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COUNCIL DIRECTIVE

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)

(82/605/EEC)

(OJ L 247, 23.8.1982, p. 12)

Corrected by:

►**C1** Corrigendum, OJ L 283, 6.10.1982, p. 24 (82/605)

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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)

(82/605/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

Whereas the Council resolution of 29 June 1978 on an action programme of the European Communities on safety and health at work [4], provides for the establishment of specific harmonized procedures regarding the protection of workers with respect to lead;

Whereas Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work [5], lays down certain provisions which have to be taken into account for this protection; whereas that Directive provides for the laying down in individual Directives of limit values and specific requirements for those agents listed in Annex I, which include lead;

Whereas metallic lead and its ionic compounds are toxic agents found in a large number of circumstances at work; whereas many workers are therefore exposed to a potential health risk;

Whereas, therefore, preventive measures for the protection of the health of workers exposed to lead and the commitment envisaged for Member States with regard to the surveillance of their health are important;

Whereas workers exposed to lead in the extractive industries must enjoy a level of health protection similar to that laid down in this Directive; whereas, given the specific nature of such activities, the implementation of such protection will need to be covered by special provisions embodied in a subsequent Directive;

Whereas this Directive includes minimum requirements which will be reviewed on the basis of experience acquired and of developments in technology and medical knowledge in this area, the objective being to attain greater protection of workers,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive, which is the first individual Directive within the meaning of Article 8 of Directive 80/1107/EEC has as its aim the protection of workers against risks to their health, including the prevention of such risks, arising or likely to arise at work from exposure to metallic lead and its ionic compounds; it shall not apply to alkylated lead compounds. It shall lay down limit values and other specific requirements.

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[1] OJ No C 324, 28. 12. 1979, p. 3.
[2] OJ No C 101, 4. 5. 1981, p. 14.
[3] OJ No C 300, 18. 11. 1980, p. 22.
[4] OJ No C 165, 11. 7. 1978, p. 1.
[5] OJ No L 327, 3. 12. 1980, p. 8.

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2. This Directive shall not apply to:

— sea transport,

— air transport,

— mining and quarrying of lead-containing ores and the preparation of lead-ore concentrate at the site of the mine or quarry.

3. This Directive shall not prejudice the right of Member States to apply or introduce laws, regulations or administrative provisions ensuring greater protection for workers or for a particular category of workers.

Article 2

1. Any work likely to involve a risk of absorbing lead shall be assessed in such a way as to determine the nature and degree of the exposure to lead of the workers.

Annex I contains an indicative, non-exhaustive list of activities where there is reason to consider that there may be a risk of absorbing lead.

2. If the assessment provided for in paragraph 1 reveals the presence of at least one of the following conditions:

— exposure to a concentration of lead in air greater that 40 μg/m^3, calculated as a time-weighted average over 40 hours per week,

— a blood-lead level greater than 40 μg Pb/100 ml blood in individual workers,

the provisions regarding information set out in Article 11 (1) shall apply and appropriate measures shall be taken to minimize the risk of absorbing lead which arises through smoking, eating and drinking at the place of work.

3. If the assessment provided for in paragraph 1 reveals that the blood-lead level of workers due to lead absorption is between 40 μg and 50 μg Pb/100 ml blood, Member States shall endeavour to carry out biological monitoring of the workers concerned in accordance with the procedures laid down by the Member States.

4. If the assessment provided for in paragraph 1 reveals the presence of at least one of the following conditions:

— exposure to a concentration of lead in air greater than 75 μg/m^3, calculated as a time-weighted average over 40 hours per week,

— a blood-lead level greater than 50 μg Pb/100 ml blood in individual workers,

the protection provided for in this Directive, in particular the lead-in-air monitoring and the medical surveillance set out in Articles 3 and 4, is to be given to the workers concerned.

5. The assessment provided for in paragraph 1 shall be the subject of consultation with the workers and/or their representatives within the undertaking or establishment and shall be revised where there is reason to believe that it is incorrect or there is a material change in the work.

Article 3

1. All lead-in-air measurements shall be representative of worker exposure to particles containing lead.

Particles containing lead within the meaning of this Directive shall be those particles captured by equipment having the sampling characteristics specified in Annex II, point 1, and analyzed in accordance with the methods indicated in Annex II, point 2.

