European Agency for Safety and Health at Work

Guidance for the health surveillance and biomonitoring of workers exposed to lead and its compounds

Annex

European Agency for Safety and Health at Work

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- Advisory Committee on Health and Safety at Work – Working Party 'Chemicals at the Workplace', Workers Interest Group
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- Advisory Committee on Health and Safety at Work – Working Party 'Chemicals at the Workplace', Employers Interest Group

Table of Contents

Purpose and scope

The biological and occupational exposure limit values for lead (Pb) and its inorganic compounds have been recently revised under Directive (EU) 2024/869 of the European Parliament and of the Council of 13 March 2024 amending Directive 2004/37/EC of the European Parliament and of the Council and Council Directive 98/24/EC as regards the limit values for lead and its inorganic compounds and for diisocyanates. The new directive establishes lower values to protect workers' health.

Directive EU 2024/869, Recital 15, states: 'In order to assist Member States, the Commission should draw up Union guidelines on health surveillance, including biological monitoring. Those Union guidelines should focus, inter alia, on the implementation of the provisions of Directive 2004/37/EC regarding blood lead level, taking into account the slow removal of lead from the body, and on the implementation of provisions of that Directive regarding the blood lead level for female workers of childbearing age in order to protect their foetuses and offspring.'

The European Agency for Safety and Health at Work (EU-OSHA) in collaboration with relevant stakeholders has published *Biological monitoring at work: Guidance for OSH experts and workplaces* (EU-OSHA, 2025). This annex to the guidance provides relevant information for occupational health and hygiene professionals, doctors, employers, workers and workers representatives in the context of health surveillance and biomonitoring of lead and its inorganic compounds.

This annex has also been developed in collaboration with relevant stakeholders. The bibliography consulted and references cited are provided at the end of the document.

1 Regulation of lead in the EU – classification and occupational limit values

Lead and its inorganic compounds are key occupational non-threshold reprotoxic substances that can cause adverse effects on fertility and the development of the foetus. They meet the criteria for classification as a Category 1A reproductive toxicant, in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council. Therefore, they are reprotoxic substances as defined in Article 2 of Directive 2004/37/EC.

Under the Regulation for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH; Regulation (EC) No 1907/2006), lead and its inorganic compounds are considered substances of very high concern (SVHC) and are included in the candidate list for authorisation.[1]

Besides REACH, lead is regulated under several EU legislation products, particularly in the areas of environmental protection (Directive 86/278/EEC, on the use of sewage sludge on agriculture, Directive 94/62/EC on packaging and packaging waste, Directive 2000/53/EC on end-of-life vehicles and Directive 2011/65/EU on electrical and electronic equipment) and consumer safety (Directive 84/500/EEC on ceramic articles intended to come into contact with foodstuffs, Directive 98/83/EC on drinking water, Directive 2003/40/EC on natural mineral waters, Directive 2008/50/EC on ambient air quality, Directive 2009/48/EC on the safety of toys, Directive (EU) 2020/2184 on the quality of water for human consumption, Regulation (EU) 2023/915 on food contaminants and Regulation (EC) 1223/2009 on cosmetics).

In the frame of **health and safety at work**, lead and its inorganic compounds are addressed in the Chemical Agents Directive 98/24/EC (CAD), the Carcinogens, Mutagens and Reprotoxic Substances Directive 2004/37/EC (CMRD), the pregnant workers and workers who have recently given birth or are breastfeeding Directive 92/85/EEC and young people at work Directive 94/33/EC.

A non-threshold reprotoxic effect means: 'It is not scientifically possible to identify a level below which exposure to lead and its inorganic compounds would be safe for the development of the offspring of female workers of childbearing age' (Recital 7, Directive (EU) 2024/869).

[1] https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e182607ea6?_disslists_WAR_disslistsportlet_businessIdentifier=0b0236e182607ea6

The regulatory implications are that, to comply with Article 5 of CMRD, employers shall ensure that lead and its inorganic compounds are manufactured and used in a closed system. When this is not technically possible, **exposure should be reduced to as low as is technically possible, not just below the occupational and biological exposure limits**.

The Occupational Exposure Limit (OEL) values are indicated in Annex III of CMRD, as amended by Directive (EU) 2024/869. The OEL for the inhalable fraction is 0.03 mg/m^3 measured or calculated in relation to a reference period of an eight-hour time-weighted average (TWA).

For human biomonitoring, the biological limit value (BLV) (measured as lead in blood using absorption spectrometry or a method giving an equivalent result) according to Annex IIIa of CMRD, as amended by Directive (EU) 2024/869, is:

- 30 µg Pb/100 ml blood until 31 December 2028;
- 15 µg Pb/100 ml blood from 1 January 2029.

For women of childbearing age, CMRD recommends remaining within the reference values of the general population that is not occupationally exposed to lead in the respective EU Member State. When national reference levels are not available, blood lead (B-Pb) levels in women of childbearing age should not exceed the biological guidance value of 4.5 µg/100 ml. However, to current knowledge, this level does not protect the unborn child due to high developmental neurotoxicity of lead.

2 Work activities that may represent a risk of exposure

Lead is a blue-grey metal that is malleable and ductile, with a low melting point (327 °C) – properties that enable its use in multiple applications. According to data from the European Chemicals Agency (ECHA), lead is manufactured in and/or imported to the European Economic Area at ≥ 1,000,000 tonnes per annum.[2] Lead can be used pure as a metal in combination with another metal to form an alloy or as an inorganic or organic compound.

Exposure can occur via inhalation of airborne dust, fumes and vapours, but also by ingestion of dust. The following is a non-exhaustive list of lead industrial processes and professional uses that may involve exposures to dust, fumes or vapours containing lead.

Mining and processing of lead:

- lead and zinc mining; recovering lead from its ores, oxides or other compounds by thermal reduction processes
- metallurgy of lead and zinc; melting or casting lead alloys; melting lead metal
- foundry processes involving:
    - lead smelting, refining, alloying and casting
    - dry machine grinding, discing, buffing or cutting by power tools of lead alloys
    - spraying molten lead metal or alloys.

Manufacture of lead-containing products:

- accumulators; batteries; work in connection with manufacturing, assembly, handling or repair of, or parts of, batteries containing lead that involves the manipulation of dry lead compounds, or pasting or casting lead
- ammunition
- pigments, colours and ceramic glazes, for example for varnishes, enamels and paints
- leaded glass and ceramics*

[2] https://echa.europa.eu/substance-information/-/substanceinfo/100.028.273

- lead sheet stabilisers in polyvinyl chloride (PVC)[3]
- catalysts
- rubber and adsorbents.

