


# Procedure file

Basic information		
SYN - Cooperation procedure (historic)	<a href="#">1995/0229(SYN)</a>	Procedure completed
Safety at work: protection of workers against exposure to carcinogens agents		
Repealed by <a href="#">1999/0085(COD)</a>		
Subject 4.15.15 Health and safety at work, occupational medicine		

Key players			
European Parliament	Former committee for opinion		
	<b>ENVI</b> Environment, Public Health and Consumer Protection		21/11/1995
		V <a href="#">LANNOYE Paul A.A.J.G.</a>	
Council of the European Union	Council configuration	Meeting	Date
	Social Affairs	<a href="#">2015</a>	27/06/1997
	Social Affairs	<a href="#">1974</a>	02/12/1996
	Social Affairs	<a href="#">1948</a>	24/09/1996

Key events			
13/09/1995	Legislative proposal published	COM(1995)0425	Summary
13/10/1995	Committee referral announced in Parliament		
26/03/1996	Vote in committee		Summary
26/03/1996	Committee report tabled for plenary, 1st reading/single reading	<a href="#">A4-0103/1996</a>	
19/06/1996	Debate in Parliament		Summary
20/06/1996	Decision by Parliament	T4-0350/1996	Summary
24/07/1996	Modified legislative proposal published	COM(1996)0414	Summary
02/12/1996	Council position published	<a href="#">10591/1996</a>	Summary
12/12/1996	Committee referral announced in Parliament, 2nd reading		
27/02/1997	Vote in committee, 2nd reading		Summary
27/02/1997	Committee recommendation tabled for plenary, 2nd reading	<a href="#">A4-0072/1997</a>	
07/04/1997	Debate in Parliament		Summary

09/04/1997	Decision by Parliament, 2nd reading	T4-0143/1997	Summary
28/04/1997	Modified legislative proposal published	COM(1997)0191	
27/06/1997	Act adopted by Council after consultation of Parliament		
27/06/1997	End of procedure in Parliament		
08/07/1997	Final act published in Official Journal		

### Technical information

Procedure reference	1995/0229(SYN)
Procedure type	SYN - Cooperation procedure (historic)
Procedure subtype	Legislation
	Repealed by <a href="#">1999/0085(COD)</a>
Legal basis	EC before Amsterdam E 118A
Stage reached in procedure	Procedure completed
Committee dossier	EMPL/4/08496

### Documentation gateway

Legislative proposal	<a href="#">COM(1995)0425</a> <a href="#">OJ C 317 28.11.1995, p. 0016</a>	13/09/1995	EC	Summary
Economic and Social Committee: opinion, report	<a href="#">CES0095/1996</a> <a href="#">OJ C 097 01.04.1996, p. 0025</a>	31/01/1996	ESC	Summary
Committee report tabled for plenary, 1st reading/single reading	<a href="#">A4-0103/1996</a> <a href="#">OJ C 141 13.05.1996, p. 0006</a>	26/03/1996	EP	
Text adopted by Parliament, 1st reading/single reading	T4-0350/1996 <a href="#">OJ C 198 08.07.1996, p. 0160-0182</a>	20/06/1996	EP	Summary
Modified legislative proposal	COM(1996)0414	24/07/1996	EC	Summary
Commission communication on Council's position	SEC(1996)2034	07/11/1996	EC	Summary
Council position	<a href="#">10591/1996</a> <a href="#">OJ C 006 09.01.1997, p. 0015</a>	02/12/1996	CSL	Summary
Committee recommendation tabled for plenary, 2nd reading	<a href="#">A4-0072/1997</a> <a href="#">OJ C 115 14.04.1997, p. 0005</a>	27/02/1997	EP	
Text adopted by Parliament, 2nd reading	T4-0143/1997 <a href="#">OJ C 132 28.04.1997, p. 0067-0079</a>	09/04/1997	EP	Summary
Modified legislative proposal	COM(1997)0191	28/04/1997	EC	

### Additional information

European Commission	<a href="#">EUR-Lex</a>
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### Final act

[Directive 1997/42](#)

