



EUROPEISKA GEMENSKAPERNAS KOMMISSION

Bryssel den 13.09.1995

KOM(95) 425 slutlig

95/0229 (SYN)

Förslag till

RÅDETS DIREKTIV

**om en första ändring av direktiv 90/394/EEG om skydd för arbetstagare mot
risker vid exponering för carcinogener i arbetet**

(framlagt av kommissionen)

**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**

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 I 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.

Utkast
Förslag till rådets direktiv
om en första ändring av direktiv 90/394/EEG om skydd för arbetstagare mot
risker vid exponering för carcinogener i arbetet

EUROPEISKA UNIONENS RÅD HAR ANTAGIT DETTA DIREKTIV

med beaktande av Fördraget om upprättandet av Europeiska gemenskapen, särskilt artikel 118a i detta,

med beaktande av rådets direktiv 90/394/EEG av den 28 juni 1990 om skydd för arbetstagare mot risker vid exponering för carcinogener i arbetet¹, särskilt artikel 16 i detta,

med beaktande av kommissionens förslag² som upprättats efter samråd med Rådgivande kommittén för arbetarskyddsfrågor,

i samarbete med Europaparlamentet³,

med beaktande av Ekonomiska och sociala kommitténs yttrande⁴, och

med beaktande av följande:

I artikel 118a i Fördraget föreskrivs att rådet genom direktiv skall anta minimikrav för att främja förbättringar av arbetstagares hälsa och säkerhet, främst i fråga om arbetsmiljön.

Enligt denna artikel skall i dessa direktiv sådana administrativa, finansiella och rättsliga ålägganden undvikas som motverkar tillkomsten och utvecklingen av små och medelstora företag.

¹ EGT nr L 196, 26.7.1990, s. 1.

² EGT nr

³ EGT nr

⁴ EGT nr

I bilaga 3 i kommissionens direktiv 91/325/EEG⁵ av den 1 mars 1991 om en tolfte teknisk anpassning av rådets direktiv 67/548/EEG⁶ om tillnärmning av lagar och andra författningar om klassificering, förpackning och märkning av farliga ämnen, införs nya riskbeteckningar för att ange de hälsofaror som uppstår vid en längre exponering och risken för cancer genom inandning.

I alla arbetssituationer måste arbetstagarna skyddas mot preparat som innehåller en eller flera carcinogener.

För vissa agenter måste man beakta alla de sätt varigenom absorbering kan ske, inklusive inträngning genom huden, för att uppnå bästa möjliga skyddsnivå.

Formuleringen i punkt 2 i bilaga 1 i direktiv 90/394/EEG angående aromatiska polycykliska kolväten har lett till tolkningsproblem i många medlemsstater, varför det behövs en ny och mera exakt ordalydelse.

I artikel 16 i rådets direktiv 90/394/EEG föreskrivs att det skall fastställas gränsvärden för exponering på basis av tillgänglig kunskap inklusive vetenskapliga och tekniska uppgifter för alla de carcinogener för vilka detta är möjligt.

Gränsvärden för exponering på arbetsplatser måste ses som en viktig beståndsdel i de allmänna föreskrifterna för arbetarskydd. Dessa gränsvärden måste revideras närhelst det visar sig nödvändigt mot bakgrund av nya vetenskapliga rön.

Bensen är en carcinogen som förekommer i många arbetssituationer, vilket innebär att ett stort antal arbetstagare är exponerade för en potentiell hälsorisk. Även om vetenskapen idag inte kan fastställa en nivå under vilken hälsoriskerna upphör, kommer dessa risker att minska om man minskar exponeringen för bensen.

Respekt för minimikraven för skydd av arbetstagarnas hälsa och säkerhet mot de specifika risker som uppkommer av carcinogener säkerställer inte bara att varje individuell arbetstagares hälsa och säkerhet skyddas utan innebär även att det inrättas ett minimiskydd för alla arbetstagare i gemenskapen vilket leder till att man undviker potentiella snedvridningar av konkurrensen.

Det bör föreskrivas bestämmelser som säkerställer skyddet av hälsa och säkerhet hos de arbetstagare som berörs av de avvikelser som godkänns för vissa angivna verksamheter eller verksamhetssektorer där tillämpningen av det föreslagna gränsvärdet för bensen kanske inte kan påbörjas inom den föreslagna tidsfristen.

⁵ EGT nr L 180, 8.7.1991, s. 1.

⁶ EGT nr L 196, 16.8.1967, s. 1.

I de flesta små och medelstora företag där det huvudsakliga användningsområdet för bensen sannolikt är som lösningsmedel behövs inte några bestämmelser om lägre gränsvärden eftersom det redan finns lagar i nästan alla medlemsstater som begränsar eller förbjuder användningen av bensen.

En enhetlig skyddsnivå mot de risker som uppkommer av carcinogener måste fastställas för gemenskapen som helhet och denna skyddsnivå bör inte fastställas genom detaljerade föreskrifter utan genom att det fastställs en ram med generella principer som gör det möjligt för medlemsstaterna att tillämpa minimikraven på ett enhetligt sätt.

