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Proposal for a

COUNCIL DIRECTIVE

**amending for the first time Directive 90/394/EEC
on the protection of workers from the
risks related to exposure to carcinogens at work**

(presented by the Commission)

**Proposal for a Council Directive
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EXPLANATORY MEMORANDUM

1. Introduction

a) Reason for Community action

The approval by the Council on 28 June 1990 of Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work⁽¹⁾ was a major step forward in the improvement of protection of the health and safety of workers.

This Directive, which was due to enter into force not later than 31 December 1992 at the latest, stipulates that employers must ensure that the level of exposure of workers is reduced to as low a level as is technically possible.

It is also significant that the Directive provides for the establishment of limit values and on the basis of the available information, including scientific and technical data, in respect of all those carcinogens for which this is possible, and, where necessary, other directly related provisions.

The main purpose of this proposal for an amendment to Directive 90/394/EEC is the resolve oft-reiterated by the various Community institutions to set limit values for occupational exposure to carcinogens, starting with benzene. The latter substance was in fact the subject of a proposal for a directive submitted by the Commission to the Council in January 1986 but which was not in the end adopted because of divergences between the Member States as regards certain limit values proposed, and particularly because of the stated aim to adopt a single directive covering carcinogens at the place of work.

¹⁾ OJ No L 196, of 26.7.1990, p. 1

The wording of the existing directive also excludes, as regards the protection of workers, a whole series of preparations such as medicinal preparations, cosmetics and pesticides. The present modification removes this exclusion.

Lastly, the submission of this amendment has also been taken as an opportunity to improve the wording of two specific points of Directive 90/394/EEC, viz. Art. 3(3) and Annex I (2), which had given rise to diverging interpretations in the different language versions.

b) Subsidiarity

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 carcinogens can be assured in all Member States. This 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 unduly distorted as a result of differences in the levels of protection of health and safety at work.

2. Benzene

Benzene is a colourless liquid and a normal constituent in petroleum; it is present in low concentrations in the natural environment.

The extraction of benzene for commercial purposes dates from 1849, the benzene being derived from coal; today, however, approximately 90% of benzene is obtained by the distillation of petroleum, using various processes, such as fractional distillation of catalytic cracking.

Benzene is mainly used as a raw material in the manufacture of organic compounds such as phenol, styrene, cyclohexone and maleic anhydride; as a component of petroleum, it is also present in petrol (4% on average in Europe). In the past benzene was widely used as a solvent, but this use is now being abandoned in the more highly industrialised countries, because of the risk to the health of the users. However, it is still used as a laboratory reagent, in the collection, preparation and extraction of samples.

An estimated 7 million tonnes of benzene are produced in the Member States each year, mainly in the United Kingdom, the Federal Republic of Germany and the Netherlands.

For at least 100 years benzene has been recognised as constituting a health risk for persons coming into contact with it. It enters the body almost exclusively via the airways; very small quantities can also be absorbed via the skin.

Benzene's high fat solubility facilitates its distribution in tissues which are rich in lipids, such as the adipose tissue, the nervous system and the bone marrow.

Benzene is rapidly oxidised in these tissues, mainly into phenol and also into catechol and hydroquinone. Whereas 25 to 50% of the benzene is eliminated in unchanged form by respiration, the remaining fraction is secreted, together with the oxidation products, in urine.

Acute health effects are observed following exposure to high levels (over 500 ppm), with symptoms of poisoning.

Prolonged exposure to toxic doses can, however, lead to changes in the bone marrow which may culminate in a persistent pancytopenia, i.e. a reduction of all blood cell components. There may be early symptoms, such as anaemia, leukocytopenia and thrombocytopenia. In serious cases, the victim may develop aplastic anaemia provoked by a functional deficiency of the bone marrow.

Numerous studies have shown that exposure to benzene at levels capable of provoking haemotoxic effects is associated with the appearance of chromosomal changes in the circulating lymphocytes and in the medullary cells; these changes may be reversible or irreversible, but their prognostic value has not yet been clarified.

A certain number of cases of myeloblastic and erythroblastic leukaemia associated with exposure to benzene have been reported in the literature, and less frequently, cases of chronic myeloid or lymphoid leukaemia. Numerous epidemiological studies have revealed a significant correlation between exposure and the appearance of leukaemia.

No conclusive survey has yet been conducted on the toxic and teratogenic effects of exposure to benzene during pregnancy.

Benzene is a recognised dangerous substance and, as such, has long been covered by legal provisions in the Member States as regards occupational exposure; in particular, these provisions provide for:

- restrictions on use
- licensing arrangements for production
- use of preventive means
- an order that specific categories of workers may not be exposed.