2. Monitoring of the concentration of lead in air shall take place at least every three months.

This frequency may, however, be reduced in the cases listed in paragraph 3.

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3. Frequency of monitoring may be reduced to once a year, provided that there is no material change in the work and conditions of exposure, where:

(i) the results of the measurements for individual workers or for groups of workers have shown that on the previous two consecutive occasions on which monitoring was carried out:

— the lead-in-air concentration did not exceed 100 μg/m³, or

— the conditions or exposure did not fluctuate appreciably, or

(ii) the blood-lead level of any worker does not exceed 60 μg Pb/100 ml blood.

4. The monitoring for a worker or group of workers, as stipulated in paragraph 2, shall entail taking one or more air samples.

Without prejudice to the second indent of Article 7 (b), sampling shall be carried out in such a way as to permit assessment of the probable maximum risk to which the individual worker or workers are exposed, account being taken of the work done, the working conditions and the length of exposure during the course of the work. The workers concerned and/or their representatives within the undertaking or establishment shall be consulted to this end.

For the initial monitoring, after it has been established that the values laid down in Article 2 (4) have been exceeded, the duration of the sampling period shall not be less than four hours.

Subsequently this duration shall not be less than four hours if the results obtained on the occasion of the preceding monitoring have shown higher lead-in-air concentration values than those obtained before that monitoring.

Where groups of workers are performing identical or similar tasks in the same location and are thus being exposed to the same health risk, sampling may be carried out on a group basis. In such a case, sampling shall be carried out for at least one worker out of 10.

5. The specifications referred to in paragraph 1 and Annex II, with the exception of the specification concerning the air intake velocity given at point 1 (a) of the Annex, and the technical aspects of this Article shall be adapted in the light of technical progress in accordance with the procedure set out in Article 10 of Directive 80/1107/EEC, within the limits laid down in Annex III to that Directive.

Article 4

1. Workers shall be subject to medical (clinical and biological) surveillance. This surveillance must start prior to or at the beginning of the exposure. The frequency of clinical assessment shall be at least once a year during the period of employment. Biological monitoring shall be carried out, in accordance with paragraph 2, at least every six months.

This surveillance shall take account not only of the magnitude of the exposure but also of the individual worker's susceptibility to lead.

2. The biological monitoring shall, apart from the exception mentioned in paragraph 3, include measuring the blood-lead level (PbB).

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This monitoring may also include measuring one or more of the following biological indicators:

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— delta aminolaevulinic acid in urine (ALAU),

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— zinc protoporphyrin (ZPP),

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— delta aminolaevulinic acid dehydratase in blood (ALAD).

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The methods of measuring the biological indicators referred to above are listed in Annex III and may be adapted in accordance with the procedure specified in Article 10 of Directive 80/1107/EEC.

3. The PbB measurement referred to in paragraph 2 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.

4. The frequency of biological monitoring 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 the value laid down in the first indent of Article 2 (4) and lower than 100 μg/m^3,

— the PbB level of any individual worker does not exceed the value laid down in the second indent of Article 2 (4).

5. Practical recommendations to which Member States may refer for clinical assessment are set out in Annex IV and may be adapted in accordance with the procedure set out in Article 10 of Directive 80/1107/EEC.

Article 5

1. Where the biological monitoring carried out in accordance with Article 4 (2) reveals an individual PbB level higher than 60 μg Pb/100 ml blood but lower than the limit value set out in Article 6 (1) (b), a clinical examination shall be carried out as soon as possible. However, this clinical examination may be deferred until a repeat determination of the PbB level, undertaken within one month, shows that the value of 60 μg Pb/100 ml blood continues to be exceeded.

Thereafter, biological monitoring and clinical assessment shall be carried out at shorter intervals than those laid down in Article 4 (1) at least until the PbB level is below 60 μg Pb/100 ml blood.

2. Following the clinical examination referred to in paragraph 1, the doctor or authority responsible for the medical surveillance of the workers should advise on any protective or preventive measures to be taken on an individual basis; these may include, where appropriate, the withdrawal of the worker concerned from exposure to lead or a reduction in the period of his exposure.