Construction and renovation:

- use of lead sheet:
    - in the building industry where most of the lead sheet (or strip) is used as flashings or weathering to prevent water from penetrating, the remainder being used for roofing and cladding
    - for the lining of chemical treatment baths, acid plants and storage vessels
    - lead alloyed with tin, used in making organ pipes
    - as a sound absorber
    - as a radiation shield around X-ray equipment and nuclear reactors
- restoration or renovation in historic buildings that may hold lead-containing materials, for instance stained glass windows, roofs or decorative features
- radiator repairs soldered or painted with lead-containing materials
- dry machine or hand grinding, discing, buffing or cutting by power tools of lead-containing alloys
- spray painting with lead paint
- a process by which electric arc, oxyacetylene, oxy gas, plasma arc or a flame is applied for welding, cutting or cleaning to the surface of metal coated with lead or paint containing lead
- using a power tool, machine sanding or buffing surfaces, including abrasive blasting and high-pressure water jets, to remove a surface coated with paint containing lead and handling waste containing lead resulting from the removal
- hand grinding and finishing lead or alloys containing lead.

Aviation:

- exposure to high octane fuel containing organic lead compounds for piston engine aircraft, for example during:
    - refuelling the aircraft
    - maintenance and repair activities.

Laboratories:

- work in laboratories with lead-containing substances and materials.

Waste and recycling:

- glass recycling
- breaking up or dismantling batteries containing lead, or sorting, packing and handling plates or other parts containing lead that are removed or recovered from the batteries
- scrap-processing activities, including recovering lead from scrap and waste; recycling of any materials containing lead (e.g. PVC in cables, TVs or computer monitors containing cathode ray tubes)
- other waste management and soil remediation.

[3] Restricted used under REACH Annex XVII

Firefighting and clean-up of fire sites:

- fire assessments if lead, lead compounds or lead alloys are used
- lead dust or lead fumes arising from firing weapons at an indoor firing range (e.g. as part of defence, public order or safety activities).

3 Adverse health effects associated with exposure to lead and its inorganic compounds

3.1 Exposure routes

In the workplace, lead is mainly absorbed through the respiratory tract while breathing. Soluble vapours can be effectively absorbed in the airways, while insoluble vapours can travel deeper into the pulmonary alveoli. Small lead-containing particles (< 10 µm) in fumes and dust can reach the alveolar region, where they are almost completely absorbed into the bloodstream. Larger particles are deposited in the ciliated respiratory tract (nasopharynx and tracheobronchial region) and will be cleared up and eventually swallowed, with possible absorption from the gastrointestinal tract.

If good hygiene practices are not followed, ingestion can also occur through contaminated food and drinks taken into the workplace, or through mouth contact with contaminated hands and objects (inadvertent ingestion exposure). In adults, approximately 3 to 10 % of the ingested dose is absorbed, mainly in the duodenum. Absorption is increased by fasting, iron deficiency, diets low in calcium and by vitamin D. Absorption is also increased when the ingested particles are more soluble and smaller.

The skin uptake of inorganic lead compounds is very low (< 0.5 %) if the skin is intact. Exposure from dust deposited on the skin of the hands is mostly through ingestion, resulting from hand-to-mouth contact.

3.2 Toxicokinetics and metabolism

The absorption of lead into the human body depends on the physical form (vapour, fumes or particles), the solubility of the compound in the biological medium under consideration and, in the case of particles, their size. The toxicity is attributed to the lead cation (Pb^{2+}).

Once absorbed, lead enters the bloodstream and is distributed in three compartments: blood, soft tissue (e.g. kidneys and liver) and bone. The elimination half-life ranges from approximately 30-40 days in blood and soft tissues to 10-30 years in bone tissue. This accumulative effect means that health impacts can persist after exposure has ceased.

At steady state (120 days after the start of repeated exposures), the concentration of lead in blood (B-Pb) represents only 1 to 2 % of the quantity present in the body.

In the blood, when B-Pb is less than 400 µg/l, 99 % of the lead is found in the red blood cells. The plasma fraction increases slightly at higher concentrations. Soft tissues contain 5 % of the internal dose and most of the biologically active lead. In adults, almost 95 % of the lead in the body is found in bones. Lead fixed to trabecular bone is, like lead in soft tissues, biologically active and easily mobilised under certain conditions (acidosis or decalcification) and in equilibrium with the blood. Lead bound to compact bone constitutes most of the bone lead. It does not produce any toxic effect and its movements are very slow, coupled with those of calcium. As a result, its concentration increases with age. It is redistributed in the event of depletion in other compartments and by all phenomena leading to demineralisation.

Lead easily crosses the placental barrier. At birth, the B-Pb levels of the mother and child are very similar.

Lead excretion is mainly urinary (> 75 %) and faecal (15-20 %). The elimination half-life of lead is greatly increased in cases of renal failure. There is also low excretion via sweat and via breast milk (the concentration of lead in breast milk represents between 10 and 50 % of B-Pb).

The organic compounds tetramethyl lead and tetraethyl lead can be absorbed through the skin and partly metabolised into inorganic lead (by oxidative dealkylation via the cytochrome P450 system). Most of the tetraethyl lead is excreted in the urine in the form of diethyl lead (and to a lesser extent triethyl lead) and inorganic lead. After exposure by inhalation, tetraalkyl compounds are also eliminated in exhaled air.

3.3 Health effects

Lead and its inorganic compounds are a cumulative toxicant that affects multiple body systems including the neurological, haematological, gastrointestinal, cardiovascular, musculoskeletal and renal systems, with long-lasting effects. It may cause cancer.

Lead and its inorganic compounds affect the reproductive system and may cause infertility or loss in sperm count, miscarriage, foetal death, low birth weight, premature birth or neurobehavioural effects in children due to exposure in the mother's uterus or during breastfeeding. As a non-threshold reprotoxic substance, there is no safe level of exposure.

The evidence for carcinogenicity in humans remains limited. However, some epidemiological studies have reported higher risk of cancers of the stomach, lung, kidney and brain in workers exposed to inorganic lead.

Lead compounds are not directly mutagenic, but evidence of clastogenic effects such as DNA damage, increased micronuclei (MN) frequency and chromosomal aberrations (CA) have been reported in some studies of exposed workers.

