Original papers

Occupational exposure to inorganic lead and its compounds in Romania

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Abstract

Lead and its compounds are hazardous chemical agents; some lead compounds, are classified as carcinogens in humans. In Romania, the occupational exposure to inorganic lead and its compounds occurs in many sectors: production of lead, manufacture of batteries, manufacture of thermal ceramic products (terracotta), production of electric and electronic components, manufacture of articles of metal wire, production of dyes and additives for plastics, recovery of lead from waste batteries, waste collection and treatment of electrical and electronic equipment, etc. The binding occupational limit value for inorganic lead compounds established under the national regulations is 0.15 mg/m³ in the air (measured in relation to a reference period of eight hours, time-weighted average, TWA). The binding biological limit value is 70 µg Pb/100 ml blood. We have summarized lead occupational exposure data collected from the regional public health authorities in Romania, for the period 2011-2019. The concentrations of lead recorded in the workplaces air varied between "not detected" and 0.22 mg/m³. The lead concentrations in the blood had high values (over the alert value of 40 µg/100 ml blood) in several activities (production of lead, recovery-recycling of lead from waste batteries, manufacture of batteries, and manufacture of articles of metal wire) leading to the need of continuous surveillance of health status for the exposed workers.

Keywords: *lead, occupational exposure, blood lead*

Introduction

Lead (Pb) is a naturally occurring element, the most accessible of the heavy metals in the earth's crust that is widely distributed and used in numerous industrial processes and domestic appliances.

Lead can be used as a pure metal, combined with another metal to form an alloy, or in the form of a chemical compound. A primary use of lead is for automobile lead-acid storage batteries, a type of

rechargeable electric battery that uses an almost pure lead alloy. Lead-formed alloys are typically found in ammunition, pipes, cable covering, building material, radiation shielding, and collapsible tubes. Lead is also used in ceramic glazes and as a stabilizer in plastics.

Most parts of the primary (mining, sintering, smelting) and secondary (recycling, smelting) lead manufacture process, lead-acid battery production, alloy production, stabilizer production are contained or enclosed, but there are a number of activities that

require manual intervention and this is where the occupational exposure is highest. The glass industry mainly involves manual activities with high level of exposure but once the lead is incorporated into the glass then the exposure to lead is significantly reduced for subsequent tasks.

In Romania, the provisions of Directive 98/24/EC for the protection of the health and safety of workers from the risks related to chemical agents at work were implemented in 2006. The binding occupational limit value for inorganic lead compounds established under the national regulations is 0.15 mg/m³ in the air (measured in relation to a reference period of eight hours, time-weighted average, TWA). Regarding organic lead compounds, Romania has established also limit values for tetraethyl lead (0.01 mg/m³, 8 h TWA and 0.03 mg/m³, short term).

For evaluating potential health risks in the practice of occupational health, the Romanian national regulations have set a binding biological limit value (BLV) for lead in blood (70 µg/100 ml), in accordance with Annex II of the Directive 98/24/EC.

Special medical surveillance is required if:

- the workers are exposed to a concentration of lead in air greater than 0.075 mg/m³, calculated as a time-weighted average over 40 hours per week;
- or
- a blood-lead level greater than 40 µg Pb/100 ml blood is measured in individual workers.

Lead enters the body primarily through inhalation and ingestion. Lead passes through the lungs into the blood where it can harm many of the body's organ systems. While inorganic lead does not readily enter the body through the skin, it can enter the body through accidental ingestion (eating, drinking, and smoking) via contaminated hands, clothing, and surfaces. Workers may develop a variety of ailments, such as neurological effects, gastrointestinal effects, anemia, and kidney disease [1].

Lead is a toxic metal and one expression of this property is genetic toxicity. These properties could result in mutation, changes in gene expression and cell proliferation, all of which would contribute to a carcinogenic response if exposure is sustained.

In 2006, The International Agency for Research on Cancer (IARC, Lyon, France) evaluated the carcinogenic effects of inorganic and organic lead compounds and concluded that inorganic lead compounds are probably carcinogenic to humans (Group 2A). The results of the evaluation could not classify organic lead compound as to their carcinogenicity to humans.

Some lead compounds are also classified as reprotoxic agents 1A under CLP regulation [2].

Since 2006, more scientific evidence on carcinogenic effects of lead has been accumulated, raising the level of concern especially in relation to establish more protective, health based binding occupational limit values.