Article 6

1. The following limit values shall be applied:

(a) lead-in-air concentration:

150 μg/m^3, calculated as a time-weighted average over 40 hours per week;

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(b) value of the biological parameters:

PbB level in individual workers: 70 µg/Pb/100 ml blood [1]. However, a PbB level of between 70 and 80 µg Pb/100 ml blood shall be allowed if the ALAU level remains lower than 20 mg/g creatinine or the ZPP level remains lower than 20 µg/g haemoglobin or the ALAD level remains greater than six European units.

2. Where biological monitoring is based solely on ALAU measurement in accordance with Article 4 (3), the following limit value shall be applied for ALAU: 20 mg/g creatinine.

3. The Council, acting on a proposal from the Commission, and taking into account in particular progress made in scientific knowledge and technology as well as experience gained in the application of this Directive, shall re-examine the limit values for the biological parameters within five years of adoption of this Directive, with a view to setting a maximum blood-lead limit value of 70 µg Pb/100 ml blood.

Article 7

For the purpose of establishing whether or not the lead-in-air limit value fixed in Article 6 (1) (a) has been exceeded, it is appropriate to proceed as follows:

(a) If the total sampling period is of 40 hours in one week then the lead-in-air concentrations obtained can be compared directly with the limit value laid down in Article 6 (1) (a);

(b) If the total sampling period is less than 40 hours in one week then:

— the limit value laid down in Article 6 (1) (a) shall not be considered as having been exceeded if the concentration obtained by sampling in accordance with Article 3 (4) is below the numerical level of the limit value,

— if the concentration referred to in the first indent exceeds the numerical level of the limit value then at least three additional lead-in-air samples shall be taken which are representative of average exposure to lead; the total period over which each of these three samples is taken shall be at least four hours.

If, from four samples taken over a period of one week, it is found that three levels of concentration are below the numerical level of the limit value, then it shall be deemed that this limit value has not been exceeded.

Article 8

1. Where the lead-in-air limit value laid down in Article 6 (1) (a) is exceeded the reasons for the limit being exceeded shall be identified and appropriate measures to remedy the situation shall be taken as soon as possible.

The doctor or authority responsible for the medical surveillance of the workers shall judge whether an immediate determination of the biological parameters of the workers concerned should be carried out.

In order to check the effectiveness of the measures mentioned in the first subparagraph, a further determination of the lead-in-air concentrations on the basis of the procedures laid down in Articles 3 and 7 shall be carried out.

2. Where the measures referred to in the first subparagraph of paragraph 1 cannot, owing to their nature or magnitude, be taken within one month and a further determination of lead-in-air concentrations shows that the lead-in-air limit values continue to be exceeded, work may not be continued in the affected area until adequate measures have been taken for the protection of the workers concerned, in the light of the opinion of the doctor or authority responsible for medical surveillance.

[1] Corresponds in SI units to 3 · 4 µ mol lead per litre blood.

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Where the exposure cannot reasonably be reduced by other means and where the wearing of individual respiratory protective equipment proves necessary, this may not be permanent and shall be kept to the strict minimum necessary for each worker.

3. In the case of incidents likely to lead to significant increases in exposure to lead, workers shall be immediately evacuated from the affected area. Only workers whose presence is required to carry out the necessary repairs may enter the affected area on condition that they use suitable protective apparatus.

4. In the case of certain operations in respect of which it is foreseen that the limit value set out in paragraph 1 will be exceeded and in respect of which technical preventive measures for limiting concentrations in the air are not reasonably practicable, the employer shall define the measures intended to ensure protection of the workers during operations of this kind. The workers and/or their representatives in the undertaking or establishment shall be consulted on these measures before such operations are effected.

Article 9

1. Where the biological limit value laid down in Article 6 (1) (b) has been exceeded:

— the necessary steps shall be taken immediately to ascertain the reasons for this excess and to remedy the situation. Such measures may, depending on the magnitude of the excess, and where it is considered desirable by the doctor or authority responsible for the medical surveillance of the workers include the immediate withdrawal of the worker concerned from all exposure to lead,

— a further determination of the PbB level shall be made within three months. Following this determination, the worker concerned must not continue at his work or at any other work involving an equal or greater risk of exposure to lead if the biological limit value continues to be exceeded. The worker concerned may be assigned, following an opinion from the doctor or authority responsible for medical surveillance, to other work involving a lesser risk of exposure. In this case, he shall be subject to more frequent medical assessments.