The central nervous system is the most sensitive to exposure to lead, particularly the brain where lead can cause a variety of neurological disorders such as cognitive deficits and behavioural problems. Other effects described in workers exposed to lead and its inorganic compounds are impairments of peripheral nerves (peripheral polyneuropathy). These manifestations predominate in lower limbs: paraesthesia, muscle pains and cramps, sensation of tingling and cold, loss of muscle strength and alteration of the electromyogram.

Lead induces anaemia, as lead ions block the enzymes involved in heme synthesis. The severity and prevalence of lead-induced anaemia correlates directly with the concentration of lead in blood.

Lead also affects the cardiovascular system, resulting in high blood pressure and cardiovascular mortality.

Epidemiological studies in adults show that exposure to lead can cause altered kidney function and contribute to the development of chronic kidney disease (CKD). However, studies on chronic kidney disease morbidity and mortality in workers do not lead to clear conclusions.

Acute effects may occur in days when a worker is exposed to very high levels. They include elevated blood pressure, muscle pain, mood disorders, difficulties with concentration, abdominal pain, vomiting and loss of appetite. Non-specific symptoms may include headache, fatigue, sleep disturbance, anorexia, constipation, arthralgia, myalgia and decreased libido.

Medical conditions that may be exacerbated with continued exposure to lead include chronic renal dysfunction, hypertension, neurological disorders and cognitive dysfunction.

Table 1 summarises the lowest relevant B-Pb at which effects have been observed, as reported in the review of the literature carried out by ECHA (2020).

Table 1: Summary of lead concentration in blood (B-Pb) for which there is no observed adverse effect level (NOAEL), the lowest observed adverse effect level (LOAEL) or calculated as the lower bound of the benchmark dose level (BMDL) for a 95 % confidence interval for relevant health effects

B-Pb(µg/l)	Effect
> 400	Adverse effects on sperm quality (Bonde et al., 2002; Kasperczyk et al., 2008)
ca. 300	Small (0.5-2 mmHg) increases in systolic or diastolic blood pressure (Glenn et al., 2006; Weaver et al., 2008)
≥ 300	LOAEL for clastogenic effects in workers (e.g. Chinde et al., 2014; Garcia-Leston et al., 2012; Januzzi and Alpertunga 2015; Olevinska et al., 2010; Vaglenov et al., 2001)
253	Calculated $BMDL_{10}$ (NOAEL) (Lin & Tai-Yi, 2007) for subclinical non-adverse changes of renal parameter (N-acetyl-β-D-glucosaminidase – NAG)
200-400	Increased cardiovascular mortality (Steenland et al., 2017). Note: the studies did not adjust for potential confounding effects of non-occupational risk factors
195	Calculated $BMDL_5$ (NOAEL) based on an increased probability of abnormal haemoglobin (Karita et al., 2005)
180	NOAEL for subtle neurobehavioural effects in workers (e.g. Schwartz et al., 2001); LOAEL for slight neurological effects > 300 µg/l (e.g. Krieg et al., 2008; Meyer Baron & Seeber, 2000; Seeber, Meyer Baron & Schaper, 2002)

Source: ECHA (2020)

3.4 Vulnerable groups

Special attention should be paid to vulnerable workers. These are workers who are particularly sensitive to the effects of lead and its inorganic compounds, whether permanently or temporarily.

Vulnerable groups of workers include:

- pregnant or breastfeeding workers: under Directive 92/85/EEC, pregnant workers or those who have recently given birth or are breastfeeding under no circumstances should be obliged to perform duties for which the assessment has revealed a risk of exposure that would jeopardise safety or health;
- young workers under the age of 18: Directive 94/33/EC prohibits work involving exposure to agents that are toxic, carcinogenic, cause heritable genetic damage or harm to the unborn child or that in any other way chronically affect human health, as well as substances that are in the annex of the directive, which include lead;
- any worker who shows any condition or characteristic that may imply a greater likelihood of suffering from some effect of exposure, such as:
    - workers with iron deficiency, those on diets low in calcium and vitamin D, and those that practice fasting, as these conditions increase absorption;
    - workers of reproductive age;
    - workers with a health condition in target organs (such as the blood, nervous system, digestive system, kidneys and reproductive system);
    - those with a raised body burden on account of earlier exposures, etc.

On the basis of data on neurotoxicity, nephrotoxicity and reproductive toxicity, more restrictive criteria should be applied in certain groups that require special protection. Therefore, any circumstance that, on medical advice, represents a risk to the health of the worker in question or his/her offspring should be taken into account when considering which workers are more vulnerable to the effects of lead exposure.

The identification of vulnerable workers will allow, as far as possible, a worker's job to be adapted to their condition by establishing the special prevention measures required to preserve their health or by removing workers from the activities when exposure cannot be prevented.

4 Health surveillance: biological monitoring and medical surveillance

Health surveillance means 'the assessment of an individual worker to determine the state of health of that individual, as related to exposure to specific chemical agents at work' (Article 2 (f) CAD). As stated in Article 10 (1) of CAD and Article 11 (2) of CMRD, when a binding biological limit value has been set, health surveillance is a compulsory requirement for work with the hazardous chemical agent.

According to Annex II of CMRD: 'Health surveillance of workers must be carried out in accordance with the principles and practices of occupational medicine; it must include at least the following measures:

- keeping records of a worker's medical and occupational history,
- a personal interview,
- where appropriate, biological surveillance, as well as detection of early and reversible effects.

Further tests may be decided upon for each worker when he is the subject of health surveillance, in the light of the most recent knowledge available to occupational medicine.'

Therefore, health surveillance refers to the assessment of the state of health of an individual worker, in relation to their exposures. It considers workers' individual circumstances, including any condition that may increase their disposition to adverse health, a review of their past exposures and risk assessment during their work history.

Health surveillance involves periodic biomonitoring to determine B-Pb and medical surveillance that may involve physical examinations and clinical tests to detect any acute or long-term effect.

The health surveillance programme should be free of charge for the workers, and they must be informed and consulted. Results shall be properly documented and explained individually to each worker.

Based on the results, the doctor and/or authority responsible for the health surveillance proposes to the employer any protective or preventive measures to be taken regarding any individual workers. In addition, the doctor and/or authority responsible must provide fully anonymised collective information to the employer, the health and safety committee or, failing that, the workers' representatives. Consideration of this information is particularly relevant in the context of the risk assessment.

4.1 Frequency of health surveillance: biological monitoring and medical surveillance

Health surveillance identifies whether the current prevention and protection measures that have been adopted are effectively protecting workers' health. Its content and frequency should be adapted so that, at key times, the data needed to ascertain this can be obtained. Health surveillance (including biological monitoring and medical surveillance) for each individual worker with potential exposure to lead and its inorganic compounds should be carried out in the following cases.