Denna ändring utgör ett led i det konkreta förverkligandet av den inre marknadens sociala dimension.

Enligt beslut 74/325/EEG⁷ i dess lydelse enligt 1985 års anslutningsakt skall kommissionen rådgöra med Rådgivande kommittén för arbetarskyddsfrågor vid utarbetandet av förslag på detta område.

HÄRIGENOM FÖRESKRIVS FÖLJANDE.

Artikel 1

Direktiv 90/394/EEG ändras på följande sätt:

1. Artikel 2 skall ersättas med följande:

"I detta direktiv avses med

- a) *carcinogen*
 - i) ett ämne som klassificeras som cancerframkallande enligt kategori 1 eller 2 enligt kriterierna i bilaga 6 i direktiv 67/548/EEG,

⁷ EGT nr L 185, 9.7.1974, s. 15.

- ii) ett preparat som består av ett eller flera ämnen enligt led i, och där koncentrationen av ett eller flera av de enskilda ämnena uppfyller kraven på koncentrationsgräns för klassificering av ett preparat som carcinogen enligt kategori 1 eller 2 i enlighet med
 - bilaga 1 i direktiv 67/548/EEG, eller
 - bilaga 1 i direktiv 88/379/EEG, när ämnet eller ämnena inte anges i bilaga 1 i direktiv 67/548/EEG eller anges där utan koncentrationsgräns,
 - iii) ett ämne, ett preparat eller en process som avses i bilaga 1, liksom ett ämne eller ett preparat som bildas vid en process som avses i bilaga 1,
 - b) *gränsvärde*, om inte annat anges, koncentrationsgränsen för en carcinogen i den luft som en arbetstagare inandas."
2. Artikel 3.3 skall ersättas med följande:

"När man bedömer riskerna skall man ta hänsyn till alla sätt av betydelse på vilka exponering kan ske, t.ex. skadlig inverkan på eller genom huden."
 3. I artikel 16 skall följande punkt läggas till:

"3. Vad gäller de avvikelser som föreskrivs i bilaga 3 skall medlemsstaterna säkerställa att arbetsgivarna följer de förfaranden och vidtar de förebyggande åtgärder som krävs för att skydda de berörda arbetstagarnas hälsa och säkerhet."
 4. Punkt 2 i bilaga 1 skall ersättas med följande:

"Arbete som innebär exponering för aromatiska polycykliska kolväten som finns i stenkolsot, stenkolstjära eller stenkolsbeck."

5. Del A i bilaga 3 skall ersättas med följande:

"A. GRÄNSVÄRDEN FÖR EXPONERING PÅ ARBETSPLATSER

Agent	EINECS (1)	CAS (2)	Gränsvärden mg/m ³ (3) ppm (4)		Anmärkning	Avvikelser
Bensen	200-753-7	71-43-2	3,25 (5)	1 (5)	Hud (6)	Gränsvärde: 3 ppm (=9,75 mg/m ³) fram till och med den 31 december 2000 för följande verksamheter eller verksamhetssektorer: - utvalda platser i koksverk (förkylare, bensen-/sulfat-anläggningar, anläggningar för lagring och påfyllning av bensen) - rengöring och underhåll av behållare - lastning och lossning av tankfartyg och tankbilar - sjötransport - verkstäder för reparation av motorfordon - bensinstationer där personal ansvarar för påfyllningen

- (1) EINECS: Europeisk förteckning över befintliga kommersiella kemiska ämnen.
 (2) CAS: Registreringsnummer i Chemical Abstract Service.
 (3) mg/m³ = milligram per kubikmeter luft vid 20 °C och 101,3 kPa (760 mm kvicksilver).
 (4) ppm = miljondelar i luft uttryckt i volymenheter (ml/m³).
 (5) Mätt eller beräknat i förhållande till en referensperiod på åtta timmar.
 (6) Kan förutom den normala absorberingen genom lungorna dessutom absorberas genom huden."

Artikel 2

1. Medlemsstaterna skall senast den 31 december 1998 sätta i kraft de bestämmelser som är nödvändiga för att följa detta direktiv. De skall genast underrätta kommissionen om detta.

61

När en medlemsstat antar dessa bestämmelser skall de innehålla en hänvisning till detta direktiv eller åtföljas av en sådan hänvisning när de offentliggörs. Närmare föreskrifter om hur hänvisningen skall göras skall varje medlemsstat själv utfärda.

2. Medlemsstaterna skall se till att till kommissionen överlämna texterna till de bestämmelser i nationell lagstiftning som de antar inom det område som omfattas av detta direktiv.

Artikel 3

Detta direktiv riktar sig till medlemsstaterna.

Utfärdat i Bryssel den .

På rådets vägnar
Ordförande

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.

16

ISSN 1024-4506

KOM(95) 425 slutlig

DOKUMENT

SV

04

Katalognummer : CB-CO-95-470-SV-C

ISBN 92-77-93408-5