The Member States of the EU also use limit values for occupational exposure calculated in relation to a reference period of eight hours' work, primarily for use in monitoring the working environment and forestalling risks associated with exposure to benzene. These values range from 5-10 ppm (16 and 32 mg/m approximately) and are the result, in a certain number of countries, of specific calculations made by special committees, whereas in other countries the value published by the American Conference of Governmental Industrial Hygienists (ACGIH) has been adopted.

It should be remembered that certain countries are in the process of examining the possibility of lowering the values. The trend is towards 1 ppm in two countries and 0.1 ppm in another, the latter value being in line with the ACGIH proposal currently being examined in the USA.

Considering the current situation in the different countries, the trends and the opinion expressed by a committee of high-ranking scientific experts, the limit value quoted in the current proposal for amending Directive 90/394/EEC could be a compromise between the requirements in terms of worker protection on the one hand, and technical constraints on the other.

The temporary derogations to the limit value proposed in order to allow for the technical adjustments needed in certain workstations or for certain processes should not represent a specific risk for workers as long as the provisions of Directive 90/394/EEC are fully implemented.

Therefore Annex III of Directive 90/394/EEC has to be amended.

3. Scope of Directive 90/394/EEC

The present wording of Article 2 (a) and (b) of Directive 90/394/EEC stipulates the carcinogens covered by its provisions as regards exposure. More particularly, they are described as the substances and preparations requiring labelling with the risk-phrase R45 "may cause cancer" and in accordance with the terms of directives 67/548/EEC and 88/379/EEC.

In actual fact this definition substantially restricts the scope of the directive both as regards the substances whose inclusion is requested in Annex 1 of Directive 67/548/EEC and as regards preparations, many of which are not covered by Directive 88/379/EEC. In the latter instance, this is the case of medicinal and veterinary products, cosmetic products, mixtures of substances in the form of waste, pesticides, munitions and explosives, and food products.

The need for an employee exposed to carcinogens to be protected in all working situations without exception has prompted the new wording in Article 2(a) i) and ii). It makes it possible to use for the classification of the carcinogen the criteria of

Directive 67/548/EEC, irrespective of the fact that they are included in Annex I of the same directive, and at the same time to cover the substances classified with the label R 49 "may cause cancer by inhalation"; it also makes it possible to avoid the differences which could result from the present restriction to preparations classified R45 under Directive 88/379/EEC in the levels of protection for workers exposed to preparations containing carcinogens.

4. Amendment to Article 3(3)

The new wording of the paragraph in the proposal is designed to establish an effective strategy for monitoring total exposure to carcinogens at the place of work. It is essential - particularly but not only - when exposure limit values are set, to take due account of the possibility of penetration through the skin as well as the respiratory absorption pathway.

In certain cases, e.g. pesticides, the percentage of total body burden which can be attributed to absorption through the skin often significantly exceeds absorption via the respiratory pathway.

Although the present wording was designed to secure the same objective, it specified only "harmful effects on the skin" as if to separate these from other effects on other parts of the body, without therefore considering the effects on health from an overall standpoint.

5. Amendment to Annex I (2)

When Directive 90/394/EEC was adopted by the Council it was quickly pointed out in various quarters that there was a discrepancy between the English text - the reference text - and the other language versions.

While the stated aim was to protect workers against polycyclic aromatic hydrocarbons (PAH) present in certain by-products of coal, the language versions other than English drifted away from this objective, even including coal dust as such.

The new wording proposed restores to the text the meaning it originally should have had.

6. Consultations

In accordance with the terms of Article 118A of the Treaty establishing the European Union, the European Parliament and Economic and Social Committee must be consulted.

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**Proposal for a Council Directive
amending for the first time Directive 90/394/EEC
on the protection of workers from the
risks related to exposure to carcinogens at work**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work⁽¹⁾, and in particular Article 16,

Having regard to the proposal from the Commission⁽²⁾, drawn up following consultation with the Advisory Committee on Safety, Hygiene and Health Protection at Work,

In cooperation with the European Parliament⁽³⁾,

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

Whereas Article 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 ensure a better level of protection of the safety and health of workers;

Whereas, under the terms of that Article, such directives are to avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-size undertakings,

¹ OJ No L 196, 26.7.1990, p. 1

² OJ

³ OJ

⁴ OJ

Whereas Commission Directive 91/325/EEC⁽⁵⁾ of 1 March 1991 adapting to technical progress for the twelfth time Council Directive 67/548/EEC⁽⁶⁾ on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances introduces in Annex III new risk phrases to indicate the health hazards resulting from prolonged exposure and the risk of cancer through inhalation;

Whereas in all work situations workers must be protected in respect of preparations containing one or more carcinogens;