- **Prior to exposure and after a long absence due to a health issue**: before a worker is assigned to a job involving exposure to lead or its inorganic compounds, health surveillance must be undertaken. This should cover the specific objectives of the prevention programme and serve as a baseline for the development of the worker's health, to be studied over time. In

addition, a record of the worker's exposure history should be created. Blood lead should be determined, to have a reference value to compare future biomonitoring results. Based on B-Pb and the personal characteristics of the worker, the doctor and/or authority responsible for the health surveillance may decide to carry out physical examinations.

- **Periodically**: health surveillance should be undertaken at least once a year or more frequently if the doctor and/or authority responsible considers it appropriate. This depends on the characteristics of the worker.
- **Extraordinary circumstances**: this category includes health surveillance prompted by changes appearing in one or more workers from a homogeneous risk group due to, for example, changes in work exposure (identified as lead in blood or air) or due to temporary or permanent changes in a worker's personal characteristics.
- **In case of health concern**: health surveillance is required when the worker has concerns that may relate to exposure to lead or, for example, when relevant symptoms are identified.
- **Accidental exposure**: health surveillance is necessary in case of incidents or accidents that result in unusual exposures (such as spills or loss of containment).
- **End of work**: when workers are moved to other activities that do not involve the potential for lead exposure, health surveillance should be carried out.

Also, as stated in Annex IIIa of CMRD, medical surveillance is carried out on a regular basis:

- until 31 December 2028: for workers whose blood lead level exceeds the biological limit value of 30 µg Pb/100 ml blood due to exposure that occurred before 9 April 2026, but is below 70 µg Pb/100 ml blood;
- from 1 January 2029: for workers whose blood lead level exceeds the biological limit value of 15 µg Pb/100 ml blood due to exposure that occurred before 9 April 2026, but is below 30 µg Pb/100 ml blood;
- if exposure to a concentration of lead in air is greater than 0.015 mg/m^3 (50 % of the OEL), calculated as a time-weighted average over 40 hours per week;
- or a blood lead level greater than 9 µg Pb/100 ml blood (60 % of BLV) is measured in individual workers;
- for female workers of childbearing age whose blood lead level exceeds 4.5 µg Pb/100 ml blood or the national reference value of the general population not occupationally exposed to lead, if such a value exists.

These are minimum requirements. The doctor and/or authority responsible for the health surveillance programme may decide, based on a worker's individual characteristics and cumulative exposure, in what other circumstances and with what frequency medical surveillance is recommended. In all cases where medical surveillance is carried out, in addition to the medical tests recommended by the doctor and/or authority responsible for the health surveillance, biological monitoring should be continued with the frequency considered by the doctor, taking into account the worker's characteristics and B-Pb.

In the case of female workers who have been exposed before pregnancy, maternal B-Pb levels should be monitored during pregnancy, since they do not stay constant. Instead, they have a U-shaped pattern, with a decrease in the second trimester due to haemodilution, followed by an increase in late pregnancy and postpartum, when lead is mobilised from maternal bone and released in the blood circulation to meet foetal demands for calcium to build bones and teeth. A substantial fraction of maternal lead can be transferred to the foetus, with additional transfer occurring during breastfeeding (Ali Daoud et al., 2023; Hertz-Picciotto et al., 2000).

Since lead and its inorganic compounds bioaccumulate in human tissues, health surveillance may continue after the end of exposure for as long as the doctor and/or authority responsible for the health surveillance, following national law or practices, considers it to be necessary to safeguard the health of the worker concerned.

4.2 Records of medical history and symptoms

With regard to reprotoxic substances, workers' medical records shall be kept for at least five years following the end of exposure, in accordance with national law or practice. This applies to the list of all workers engaged in activities in which risk assessments reveal a risk to their health or safety (Article 15, CMRD).

The following details about the worker's medical history should be collected by the doctor and/or authority responsible for the health surveillance programme at the start of the work contract, prior to carrying out any job where there is potential exposure to lead, and then updated over the working period:

- a clinical history that explores previous medical conditions and neuropsychological problems, haematological disorders and effects on the digestive system and kidneys, as well as information on smoking and alcohol intake;
- depending on exposure (B-Pb), an enquiry about the presence of symptoms, with an emphasis on reproductive history including current pregnancy or breastfeeding;
- prior history of non-work-related lead exposure e.g. hobbies like shooting (exposure to gunshot residue or preparation of ammunition using lead primers) and fishing (e.g. home casting of lead sinkers);
- history of medication (including alternative supplements) or medical treatment including recent chelation therapy (e.g. ethylenediaminetetraacetic acid – EDTA);
- exposure assessment results including the nature, degree and duration of workers' exposure.

The list below shows most of the symptoms that should be kept under surveillance when monitoring workers exposed to lead and its inorganic compounds. However, the doctor and/or authority responsible for the health surveillance should bear in mind that these symptoms occur mostly when B-Pb is over 180 µg/l or 18 µg/100 ml (ECHA, 2020), as indicated in Table 1.

- Health problems and diseases of the peripheral and central nervous system (difficulty concentrating or with memory, irritability, personality changes, depression or feeling low, headaches, sensory disorders and feelings of weakness, feeling of pins and needles or tingling in the limbs, and muscle weakness). Often symptoms are mild and subclinical and may be observed only, for example, as mild decreases in nerve conduction velocities.
- Reproductive problems (e.g. reduced fertility in men and women, and miscarriages).
- Neurodevelopmental delays observed in the offspring.
- Arterial hypertension.
- Kidney diseases.
- Health problems or diseases in the erythropoietic and gastrointestinal systems (particularly pale skin, fatigue, loss of appetite, metallic taste, abdominal pains or constipation, and colic). These symptoms are generally related only to very high B-Pb.

4.3 Work history and past/cumulative exposure

Lead bioaccumulates in the body tissues and can be released to the blood stream after exposure ceases at different rates depending on the worker's characteristics (e.g. age, health condition and diet). The results of B-Pb measurements do not differentiate between lead released to the blood stream from tissues as a result of bioaccumulation and lead from current exposure. Therefore, workers' past exposures should be considered in the interpretation of biomonitoring results, to avoid misclassifying current exposure.