## Safety at work: protection of workers against exposure to carcinogens agents

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**OBJECTIVE:** to amend Directive 90/394/EEC in order to set new limit values for occupational exposure to carcinogens, particularly benzene, and to make provision for the inclusion of certain preparations which are currently excluded from the scope of the directive. **CONTENT:** the main amendments to the directive seek to: - amend the annex to Directive 90/394/EEC so as to set limit values for the exposure of workers to benzene (3.25 mg/m<sup>3</sup>). The directive makes provision for derogations for certain sites or sectors of activity, the limit value for which is set at 9.75 mg/m<sup>3</sup> until 31 December 2000 (e.g. garages, non-self-service petrol stations etc.). - extend the scope of the directive: the directive has been reworded to include exposure to preparations such as medicines for human or veterinary use, cosmetic products, mixtures of substances in the form of waste, pesticides, munitions and explosives, and foodstuffs. At the same time the directive also covers class R45 substances which "may cause cancer" and class R49 substances which "may cause cancer by inhalation" in order to avoid different levels of protection between workers exposed to preparations containing carcinogens; - amend the directive in order to formulate a new strategy for monitoring exposed workers, taking account of the total effect of exposure (i.e. not only respiratory exposure but also exposure from penetration through the skin); - correct certain editorial shortcomings which totally negated the purpose of the original text in certain language versions, the aim being to provide unambiguous protection for workers against polycyclic aromatic hydrocarbons (PAHs) present in certain by-products of coal

**DEADLINE FOR TRANSPOSITION:** Member States must comply with this directive by 31 December 1998. ?

## Safety at work: protection of workers against exposure to carcinogens agents

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The Committee generally considers the Commission draft amendment to be a valuable advance in worker protection and an enhancement of regulatory controls, provided that: (i) it in no way conflicts with the effect of established Health and Safety Directives; (ii) the Committee is informed by the Commission on the proposed arrangements for extending the list of substances to which specific limit values will be applied and the methods by which these will be agreed and established within the European Union. The Committee stresses that the protective measures in the Carcinogenics Directive of 90/395/EEC are in no way affected by the present proposal. They must also be observed in those sectors and activities selected for derogations. The Committee further reminds the Commission of the criticisms and suggestions expressed in its 1988 Opinion on the draft Carcinogenics Directive and urges the Commission to take further action on the basis of it. In the "Specific Comments", the Committee addresses the following issues: - the case for a "guidance note" to help employers and workers to understand the application of the revised Directive to their working environment. This will be of particular help to small and medium-sized undertakings; - the classification of carcinogenic substances; - the reasons for the scope and the duration of the proposed derogations; - the 1 p.p.m. occupational exposure limit for benzene; - the need for a uniform measuring procedure; - cooperation with and between specialist institutes and other bodies in the field of occupational health and safety; - comparability of data.?

## Safety at work: protection of workers against exposure to carcinogens agents

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The Committee adopted the report by Mrs Marjatta STENIUS-KAUKONEN (FIN, GUE/NGL) on a Commission proposal to amend Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work. The rapporteur welcomed the Commission's proposal to extend the scope of the directive to cover, inter alia, medicinal products, cosmetics, waste, pesticides, explosives and foodstuffs. The widening of the scope of application is important and logical, since the risks of workers does not depend on the use to which the chemical agents are put. It is also important to know how and by whom these medicines, cosmetics, explosives etc. were deemed to be carcinogenic. A specific course of action must be worked out to produce a speedy classification e.g. in the area of the chemicals in the extended area of application. The risks of cancer from heavy metals will increase perceptibly in the future. This will, says the rapporteur, become apparent as the section of the population which has been exposed to these begins to age. Urgent measures must be taken to set limit values for new heavy metals. Arsenic has been shown with certainty to cause human skin cancer. There are therefore reasons for setting a limit value for arsenic as well as for benzene. The Committee adopted amendments proposing a limit value of 0,01 mg/m<sup>3</sup> in an average period of 8 hours.

## Safety at work: protection of workers against exposure to carcinogens agents

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The rapporteur, Mrs Stenius-Kaukonen (GUE/NGL, FIN), expressed support for the proposal to extend the scope of the 1990 Directive on the exposure of workers to the risk of cancer at the workplace. However, she rejected a compromise on concentration limits for benzene in the air, as proposed by the Commission (1 ppm exposure over a period of 8 hours), proposing instead a long-term reduction of 0.1 ppm in the limit value for occupational exposure. Commissioner Flynn stated that he could not accept Amendments Nos 11, 14 and 15 as these would negate the temporary exemptions required in certain industrial sectors in order to comply with the benzene tolerability threshold, though this would not rule out the possibility of a future reduction in the limit period for exposure to this carcinogenic substance. Finally, Amendments Nos 17, 18, 19 and 20 could not be taken over, as they were incompatible with the exemptions in place; Amendments Nos 3, 4, 7 and 10 were also rejected because they were not in keeping with the wording of the Directive. However, the Commission was prepared to implement the proposal for a uniform procedure for benzene testing (Amendment No 16).