Whereas, for some agents it is necessary to consider all absorption pathways, including the possibility of penetration through the skin, in order to ensure the best possible level of protection;

Whereas the wording of point 2 of Annex I to Directive 90/394/EEC relating to polycyclic aromatic hydrocarbons has posed problems of interpretation in many Member States; whereas, therefore, a new, more precise wording is called for;

Whereas Article 16 of the aforementioned Council Directive 90/394/EEC makes provision for the establishment of exposure limit values on the basis of the available information, including scientific and technical data, in respect of all those carcinogens for which this is possible;

Whereas occupational exposure limit values must be regarded as an important component of the general arrangements for the protection of workers; whereas such limit values must be revised whenever this becomes necessary in the light of more recent scientific data;

Whereas benzene is a carcinogen which is present in many work situations whereas, therefore, a large number of workers are exposed to a potential health risk; whereas, although current scientific knowledge is not such that a level can be established below which risks to health cease to exist, a reduction in exposure to benzene will nonetheless reduce these risks;

Whereas the respect of the minimum requirements on the protection of health and safety of workers from the specific risks related to carcinogens 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;

⁵ OJ No L 180, 8.7.1991, p. 1

⁶ OJ No L 196, 16.8.1967, p. 1

Whereas provision should be made to ensure the protection of the health and safety of workers concerned, in the case of derogations provided for specified activities or sector of activity where the implementation of the limit value proposed for benzene may be difficult to meet within the date proposed;

Whereas in most small and medium sized enterprises where the main use of benzene might be as a solvent, provisions to lower exposure will not be required as legal provisions already exist in nearly all the member States to restrict or prohibit its use.

Whereas a consistent level of protection from the risks related to carcinogens 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 this amendment constitutes a practical aspect of the realisation of the social dimension of the internal market;

Whereas, pursuant to Decision 74/325/EEC⁷, as last amended by the 1985 Act of Accession, the Advisory Committee on Safety, Hygiene and Health Protection at Work is to be consulted by the Commission with a view to drawing up proposals in this field,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 90/394/EEC is hereby amended as follows:

1. Article 2 shall be replaced by the following:

"For the purposes of this Directive,

(a) "carcinogen" means:

- i) a substance which meets the requirements for classification as category 1 or 2 carcinogen according to the criteria of Annex VI of Directive 67/548/EEC.

ii) a preparation composed of one or more substances referred to in point (a)i) where the concentration of one or more of the individual substances meets the requirements for concentration limits for the classification of a preparation as a category 1 or 2 carcinogens set out either:

- in Annex I to Directive 67/548/EEC
- or
- in Annex I of Directive 88/379/EEC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits.

iii) a substance, preparation or process referred to in Annex I as well as a substance or preparation released by a process referred to in Annex I.

(b) "limit value" means, unless otherwise specified, the limit of concentration for a "carcinogen" in the air within the breathing zone of a worker."

2. Article 3(3) shall be replaced by the following:

"Furthermore, when assessing the risk, account shall be taken of all other routes of exposure, such absorption into and/or through the skin".

3. In Article 16, the following paragraph shall be added:

"3. In the case of derogations provided for in Annex III, the Member States shall be obliged to ensure that employers comply with procedures and measures in order to take adequate precautions to protect the health and safety of the workers concerned."

4. Item 2 of Annex I shall be replaced by the following:

"Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch".

5. Part A of Annex III shall be replaced by the following:

"A. LIMIT VALUES FOR OCCUPATIONAL EXPOSURE

Name of agent	EINECS (1)	CAS (2)	Limit values		Notation	Derogations
			mg/m ³ (3)	ppm (4)		
Benzene	200-753-7	71-43-2	3.25 (5)	1 (5)	Skin (6)	Limit value: 3 ppm (= 9.75 mg/m ³) until 31 December 2000 for the following activities or sector of activity: - Selected sites in coke plants (primary coolers, benzol/sulphate houses, benzol storage and loading) - cleaning and maintenance of tanks - loading and unloading of tanker vessels and lorries - marine transport - motor vehicle repair shops - service station with filling attendant

- (1) **EINECS: European Inventory of Existing Chemical Substances**
 (2) **CAS: Chemical Abstract Service Number**
 (3) **mg/m³ = milligrams per cubic metre of air at 20°C and 101,3 KPa (760 mm mercury pressure)**
 (4) **ppm = parts per million by volume in air (ml/m³).**
 (5) **Measured or calculated in relation to a reference period of eight hours.**
 (6) **Substantial contribution to the total body burden via dermal exposure possible."**

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 31 December 1998. They shall forthwith inform the Commission thereof.

When Member States adopt these provisions, 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 laid down by the Member States.