Risk assessments throughout the occupational history are an essential part of the health surveillance programme and must be collected and documented with particular care and depth, along with data on past exposures to lead. The work history should include:

- a description of the past and current activity/activities;
- any previous measurement of B-Pb;
- the duration of exposure per working day, or week if it is very variable over a day;
- the technical, organisational and personal protective measures that were in place, including the type of respiratory protective equipment, if used;
- the measures for selection, storage, cleaning and use of personal protective equipment or clothing;
- all practices that may result in increased exposure to lead, such as inadequate hygiene habits or eating, drinking or smoking in the workplace;
- any incidents or accidents that may have resulted in increased exposure to lead;
- the concentration of lead in the workplace air where the worker carried out the activity/activities;
- the hazard information and instructions for work provided to the workers.

4.4 Physical examinations

Specific physical examinations should always be properly justified on medical advice. The doctor and/or authority responsible for the health surveillance should decide which tests are most appropriate, based on current B-Pb, previous B-Pb and cumulative exposure to lead over the years. Individual health risks are also taken into account, considering worker characteristics (age, female workers of childbearing age, pregnant, breastfeeding, or in the pre or post-menopausal period) including pre-existing health problems like osteoporosis.

National legislation and guidelines must always be checked, as they may provide details on what specific medical tests should be carried out. The medical examination should be focused primarily on the nervous and cardiovascular systems (including blood pressure) and kidneys. Assessment of pulmonary status may be required in cases where respiratory protective equipment is or is likely to be needed.

The following paragraphs summarise the tests that can be carried out to identify effects on blood, kidney and the nervous system. However, current evidence has shown effects at B-Pb concentrations higher than the BLV of 18 µg/100 ml (Table 1). To ensure the highest level of worker protection, protocols should be kept updated in line with the most recent scientific evidence. The doctor and/or authority responsible for the health surveillance should stay informed about new knowledge.

Blood pressure

Data that are currently available suggest a link between exposure to lead and an increase in blood pressure. Measurement frequency is established based on medical advice, according to age and the time and level of exposure. It would be advisable for blood pressure to be taken in the initial examination and during the periodic examinations.

Complete haematocrit/haemoglobin blood count

Another of the effects of lead is the generation of anaemia due to the increased destruction of red blood cells and the inhibition of haemoglobin synthesis. For this reason, the inclusion of tests to determine haemoglobin concentration and the haematocrit value in venous blood may be considered. Workers with an iron deficiency (an anomaly that is more common among women) are more susceptible to anaemia. In the initial examination, it would also be appropriate to consider testing for thalassemia minor (a genetic disorder related to a decrease in haemoglobin and red blood cells) or deficiency of glucose-6-phosphate dehydrogenase (G6PD), an enzyme that helps red blood cells to work correctly. G6PD deficiency is common in the population from Mediterranean countries and in the African and South-East Asian populations and may worsen with exposure to lead.

Kidney function tests

Kidney function and structure can be affected by the action of lead. One of the biggest problems in the use of kidney function tests is that many of them show significant changes only when function has

decreased by more than half. This serves to determine the severity and monitor development of the disorder but does not meet the requirement of early detection, which is vital in preventive examinations. The use of tests such as levels of N-acetyl-glucosaminidase or ß-2-microglobulin in urine may be considered to monitor certain groups, depending on the level and time of exposure.

Study of the effects on the nervous system

There are some screening tests for the early detection and assessment of nervous system effects. These are basically neurobehavioural and electrophysiological tests. Both types of tests should be used in a way that is compatible with the clinical history and with an appropriate physical examination and B-Pb monitoring.

An example of these tests is the Euroquest questionnaire[4] developed by the Finnish Institute of Occupational Health (FIOH) and recommended in Finland. Although the questionnaire was designed for the screening of chronic solvent-induced encephalopathy, it is also adequate for the screening of neurotoxic effects of neurotoxic metals.

Lead and its inorganic compounds cause developmental neurotoxicity (DNT) disorders during prenatal development, such as autism, attention deficit disorder and mental retardation, and might act together with other DNT chemicals such as toluene, arsenic, methylmercury and polychlorinated biphenyls (PCBs). Therefore, in cases of complex mixtures, the use of effect biomarkers is recommended (OECD, 2022). Neurofilament light chain (NfL) for axonal damage and brain-derived neurotrophic factor (BDNF), which is indicative of neuronal survival, development and synaptic plasticity, can both be used to assess cumulative risks in an integrative way (OECD, 2022).

Bone lead measurement

X-ray fluorescence (XRF) or K-shell XRF (KXRF) can be used for rapid, non-invasive quantification of lead in bones (Spetch et al., 2024). In adults, almost 95 % of the lead in the body is found in bones. Therefore, bone lead can be used as an indicator of long-term exposure.

The results depend on the bone being measured (commonly the tibia) and the penetration, which is cortical bone and no deeper, so these techniques do not capture the entire skeletal lead burden.

KXRF provides lower detection limits and less uncertainty than XRF but it is not portable and requires longer scanning times.

As with any technique that uses ionising radiation, although the dose level is low, it is not risk free. Tests should be justified and agreed with the doctor and/or authority responsible for the health surveillance.

4.5 Biological monitoring

Annex IIIa of CMRD specifies that biological monitoring must include measuring B-Pb using absorption spectrometry or a method giving equivalent results.

It is important to follow a standard procedure for the sampling, storage and transport of samples to ensure the traceability of the samples and the reliability of the results.

4.5.1 Procedure and equipment for blood sampling for lead analysis

Blood sampling for lead analysis requires a stringent procedure given the risk of sample contamination, which can occur especially during sampling from contact with contaminated skin or work clothes. Trained healthcare staff are required for sample collection. Universal precautions for preventing blood-borne transmission of infection should be observed for all types of blood sampling.

Samples must be taken outside the workplace, in a clean environment free from lead contamination (e.g. with no soil, dust or recycled paper present). The subjects must have showered and must not be wearing their work clothes. The skin must be thoroughly washed before sampling. Uncoagulated, undecanted whole venous blood is preferred (around 5 ml). This is taken using sterilised syringes in a tube for trace

[4] https://www.ttl.fi/sites/default/files/2021-12/euroquest-questionnaire-long-verision-en.pdf

element analysis with anticoagulant. EDTA is the preferred anticoagulant because with heparin clots may form in the blood after collection (e.g. > 24 hours).

Since metal contamination is the main pitfall in the analysis of trace elements, all sampling and analytical equipment must be certified as lead free (needle, tubes, caps, antiseptics and analytical tubes). The analysis of a laboratory blank is also recommended, to verify any possible contamination during the analysis.

To ensure the quality of the measurements, it is good practice to use an accredited laboratory qualified for the analysis of lead in blood and ideally a laboratory that participates in external quality assurance programmes.