However, Member States may take different measures for workers who, having been exposed to lead over a number of years, have a very high body burden of lead when this Directive becomes applicable.

2. The worker concerned or the employer may ask for a review of the assessments referred to in paragraph 1.

Article 10

1. For all work carried out under the conditions set out in Article 2 (4), appropriate measures shall be taken to ensure that:

(a) (i) the risk of absorbing lead through smoking, eating or drinking is avoided,

(ii) areas are set aside where workers can eat and drink without risking contamination by lead,

(iii) in very hot workplaces where workers should be encouraged to drink, workers are provided with drinking water or other drinks not contaminated by the lead present in the workplace;

(b) (i) workers are provided with appropriate working or protective clothing, taking into account the physico-chemical properties of the lead compounds to which they are exposed.

(ii) this working or protective clothing remains within the undertaking. It may, however, be laundered in establishments outside the undertaking which are equipped for this sort of work, if the undertaking itself does not carry out cleaning; where this is the case, the clothing shall be transported in closed containers,

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(iii) working or protective clothing and street clothes are stored separately,

(iv) workers are provided with adequate and appropriate washing facilities, including showers in the case of dusty operations.

2. The cost of the measures taken pursuant to paragraph 1 shall not be borne by the workers.

Article 11

1. For all work carried out under the conditions set out in Article 2 (2), appropriate measures shall be taken so that workers and their representatives in the undertaking or establishment are provided with adequate information on:

— the potential risks to health from lead exposure, including the potential risks for the foetus and infants being breast-fed,

— the existence of statutory limit values and the need for biological and atmospheric monitoring,

— hygiene requirements, including the need to refrain from smoking, eating or drinking at the workplace,

— the precautions to be taken as regards the wearing and use of protective equipment and clothing,

— the special precautions to be taken to minimize exposure to lead.

2. In addition to the measures referred to in paragraph 1, for all work carried out under the conditions set out in Article 2 (4), appropriate measures shall be taken so that;

(a) workers and/or their representatives within the undertaking or establishment have access to:

— the results of lead-in-air measurements,

— the statistical (non-personalized) results of biological monitoring,

and explanations of the significance of these results are available to them;

(b) if the results exceed the lead-in-air limit value laid down in Article 6 (1) (a) the workers concerned and their representatives in the undertaking or establishment are informed as quickly as possible of the excess and the reason for it and the workers and/or their representatives in the undertaking or establishment are consulted on the measures to be taken or, in an emergency, are informed of the measures which have been taken;

(c) each time PbB tests, ALAU tests or any other biological measurements for assessing lead exposure are carried out, the workers concerned are informed, on the authority of the doctor responsible, of the results of those measurements and the interpretation placed on the results.

Article 12

The doctor or authority responsible for medical surveillance of the workers shall have access to all information necessary for determining the extent of workers' exposure to lead, including the results of the lead-in-air monitoring.

Article 13

Steps shall be taken to ensure that individual data relating to the exposure of workers and their clinical and biological examinations are recorded and stored in an appropriate form, in accordance with national laws and practices.

Article 14

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 1986 at the latest and shall forthwith inform the Commission thereof.

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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 15

This Directive is addressed to the Member States.

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ANNEX I

List of activities referred to in the second subparagraph of Article 2 (1)

1. Handling of lead concentrate.
2. Lead and zinc smelting and refining (primary and secondary).
3. Lead arsenate spray manufacture and handling.
4. Manufacture of lead oxides.
5. Production of other lead compounds (including that part of the production of alkyl lead compounds, where it includes exposure to metallic lead and its ionic compounds).
6. Manufacture of paints, enamels, mastics and colours containing lead.
7. Battery manufacture and recycling (1).
8. Craftwork in tin and lead.
9. Manufacture of lead solder.
10. Lead ammunition manufacture.
11. Manufacture of lead-based or lead-alloy objects.
12. Use of paints, enamels, mastics and colours containing lead.
13. Ceramic and craft pottery industries (1).
14. Crystal glass industries.
15. Plastic industries using lead additives.
16. Frequent use of lead solder in an enclosed space.
17. Printing work involving the use of lead.
18. Demolition work, especially the processes of scraping off, burning off and flame-cutting executed on materials coated with paint containing lead, as well as the breaking up of plant (e.g. lead furnaces) (1).
19. Use of lead ammunition in an enclosed space.
20. Automobile construction and repair work (1).
21. Manufacture of leaded steel.
22. Lead tempering of steel.
23. Lead coating.
24. Recovery of lead and metallic residues containing lead.