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2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive

Article 3

This Directive is addressed to the Member States.

Done at Brussels,

For the Council
The President

IMPACT ASSESSMENT FORM

The impact on business of the proposal for a Council Directive amending for the first time Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work.

I. Rationale for the proposal

Article 16 of Council Directive 90/394/EEC of 28 June 1990 stipulates that the Council shall set out limit values for exposure at the place of work on the basis of the available information, including scientific and technical data, in respect of all those carcinogens for which this is possible. The Commission was subsequently called upon by various parties during the different phases of consultation to submit a preliminary proposal covering benzene.

It is mainly to cater for these requests that the Commission is now submitting this text to the Council. The other amendments proposed concerning partly the definition of carcinogen and partly changes in wording, can be considered incidental and without any specific impact other than that requested under the original directive. Only in the event that the definitions should be expanded need the other industrial sectors covered by the Directive be involved.

The principle of subsidiarity is complying with as indicated in the introduction to the explanatory memorandum.

II. The impact on business

1) Characteristics of the firms concerned

As a major raw material used in the chemical industry, benzene is a constituent of many items found in homes, offices, and factories. Worker exposures to benzene can occur during the production, use and transportation of benzene as well as during the production and use of chemicals, liquid mixtures and solvents that contain benzene as a natural ingredient, an intentional ingredient, or a contaminant. The main sources of potential benzene exposures and the industries in which they can occur are listed below:

- a) production of benzene (petrochemical producers, petroleum refineries, producers of coke in the iron and steel industry),

- b) transportation and storage of benzene and benzene-containing liquids,
- c) production of products containing benzene as a natural ingredient,
- d) production of products using liquid mixtures containing solvents, e.g. rubber products, paints, glues, inks....
- e) use of pure benzene as a process solvent, e.g. the perfume industry, in addition to those listed in d).

2) Size of business

Generally speaking, the arrangements cover more often than not medium and large-sized companies involved *inter alia* in production activities. In the small and medium-sized enterprises, where benzene might be used mainly for its qualities as a solvent, the legal provisions which exist in nearly all the Member States to restrict or prohibit its use, limit the scope of the directive.

Only in respect of research laboratories and small companies producing perfumes would provisions designed to lower exposure levels be required.

3) Geographical area

No specific geographical distribution does exist for these businesses.

4) Obligations on enterprises

Establishing a limit value for occupational exposure to benzene implies the additional obligation on companies to adhere to this value, the value itself being the average weighted value of exposure for the worker during an 8-hour working cycle.

This definition needs to be stressed given that in a great many industrial situations where the concentration of benzene in the ambient air exceeds the limit value for exposure, the worker is often exposed for short periods and this leads to a substantial lowering of the average weighted value.

In order to allow for certain specific difficulties arising from the nature of the work station, the proposal provides for certain temporary derogations to the limit value by establishing a higher value which, considering the actual time and the number of workers involved, should only negligibly increase the risk to health.

5) Effects on the competitiveness of companies

a) Advantages

The advantages of improved working conditions, in this particular case meaning a lowering of the exposure level, will result in a lowering of the number of cases of leukaemia, as has also been stressed (and evaluated) by the committee of scientific experts.

These benefits will be felt not only by individual workers as members of society but also by the companies themselves, for which the cost advantages will be expressed as:

- fewer absences through illness
- lower retraining costs, and,
- fewer cases of persons having to be pensioned off because of invalidity.

b) Disadvantages

Two types of additional expenditure will have to be incurred, the first concerning the actual measuring of the limit value for exposure and, the second, arising from modifications on the older items of plant and equipment to the systems for preventing the release of benzene vapours into the ambient air.

The costs as regards the first provision may obviously be comparatively low as there is no absolute need for companies to have their own measuring instruments. The second aspect will undoubtedly weigh more heavily, particularly in the older installations, although the actual scale of intervention can be limited in this case, too, as was pointed out previously, to those work stations where the worker actually carries out his tasks.

Nevertheless, as these arrangements are designed to protect the worker against the risks of the onset of leukaemia, the cost/benefit ratio should have a substantial impact.

Lastly, there should be no significant effects on competitiveness or on employment levels.

III. Consultation

The Advisory Committee on Safety, Hygiene and Health Protection at Work gave its opinion on this proposal and agreed on its need, namely as concerns the amendment to the field of application of the Directive.

As regards benzene, the proposed value was not generally agreed among the different Parties, even if the groups unanimously agreed that 1 ppm should be regarded as feasible within a reasonable period.

Thus a system of derogations, limited in time, has been incorporated into the proposal itself in order to allay the misgivings expressed by the representatives of the industrial sector as to the applicability of this exposure limit value.

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