Sampling time is not critical, and samples can be collected at any point during the working week.

4.5.2 Sample conservation, transport and storage

After collection, samples should be coded and kept vertically in a fridge (+2 °C to +8 °C) until their transport to the laboratory. Samples are meant to be stable at that temperature for at least 10 weeks. Samples can also be frozen in suitable containers and kept at -20 °C for up to a year.

Samples should not be kept at room temperature.

4.5.3 Information to be recorded

The following information should be recorded to facilitate the interpretation of the results and the implementation of any work changes or additional risk management measures:

- time of sampling
- job description
- work procedure (automatic, manual, closed or open system for the handling of lead/process-generated lead)
- quantities being handled and physical form of the compounds (vapour, fumes, particles/powder)
- frequency of exposure (number of shifts a week where exposure can occur)
- duration of exposure over a typical shift
- work history: jobs and time periods where exposure to lead may have occurred, including description of tasks and risk management measures in place
- exposure control measures
- personal protective equipment, including type of personal respiratory equipment
- detail of any unforeseeable event, incident or accident since the last blood test that is likely to result in abnormal exposure
- non-occupational exposures: hobbies or activities that can result in lead exposure (for example, shooting with guns or hunting, restoring old paintings).

4.5.4 Quality of data

To be able to obtain reliable lead biomonitoring data, the laboratory must have in place a quality assurance and quality control system. Errors can be introduced at every step of the process (sampling procedure, transport, conservation and analysis of samples). It is therefore key to follow a protocol to prevent these errors and to have a system that helps to identify them in case they occur.

4.5.5 Interpretation of results

The concentration of lead in whole blood is at present the best indicator of current and cumulative exposure to lead. B-Pb correlates with the health effects of lead. Consequently, B-Pb measurements are a good surrogate for body burden.

Since lead bioaccumulates in bones and is released to the blood stream at different rates depending on workers' characteristics, blood levels could remain high for a long time after exposure has been reduced or ceased. In this sense, air measurements can help with the interpretation of results of lead biomonitoring at a collective level, among workers expected to have similar exposures (based on current activities and past work history), since air measurements represent current exposures.

In the interpretation of B-Pb results, it is also important to consider the following aspects:

- sex: higher B-Pb levels are found in men;
- age: B-Pb levels increase with age;
- health conditions: certain health conditions like osteoporosis mobilise lead from the bones to the blood;
- sources of extra-occupational exposure linked to the environment (exhaust gases), food (drinking water supplied through lead pipes, alcohol, acidic foods kept in enamelled containers) and leisure (indoor shooting, restoration of old paintings, etc.);
- active and passive smoking, which can increase B-Pb levels, due to the presence of lead in cigarettes;
- the type of chemical compound the worker is exposed to, as the bioavailability in the human body of the different forms of lead (oxide, metal and silicate) is variable.

In addition, it is important to account for the uncertainty associated with the chemical analysis. The analysis should meet the performance criteria set by standard EN ISO 15189: Medical laboratories – Requirements for quality and competence.

Recommendations for establishing a declining trend in exposure levels are provided in Section 7.4 of this annex.

The formula to convert moles of lead to mass is as follows:

$$\text{mass (g)} = \text{moles} \times \text{molar mass of Pb}$$

The molar mass of lead is approximately 207.2 g/mol. So, for example:

- **1 mole of Pb = 207.2 grams**
- **1 µmol/l = 207 µg/l**
- **1 µg/dl = 0.0483 µmol/l**

Also:

- **1 µg/dl = 1 µg/100 ml**
- **1 µg/dl = 10 µg/l**

4.5.6 Ethical considerations

Workers should be informed of the purposes of the health surveillance programme. The biological sample should only be used for the purposes of analysing the concentration of Pb in blood and any other tests requested by the doctor and/or authority responsible for the health surveillance. Any incidental findings considered relevant for the worker's health should be shared with them.

Communication of the results to each individual worker should be done by a health professional who can explain the meaning of the results from a health perspective and whether any prevention measure

or further tests are required. Workers should be allowed to ask any questions in relation to their individual results and personal circumstances.

The results of the health surveillance programme, including the biomonitoring results and any medical information, shall be treated as personal data under the General Data Protection Regulations (GDPR; Regulation (EU) 2016/679).

5 Analytical methods for measuring lead in blood

The analytical method for the analysis of lead in blood as indicated in CMRD is atomic absorption spectrometry or a method that gives equivalent results. Currently, most laboratories use inductively coupled plasma mass spectrometry (ICP-MS), as it allows lower detection limits.

To obtain reliable analytical results, the selected laboratory should follow standards such as ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories and have a quality management system for quality assurance and quality control. Ideally, the laboratory should be accredited for the specific analytical method used, especially for checking compliance with biological limit values for workers exposed to lead and its compounds. The conditions or requirements on accreditation of the laboratories responsible for the analyses may be set out in national legislation.

Together with results on the blood lead concentration, the laboratory should provide the limit of detection (LoD) and the limit of quantification (LoQ) of the analytical method. In addition, the laboratory should provide the uncertainty of the measurement, since these data are required to interpret the results and establish a declining trend.

6 Employers' obligations

6.1 Prevention and reduction of exposure

In addition to the obligations stipulated in the main guidance on biological monitoring at work (EU-OSHA, 2025), CMRD establishes other general requirements. Under these, employers must regularly assess the risks of exposure to lead at work; ensure the replacement of lead, where technically possible, with other less toxic substances; use closed systems and, if that is not possible, reduce exposure to as low as technically possible, beyond OEL or BLV (Articles 4 and 5, CMRD).

Therefore, alternatives for substitution of lead should be investigated and documented, since employers shall, upon request, submit the findings of their investigations to the relevant authorities (Article 4, CMRD).

If air concentrations or blood levels in individual workers increase above previous levels, even if they are below the levels established in Annex IIIa of CMRD for health surveillance, an investigation should be carried out to identify the source of exposure. In addition, appropriate risk management measures should be implemented to reduce exposure.

Air measurements can help to evaluate the effectiveness of the implemented engineering controls to ensure exposure is as low as technically possible, in accordance with regulatory requirements.

6.2 Information and training

It is the employer's obligation to ensure that workers and/or workers' representatives in the undertaking or establishment receive sufficient and appropriate training. Training must be adapted to take into account changing circumstances related to work and it must be repeated periodically (Article 11, CMRD). It should be offered prior to the start of the activity and when changes are introduced.