(1) Inasmuch as lead is used or is present.

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ANNEX II

Technical specifications referred to in the second subparagraph of Article 3 (1)

1. The equipment is that which complies with the technical specifications listed below:
   (a) *Air intake velocity at the orifice:* 1 · 25 m/s ± 10 %;
   (b) *Air flow rate:* at least 1 l/min.;
   (c) *Sampling head characteristics:* a closed face sampling head should be used, to avoid filter contamination;
   (d) *Intake orifice diameter:* at least 4 mm diameter in order to avoid wall effects;
   (e) *Filter or intake orifice position:* as far as possible kept parallel to the face of the worker during the whole sampling period;
   (f) *Filter efficiency:* a minimum of 95 % efficiency for all particles sampled down to an aerodynamic diameter of 0 · 3 μm;
   (g) *Filter homogeneity:* maximum homogeneity of the lead content in the filter to allow for comparison between two halves of the same filter.
2. The lead-in-air sample collected in accordance with the procedures in point 1 is to be analyzed by atomic absorption spectroscopy or any other method which gives equivalent results.

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ANNEX III

Methods of measuring biological indicators referred to in Article 4 (2)

PbB: Atomic absorption spectroscopy,

ALAU: Davis [1] or equivalent method,

ZPP: Haematofluorimetry [2]or equivalent method,

ALAD: European standardized method [3]or equivalent method.

Appropriate quality control programmes will be established by the Commission.

[1] Davis J. R., and Andelman S. L. 'Urinary delta-aminolevulinic acid levels in lead poisoning. A modified method for the rapid determination of urinary delta-aminolevulinic acid using disposable ion-exchange chromatographic columns'. Arch. Environ. Health 15, 53-9 (1967).

[2] Blumberg W. E., Eisinger J., Lamola A. A., and Zuckerman D. M. 'Zinc protoporphyrin level in blood determination by a portable haematofluometer. A screening device for lead poisoning'. J. Lab. Clin. Med. 89, 712-723 (1977).

[3] (a) Council Directive 77/312/EEC of 29 March 1977 on biological screening of the population for lead. OJ No L 105, 28. 4. 1977, p. 10 (Annex III).

(b) A. Berlin and K. H. Schaller 'European standardized method for the determination ofdelta-aminolevulinic acid dehydratase activity in blood'. 3. Klin. Chem. Klin. Biochem. 12, 389-390 (1974).

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ANNEX IV

Practical recommendations for the clinical assessment of workers referred to in Article 4 (5)

1. Current knowledge indicates that large-scale absorption may produce adverse effects in the following systems:
   - — hematopoietic,
   - — gastro-intestinal,
   - — central and peripheral nervous,
   - — renal.
2. The doctor in charge of the medical surveillance of the worker exposed to lead should be familiar with the exposure conditions or circumstances of each worker.
3. Clinical assessment of the workers should be carried out in accordance with sound practice; it should include the following measures:
   - — records of the worker's medical and occupational history,
   - — physical examination and a personal interview with special attention to the associated symptoms of early lead poisoning,
   - — evaluation of the pulonary status (for possible use of respiratory protective equipment).

   Blood analyses (and, in particular, establishment of the hematocrit level) and urine analysis should be carried out during the first medical examination and then regularly according to the doctor's judgement.
4. In addition to the decisions based on the results of biological monitoring, the examining doctor will establish the cases where exposure or continued exposure to lead is contra-indicated. The most important of these contra-indications are:
   - (i) — congenital abnormalities:
     - — thalassemia,
     - — G — 6 — PD deficiency;
   - (ii) — acquired conditions:
     - — anaemia,
     - — renal deficiencies,
     - — hepatic deficiencies.
5. Use of chelating agents:

   The prohphylactic use of chelating agents, sometimes called 'preventive therapy' is medically and ethically unacceptable. Many chelating agents may be considered nephrotoxic when administered for long periods.
6. Intoxication therapy:

   To be carried out by specialists.