In particular, in 2019, The European Commission started a stakeholder's consultation to collect information for a certain number of substances to analyze the health, socio-economic and environmental impacts in connection with possible amendments of the existing EU directives (in particular carcinogen mutagen EU directive, including the possibility of extending its scope to cover all reprotoxic (R) 1A/1B substances). An important task of the study was to assess EU workers' exposure to inorganic lead and its compounds.

The National Institute of Public Health, Regional Center Bucharest (CRSPB), took part in the study and the national data obtained are briefly summarized here.

Methods

Two types of data were collected: occupational exposure data and biological monitoring data.

The source of data was represented by the routine surveillance programs run by the employers through the regional public health authorities, toxicology laboratories, between 2011 and 2019.

For inclusion in our study, lead measurements in air had to be: 1) personal measurements or area measurements representative of personal exposure; 2) sampled with duration longer than 2 hours; 3) representative of typical exposures experienced by workers (i.e. not worst-case or complaint-driven sampling); and 4) taken in actual workplaces.

The analytic method recommended for occupational exposure monitoring is atomic absorption spectrometry or a method giving equivalent results.

Sampling results were recorded as range (minimum-maximum values reported for the respective economic sector) or as unique values. The total number of lead measurements in air was 150.

For blood lead measurements the recommended method is atomic absorption spectrometry or a method giving equivalent results.

The results of bio monitoring were recorded by sex (when available), by year (2011-2019) and by economic sector. The values were expressed as mean or range. The values were compared against the alert value of 40 µg Pb/100 ml blood. The total number of blood lead measurements was 4682.

The data on occupational acute and chronic lead poisonings were extracted from the National Registry of Occupational Diseases.

All the data were centralized by CRSPB using a table template for the key variables: type of economic sector, lead concentrations in air measured at workplaces, number of exposed workers employed, and blood-lead levels in exposed workers.

Results

Exposed workforce

The number of exposed workers reported by the regional health authorities varied between 703 and 1783 (with a yearly average of 1164 workers). According to the national statistics, these workers represents 1.3% of the yearly mean number of people employed in Romania between 2011-2018 [3].

The data reported reflects a fluctuation of the number of employees by the economic sector with a marquee decrease of those working in manufacture of batteries (Table 1).

Lead air concentrations measured in occupational settings by economic sectors and years

A summary of the inorganic lead concentration measured in various workplaces is presented in Table 2.

The national binding limit values were exceeded in several economic sectors: manufacture of batteries, manufacture of thermal ceramic products (terracotta), production and sale of dyes and additives for plastics and research. The highest values for inorganic lead concentration by year are presented in Figure 1.

Table 1. Number of exposed workers to lead by economic sector

Economic sector/year	2012	2013	2014	2015	2016	2017	2018	2019
Production of lead	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Manufacture of batteries	N/A	N/A	371	932	637	616	614	N/A
Recovery of lead from waste batteries	75	73	73	68	73	78	77	77
Production of electric and electronic components	565	564	551	549	571	564	533	529
Manufacture of thermal ceramic products (terracotta)	31	31	31	41	26	26	26	N/A
Production and sale of dyes and additives for plastics	38	N/A	18	96	N/A	N/A	N/A	N/A
Metalwork	N/A	N/A	N/A	N/A	N/A	150	N/A	N/A
Geochemical analysis laboratory	N/A	23	N/A	N/A	N/A	N/A	N/A	N/A
Manufacture of articles of metal wire	N/A	N/A	97	97	97	97	97	97
Total	709	691	1141	1783	1404	1531	1347	703

Table 2. Inorganic lead concentrations (mg/m³) measured as time weighted average (8 h, TWA)