## Safety at work: protection of workers against exposure to carcinogens agents

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In adopting the report by Mrs Marjatta STENIUS-KAUKONEN (GUE/NGL, FIN), Parliament approved the proposal for amending the directive with the following amendments: - it asked the Commission to find solutions for simplifying the setting of limit values for carcinogens, particularly those for which limit values based purely on health grounds have already been obtained from scientific evidence and reliable studies; limit

values should be set as quickly as possible for all the substances listed as class 1 and 2 carcinogens in Annex VI to Directive 67/548/EEC; - expressing concern about the carcinogenic effects of arsenic and its compounds, Parliament thought they should be added to the priority list of substances for scientific evaluation so limit values could be set as soon as possible; - on the definition of 'limit value' under the directive, Parliament thought this was a compulsory value that could not be exceeded; consequently all derogations envisaged by the Commission, concerning sites and sectors of activity (service stations, garages, etc.) have been deleted. Parliament also defined a worker's 'breathing zone': 'the space from where he takes his breath' and where the carcinogen might be found; - drawing attention to the importance of setting biological limit values for carcinogenic agents, to assess the degree of absorption by means other than breathing; Parliament defined it as the limit of concentration in the appropriate biological medium; - considering that the limit value of concentration of benzene in the air proposed by the Commission (1 ppm over an average period of eight hours) was a compromise between protection of workers and technical constraints, Parliament retained the limit value for benzene proposed by the Commission: a reducing it to 0.1 ppm by 31 December 2000. It also asked for a uniform measuring system for determining the limit value for benzene in the air and that companies that have carcinogens present at the work place prove that they regularly inform workers of the risks of exposure. ?

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## Safety at work: protection of workers against exposure to carcinogens agents

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The amended Commission proposal included a substantial number of the amendments adopted by Parliament at first reading. These concerned: - the role of biological monitoring in health surveillance for exposed workers; - the need for consistency with other Community acts on the same subject: especially the directives on health protection of workers and directives on general public health and environmental protection; - the advisability of having a uniform method for measuring benzene concentrations in air and for analysis by setting a standard of CEN 689:1995 for the measuring procedure. It also included Parliament's amendments on definition of the worker's breathing zone and the definition of the 'biological limit value'. The Commission included primary synthesis in fragrance material production among the temporary derogations for limit values of benzene. It did not include the amendments setting limit values for a series of other substances (such as arsenic and its compounds) and did not withdraw the derogations set out in Annex III to the directive, as Parliament wished. ?

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## Safety at work: protection of workers against exposure to carcinogens agents

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In its opinion on the Council's common position on the amendment of Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work, the Commission stated that it supported the text adopted by the Council. However, it also pointed out that: - it would possibly put forward other proposals to define the biological limit value for the levels of specific substances, as requested by the European Parliament; - it would discuss the introduction of a uniform measuring procedure. At the same time, the Commission pointed out to Parliament that the Council hoped to pursue its policy to simplify legislation in this field and make it more coherent so that all carcinogenic agents defined as such in the directives were listed together in a single and easily accessible source. It also stated that the Council had expressly requested that a new proposal to amend this directive be submitted before 31 December 1997 with a view to including the risks associated with mutagenic substances. Similarly, it was hoped that the scope of Directive 90/394/EEC could eventually be extended to include hardwood dust, after the Scientific Committee for Occupational Exposure Limits had given its opinion on whether or not these substances were carcinogenic. ?

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## Safety at work: protection of workers against exposure to carcinogens agents

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In its common position on the Council Directive amending Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work, the Council takes into account a limited number of amendments made by Parliament at first reading. The amendments accepted seek to: - stress the presence of carcinogens at work; - take over, in part only, the definition given by Parliament to the limit value for occupational exposure (limit value for the concentration of a carcinogen in the breathing zone of a worker over an 8 hour reference period). However, the Council did not take over any of the amendments approved by Parliament and taken up by the Commission in its modified proposal with regard to: - the definition of a worker's breathing zone, - the definition of a biological limit value, - the setting of a uniform method for measurement and analysis of benzene (standard CEN 689:1995), - ensuring that this directive is consistent with those on the protection of health and general environment of citizens, - the principle of biological monitoring of exposed workers. The Council also adds new items to the text of the Commission proposals. These modifications include: - the addition of a new paragraph to specify the methods for applying this directive to asbestos and vinyl chloride monomer, which is the subject of specific directives; - clarification of the definition of the occupational limit value for exposure to carcinogens by introducing a new paragraph covering the binding nature of these limit values: it is essential to ensure that these values are never exceeded. At the same time the Council accepts the exposure limit value for benzene proposed by the Commission (1 ppm over an 8 hour reference period) but has extended the time-scale and the scope of the transitional measures for the implementation of this value so that all the sector concerned can comply with it. It sets the date by which these transitional measures should end at three years after the date of transposition of the directive by the Member States. Thus the derogations provided for by the Commission to allow certain sectors to adapt to the directive have been deleted (filling stations, garages, primary synthesis in perfume production, etc.). ?

