compounds and the Directive 88/364/EEC relating to the banning of certain agents and certain work activities;
- (d) to establish additional requirements with respect to improving the protection of workers against the risks arising from activities involving chemical agents;
- (e) to remove ambiguities in the requirements of existing Directives and uncertainty in the extent of their application;
- (f) to clarify the Community provisions relating to the health and safety of workers exposed to chemical agents, and to provide an improved basis for the provision of information to workers;
- (g) to ensure that all precautionary measures at work are based on a proper assessment of risks arising from the way chemical agents are used and that measures to afford protection take account of the features of the workplace, the activity, the circumstances and any specific risk. In this way, the measures taken can properly reflect the scale of risk, the appropriate precautions and the size of the undertaking without unnecessarily imposing burdens on employers;
- (h) to render more explicit the existing alignment of Community provisions with the ILO Convention No. 170 ⁽¹⁾ and its associated Recommendation No. 177 on Chemical Agents at work;

⁽¹⁾ Convention No 170 concerning safety in the use of chemicals at work, adopted by the International Labour Conference at its 77th session, Geneva, 25 June 1990

- (i) to ensure that the Directive on Carcinogens (90/394/EEC) remains in force, and is excluded from this text, as it contains specific additional requirements for carcinogenic chemical agents.

The impact on business

2. *Who will be affected by the proposal?*

- which sectors of business
- which sizes of business (what is the concentration of small and medium sized firms)
- are there particular geographical areas of the Community where these businesses are found

The proposal covers all enterprises that manufacture or use chemicals. It will apply to enterprises in manufacturing, construction, agriculture and to some degree in services, including public services.

The impact on businesses will depend on the number of chemicals used and the number of exposed workers.

Of the enterprises within the scope of the Directive approximately 40-60% are expected to be SME's (less than about 75 employees). It is not possible to be precise about the number and proportion of SME's because the data on their use of chemicals do not exist. Consequently it is not possible to say whether the impact will be greater on SME's in general as opposed to larger firms.

3. *What will business have to do to comply with the proposal?*

There are few additional obligations on employers because most of the requirements have already been established by previous Directives for the protection of the health and safety of workers at work. This text amplifies these existing general provisions as they apply to chemical agents.

Examples of this amplification of the framework Directive 89/391/EEC are to be found in these parts of the proposal dealing with the assessment of risk, protection and prevention measures, control of exposure, plan of action in the case of an emergency and information to and consultation and participation of workers.

The provisions on Health surveillance too which specify those chemical agents where health surveillance is considered to be necessary are an amplification of the framework Directive 89/391/EEC in this case Article 14.

The text also consolidates some specific requirements again already in existence, e.g. prohibition of use of certain chemical agents or work activities, requirements concerning lead and record keeping.

The obligation to draw up an inventory of chemical agents used at work can be seen as an amplification of the requirement in the framework Directive 89/391/EEC for making a risk assessment at work. It is a logical extension of this requirement which enables the Community to carry forward the requirements of ILO convention 170 and its associated recommendation 177 on chemicals at work.

4. *What economic effects is the proposal likely to have?*

- on employment
- on investment and the creation of new businesses
- on the competitive position of businesses

The provisions concerning health surveillance (Art. 9 and Annex paragraph 7) are in addition to current requirements and will have some impact in all Member States, with the possible exception of France. The most significant impact is expected for enterprises in Denmark, Greece, Ireland, Netherlands and United Kingdom, where few such provisions exist today.

Financial calculations have been possible for Article 9 only (Health surveillance). A partial estimate, based on current costs for between 8-30 chemical agents in each Member State have been made, covering 31 percent of the Community's employed workers (Denmark, Ireland, Netherlands, United Kingdom). This showed additional costs of at least 100-120 million ECU per year for 22 originally listed agents on the basis of data from these five Member States. With the reduction in the size of the list from 22 to 10, for those chemical agents requiring health surveillance, the overall cost for the implementation of Article 9 can be reduced to approximately 50 million ECU on a pro rata basis.

The cost per health examination varies widely, both according to the agent in question and according to the cost level in Member States. The lowest minimum cost reported is 20 ECU per examination the highest cost 130 ECU (both including biological monitoring).

The cost per worker is likely to be a little higher in small enterprises because larger enterprises may be able to get discounts on laboratory tests, etc. The variation relative to the size of the enterprise is expected to be much narrower than the variation between Member State price levels. The aggregate costs are unlikely to have any measurable impact on employment, investment or the creation of new businesses.

The requirement in Article 3(2) for employers to keep a list of chemical agents used is expected to have only a minor economic impact.

5. *Does the proposal contain measures to take account of the specific situation of small and medium sized firms (reduced or different requirements etc.)?*

The intention behind the proposal is to create acceptable minimum level of protection for all workers, irrespective of the size of the employers undertaking.

For chemical agents which have been the subject of specific evaluation within the Community as part of the process of authorisation for placing on the market, e.g. for plant protection products, this evaluation and any related labelling or safety instructions will often provide the basis for a major part of the work assessment under this Directive. What has to be done, in addition, is an assessment of the way in which the hazards of the chemical agents interact with other aspects of the workplace and the methods of use.

Only one Article (health surveillance) obliges the employer to use a specific method. The remaining Articles define the goals to achieve, but the employer can choose between various methods to reach this goal. This gives him the maximum possibility to choose the methods suited to the workplace, the technology or the size of the undertaking.

Consultation

6. *List the organisations which have been consulted about the proposal and outline their main views.*

The opinion of the Advisory Committee on Safety, Hygiene and Health Protection at Work has been obtained on the proposal. The Commission has taken due note of the Committee's opinion in preparing the text now submitted to the Council, in particular in relation to the procedure for setting limit values, the requirements for the assessment and for record keeping, the strengthening of the provisions relating to safety, and the limit value for lead in air, which remains unchanged from the limit value in Directive 82/605/EEC on lead.

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