According to Article 11 of CMRD, before workers are assigned to a task involving the risk of exposure to lead and its inorganic compounds, they shall be told that health surveillance is mandatory, given that there is a binding BLV for lead and its inorganic compounds.

Systems should be in place to ensure workers follow safety standards and procedures when they work in processes where there is potential exposure to lead and its inorganic compounds.

6.3 Female workers of childbearing age

It is not scientifically possible to identify a level below which exposure to lead and its inorganic compounds would be safe for the development of the offspring of female workers of childbearing age. The notation of 'non-threshold reprotoxic substance' has therefore been introduced for lead and its inorganic compounds. Employers should ensure that workers' occupational exposure to lead and its inorganic compounds is reduced to a level as low as is technically possible (Recital 7, Directive (EU) 2024/869).

Under no circumstances should pregnant workers, or those who have recently given birth or are breastfeeding, be obliged to perform duties for which the assessment to lead and it is inorganic compounds has revealed a risk of exposure that would jeopardise safety or health. This applies to the agents and working conditions listed in Annex II, Section A of Directive 92/85/EEC, and includes lead.

Since lead bioaccumulates and is released to the blood for years after exposure, women of childbearing age should not be exposed. CMRD states that B-Pb in women of childbearing age should not exceed the reference value of the general population not occupationally exposed to lead in the respective EU Member State. When national reference levels are not available, B-Pb should not exceed the biological guidance value of 4.5 µg/100 ml (Annex IIIa, CMRD).

The value 4.5 µg Pb/100 ml is an indicator of exposure but not of identifiable adverse health effects. This value therefore acts as a sentinel marker to alert employers of the need to introduce measures to ensure that any exposure to lead and its inorganic compounds does not result in adverse developmental health effects in the foetuses or offspring of female workers. This provision complements the existing employer's obligations on risk assessments and information and training, which are important tools to minimise the exposure risk.

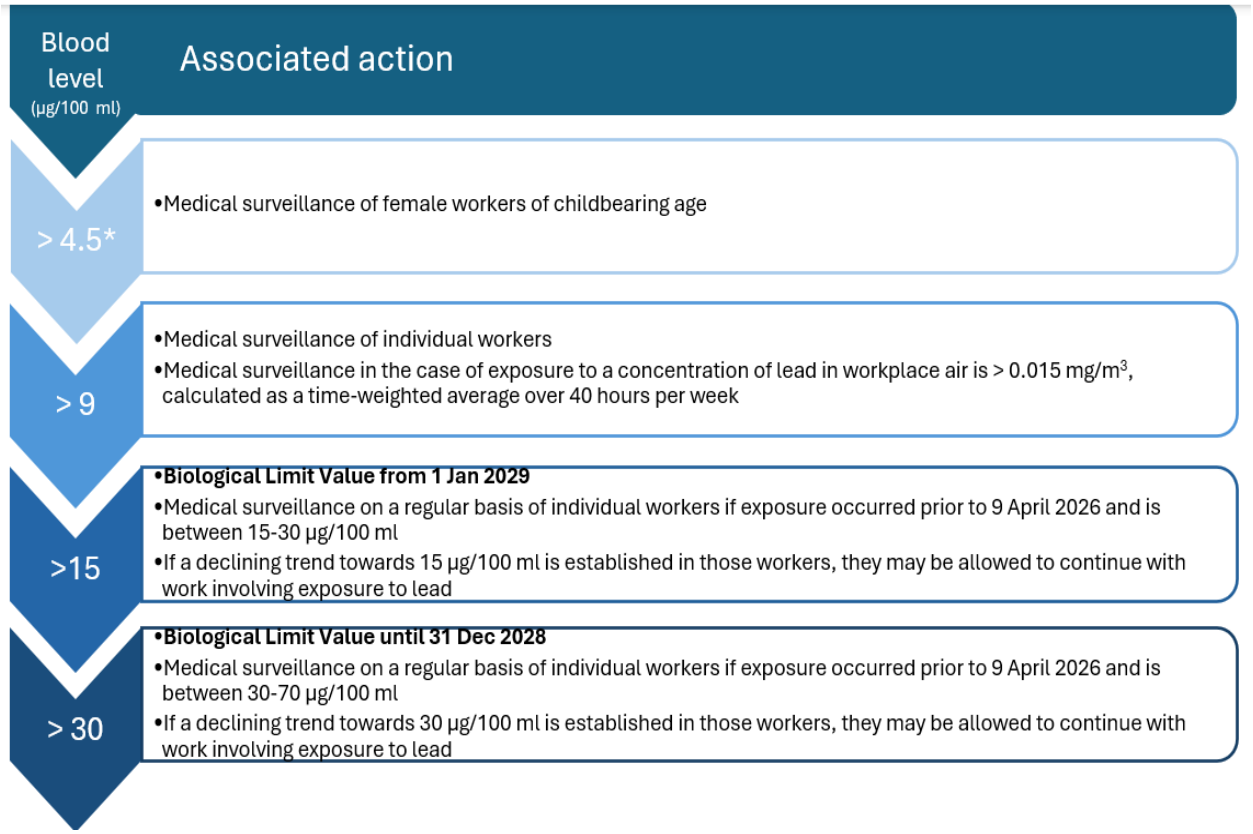
6.4 Alternative job and declining trend on exposure

Article 10 of CAD establishes certain obligations for the employer on health surveillance when a worker is found to have an identifiable disease or adverse health effect that is considered by a doctor or occupational healthcare professional to be the result of exposure at work, or a binding biological limit value is found to have been exceeded. In these cases, the employer must take into account the advice of qualified specialists or the competent authority on the implementation of prevention and protection measures to eliminate or reduce risk, 'including the possibility of assigning the worker to alternative work where there is no risk of further exposure'.

Directive (EU) 2024/869 (deadline for transposition 9 April 2026) has introduced a substantial reduction of the biological limit value from 70 µg Pb/100 ml to 15 µg Pb/100 ml by 1 January 2029. This reduction may be difficult to comply with in the short term. Therefore, a transitional period until 31 December 2028 has been established during which a biological limit value of 30 µg Pb/100 ml blood applies. Figure 1 summarises the lead blood levels and associated actions according to CMRD.

Figure 1: Blood level concentrations and associated actions according to CMRD[5] (*or the national reference value of the general population not occupationally exposed to lead)

[5] Detailed obligations of the employer are contained in Annex IIIa of Directive (EU) 2024/869 of the European Parliament and of the Council of 13 March 2024 amending Directive 2004/37/EC of the European Parliament and of the Council and Council Directive 98/24/EC as regards the limit values for lead and its inorganic compounds and for diisocyanates.