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## Safety at work: protection of workers against exposure to carcinogens agents

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The Committee unanimously adopted a report (cooperation procedure, second reading) by Mrs. Outi OJALA (EUL-NGL, FIN) on the protection of workers from the risks related to exposure to carcinogens at work. Because the Council adopted only a few of the amendments tabled by the parliament on the first reading, the committee decided to retable ten original amendments. The committee considered the proposal as representing real progress in the field of health and safety of workers as it extends the scope of the directive. Among other things, it includes a limit value for benzene. The committee was disappointed, however, by the fact that the Council rejected the idea of speeding up the entry into force of the limit value. Instead, Council's decision may postpone it by as much as six years. Council's common position makes no reference to biological limit values nor measuring procedures. ?

## Safety at work: protection of workers against exposure to carcinogens agents

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Pointing out that nearly 10 million workers had contracted an occupational disease and that approximately 4% of cancer-related deaths probably resulted from occupational factors, the rapporteur regretted that the Council had taken over only five of the amendments at first reading. It had insisted on this so that the introduction of an atmospheric limit value for benzene was not delayed and so that the transposition of this directive into national law was not deferred beyond 31 December 1998. For the Commission, Mrs Bjerregaard regretted not being able to accept the amendments tabled.

## Safety at work: protection of workers against exposure to carcinogens agents

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In adopting the recommendation for second reading by Mrs Outi OJALA (GUE/NGL, FIN), the European Parliament approved the common position of the Council on the protection of workers from the risks related to exposure to carcinogens at work while proposing several amendments already approved at first reading: - it repeated its request that the Commission should simplify the possibilities for setting limit values for carcinogens, particularly those for which limit values based on health grounds have already been obtained from scientific studies; limit values should be set as quickly as possible for all substances listed as class 1 and 2 carcinogens in Annex VI to Directive 67/548/EEC; - it expressed concern about the carcinogenic effects of arsenic and arsenic compounds, saying that they should be added to the Community priority list of substances for scientific evaluation in order to set limit values as soon as possible; - it again proposed a uniform measuring procedure for determining the limit value for benzene in the air. It also wanted: - removal of the transition measures advocated by the Council in its common position for setting a limit value for benzene which could be applied after three years after incorporation of the directive into national law (or six years after its entry into force throughout the Community); - the Member States to incorporate the directive into national law before 31 December 1998 at the latest (and not three years after its entry into force). ?

## Safety at work: protection of workers against exposure to carcinogens agents

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OBJECTIVE: to amend Directive 90/394/EEC to set new limit values for occupational exposure to carcinogens, particularly benzene.

COMMUNITY MEASURE: Council Directive 97/42/EC amending for the first time Directive 90/394/EEC on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).

SUBSTANCE: the main amendments to the Directive have the purpose of: 1) amending the annex to Directive 90/394/EC so as to set limit values for the exposure of workers to benzene: 1 ppm for a reference period of 8 hours (or 3.25 mg/m<sup>3</sup>). Transitional measures are laid down to enable all the sectors concerned to comply with the new limit value, which they must do within three years of the date of transposition of the Directive in the Member States; 2) extending its scope to include exposure to preparations such as medicines for human or veterinary use, cosmetic products, mixtures of substances in the form of waste, pesticides, munitions and explosives, and foodstuffs; 3) inserting a new paragraph stipulating that the provisions to implement the Directive also apply to asbestos and vinyl chloride monomer, which are dealt with by specific Directives; 4) introducing the concept of 'limit value for occupational exposure' to carcinogens, defined as the limit on the concentration of a carcinogen in the air within the breathing zone of a worker in relation to a reference period of 8 hours. The Directive lays down that these values must not be exceeded under any circumstances; 5) amending the Directive so as to formulate a new strategy for monitoring exposed workers, taking into account the total effect of exposure (i.e. not only respiratory exposure but also exposure from penetration through the skin); 6) remedying certain textual blemishes which had totally negated the purpose of the original text in some language versions: the aim is to provide unambiguous protection for workers against polycyclic aromatic hydrocarbons (PAHs) present in certain by-products of coal.

DEADLINE FOR TRANSPOSITION OF THE DIRECTIVE INTO NATIONAL LAW: 27.06.2000.?