According to Article 10 of CAD, the following actions are required when a worker is found to have an identifiable disease or adverse health effect as a result of exposure, or a BLV is exceeded. The employer shall review the risk assessment and the measures provided to reduce or eliminate the risk. The employer shall also take into account the occupational health professional's advice, including the possibility of assigning the worker to alternative work where there is no risk of further exposure.

These are minimum requirements and the doctor and/or authority responsible for the health surveillance should consider the worker's characteristics (age, sex, health conditions, etc.) and history of previous exposures when determining whether a change of tasks is appropriate. Decisions should not rely solely on current exposure levels.

Until 31 December 2028, workers whose blood levels are over the BLV of 30 µg Pb/100 ml (due to exposures prior to 9 April 2026, the date when Directive (EU) 2024/869 has to be transposed) but below 70 µg Pb/100 ml can continue with work involving exposure to lead if a declining trend towards the BLV of 30 ug Pb/100 ml is established.

From 1 January 2029, the BLV is 15 µg Pb/100 ml. From this date, workers whose blood levels are over 15 µg Pb/100 ml (due to exposures prior to 9 April 2026, the date when Directive (EU) 2024/869 has to be transposed) but below 30 µg Pb/100 ml can continue with work involving exposure to lead if a declining trend towards the BLV of 15 ug Pb/100 ml is established.

It is difficult to establish a general criterion for a declining trend of lead levels in blood. This is because the speed at which lead level drops after the end of exposure depends on several factors: the current B-Pb; the duration and level of previous exposures since, if bone accumulation has occurred due to long-term exposure, Pb is released slowly from bone to blood; the worker's characteristics; and their health status (e.g. presence of osteoporosis).

Therefore, the frequency of blood testing should be decided by the doctor and/or authority responsible for the health surveillance. In any case, to be able to confirm a declining trend, the reduction in B-Pb should be larger than the uncertainty of two successive measurements.

Workers who have a B-Pb below 30 µg/100 ml and do not have a history of exposure, according to their medical records, are expected to show a rapid decline in blood lead (taking into account their characteristics and health conditions). In such cases, B-Pb can be measured more frequently. In cases

where there has been long-term accumulation in the body, or current blood levels are higher, the interval between successive tests should be extended, since the decline may take several months. In this regard, the California Environmental Protection Agency used a physiologically based pharmacokinetic (PBPK) model to estimate the number of days it takes for B-Pb to drop to 15 µg/100 ml once exposure has ended, considering different exposure scenarios (OEHHA, 2013). For example, the number of days to reach 15 µg/100 ml if workers have been exposed one year is 38 days (90th percentile) when current B-Pb are 20 µg/100 ml. If current levels are 30 µg/100 ml, it takes 234 days to reach 15 µg/100 ml.

In any case, the frequency of blood tests should be established by the doctor and/or authority responsible for the health surveillance. National requirements and guidance should be checked, as they may be stricter or more detailed in this regard.

6.5 Occupational disease (OD) notification

The competent authority shall be notified of all cases of cancer, adverse effects on sexual function and fertility in adult male and female workers, or developmental toxicity in their offspring identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen, mutagen or reprotoxic substance (Article 14 (8) CMRD).

7 Information for workers

The document *Biological monitoring at work: Guidance for OSH experts and workplaces* (EU-OSHA, 2025) provides information for workers who participate in health surveillance programmes. This annex gives specific information for workers exposed to lead and its inorganic compounds.

Workers should be trained on how to perform work where there is potential exposure to lead and its inorganic compounds in a safe manner and how to use protective measures correctly (including the correct use, storage, fit testing and maintenance of personal protective equipment). A medical examination is an ideal opportunity to inform workers and reinforce their knowledge about the risks associated with lead and its inorganic compounds, and the hygiene measures that are essential to minimise exposure, which are in the worker's hands.

7.1 Health effects of lead

Workers should be informed of the potential short/acute and long-term health effects associated with exposure to lead and its inorganic compounds, including the risks to men and women and people of a younger age (i.e. less than 18 years of age).

Workers should be informed of the bioaccumulation of lead and the slow release to blood after exposure has ceased. They should be advised to follow hygiene and prevention measures strictly, to minimise exposure.

7.2 Family planning, pregnancy and breastfeeding

Workers should be counselled on the health effects of lead on male and female reproduction, as appropriate.

Male workers should be informed that exposure to lead may adversely affect reproductive function and cause a decrease in sperm count, volume and morphological alterations.

Female workers in jobs with potential exposure to lead should be informed about the reproductive health risks and that exposure to lead during pregnancy may be associated with pregnancy complications and may pose a risk to the development of the foetus. Female workers should be counselled on the effects of lead on foetal and childhood development, in particular cognitive development.

Workers who are breastfeeding should be informed on the health effects of exposure to lead on the breastfed baby.

The prevention of changes affecting reproduction in the exposed population (among both men and women) makes it advisable to reduce the exposure of workers of childbearing age to lead as far as possible.

7.3 Medical conditions

Individuals with certain medical conditions, for example impaired renal function and anaemia, haemoglobinopathies, osteoporosis, neuropathies and reproductive problems may be more susceptible to the health effects of lead. They should receive advice from the doctor and/or authority responsible for the health surveillance.

7.4 Personal hygiene

Workers should be provided with facilities to store work or protective clothing and street clothes separately. They should be educated on separate storage and encouraged to do it.

Workers should be provided with adequate facilities for washing and showering at the workplace. They should change clothes prior to lunch breaks and at the end of the shift to minimise secondary lead exposure from contaminated clothing and reduce ingestion of lead.

Workers should be counselled that respirator fit can be poor and protection ineffective if they have a beard or facial hair.

Workers should be reminded:

1. that they are not permitted to smoke, carry materials used for smoking, eat, chew gum or drink in areas where there is a risk of lead exposure;
2. of the importance of removing lead-contaminated clothing and equipment;
3. to wash their hands, nails and face and brush their teeth before entering areas designated for eating and drinking;
4. to shower at the end of the shift.

A full explanation of the reasons for these restrictions and the benefits to be gained by compliance should be given.

Workers with a history of smoking should be counselled on the possible additional lead burden from smoking.

7.5 Health surveillance

Before workers are assigned to tasks involving the risk of exposure to CMR substances, the employer shall inform them that health surveillance is mandatory, according to Article 11 (2) of CMRD, and that health surveillance may be required after the end of exposure if considered necessary by the doctor and/or authority responsible for the health surveillance programme.

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