Economic Sector	2012	2013	2014	2015	2016	2017	2018	2019
Manufacture of batteries	NA	NA	0.01 – 0.18	0.004 – 0.16	0.009–0.096	N.D* – 0.105	N.D* – 0.167	NA
Manufacture of non-ferrous metal structures	0.006	NA	NA	NA	NA	NA	NA	NA
Production of electric and electronic components	0.007–0.0131	N.D*–0.074	0.0003–0.002	0.0002–0.005	0.0002–0.0004	0.0003	0.0007	0.0001
Assembling of electronic components	NA	NA	NA	0.03	0.0001–0.0007	NA	0.002–0.004	0.01–0.02
Manufacture of thermal ceramic products (terracotta)	NA	0.02–0.06	NA	0.01 – 0.22	NA	NA	0.03 – 0.12	NA
Production and sale of dyes and additives for plastics	NA	0.006 – 0.16	NA	NA	NA	NA	NA	NA
Metalwork	NA	NA	NA	NA	NA	0.0002–0.004	NA	NA
Manufacture of articles of metal wire	NA	NA	NA	0.003 – 0.036	NA	NA	N.D*	NA
Production of auto components	0.008	NA	NA	NA	NA	NA	NA	NA
Mechanical repairs	NA	0.017	0.075–0.125	NA	NA	NA	NA	NA
Pantograph workshop (Bureau of Engraving)	NA	NA	NA	0.013	0.016	NA	NA	NA
Computer repair	NA	NA	NA	0.068	NA	NA	NA	NA
Waste collection and treatment of electrical and electronic equipment	NA	NA	0.074	NA	NA	NA	NA	NA
Research	NA	NA	NA	NA	NA	NA	0.16	NA

*N.D – Not detected; NA= not available

Figure 1.

Occupational lead concentrations measured (maximum values reported)

Biological monitoring

The number of workers under surveillance provides an indication of the extent of potential occupational lead exposure in the Romanian population. Table 3 presents the blood lead values reported for various economic sectors, by sex and year.

Blood lead levels over 40 µg/100 ml blood were found only in males working in the followings sectors: production of lead, recovery of lead from waste batteries (recycling), manufacture of batteries, and manufacture of articles of metal wire. For females working in the manufacture of batteries, the blood lead levels were lower. None of the blood lead levels reported exceeded the binding limit values.

Occupational lead poisoning

We collected information on acute and chronic lead poisoning cases confirmed as occupational diseases and reported by the regional public health authorities to the National Registry of Occupational Diseases, between 2011 and 2018. The notification of these cases is statutory under the Romanian legislation. Table 4 summarizes this information.

Discussions

According to our data, the workforce actually exposed to lead represents a small percentage of the employed population in Romania (1.3%). However, our data cannot give information on the numbers of workers likely to be exposed to lead which is expected to be greater. In a European study to collect recent information relevant to modernizing EU Occupational Safety and Health chemicals legislation with a particular emphasis on reprotoxic chemicals, the

historical potentially exposed workforce by Member State, extrapolated from HSE data (from 2016/17) indicate 1700 workers for Romania and represents an upper high estimate [4].

This figure is of a similar order of magnitude to the value of 1783 reported for 2015 (bearing in mind that the HSE data used for extrapolation do not include very low levels of exposure for short time periods).

In Romania, all workers with significant lead exposure are required to undergo medical surveillance which includes measurement of blood-lead concentrations. Employers are responsible to ensure statutory medical surveillance for workers at risk. Some employers may keep workers under surveillance on a precautionary basis where exposure is not likely to be significant, whereas others may fail to implement surveillance where it is in fact required.

The statistics in this report are compiled from annual summaries from regional public health authorities of blood-lead levels among workers they have examined under this surveillance regime. The coverage of the statistics is limited by the extent of blood-lead surveillance carried out by the regional public health authorities on employers' request.

In our data, we observed that high blood lead levels were associated with modest increase of lead air concentration in the sector of batteries manufacturing and manufacture of thermal ceramic products. However, the relationship was not directly correlated and could not be observed in both males and females suggesting that other factors (such as individual susceptibility, background level, other route of exposure such as ingestion) should be took into account. The occupational lead poisoning cases were reported more frequently in men working in economic sectors where the air concentration didn't exceeded the binding limit values but the values of blood-lead concentration were over the alert level.

Table 3. Blood-lead values for occupational exposed workers

Economic Sector	Year	Mean values or range (min-max values), µg/100 ml blood							
		Males	No	Females	No	Females of child-bearing age	No	Both sexes	No
Production of lead	2011	18.74 5.2-47.2	58						
Production and sale of dyes and additives for plastics	2012	5.23 1.4-14.5	38						
Recovery of lead from waste batteries	2012	NA	65	NA	10			46.73	75
	2013	NA	64	NA	9			45.34	73
	2014	NA	63	NA	10			40.36	73
	2015	NA	58	NA	10			34.32	68
	2016	NA	62	NA	11			33.96	73
	2017	NA	67	NA	11			35.01	78
	2018	NA	65	NA	12			32.84	77
	2019	NA	67	NA	12			32.45	79
Manufacture of thermal ceramic products (terracotta)	2012	3.4-32.3	NA	19.5-31.2	NA			NA	31
	2013	21.6-30.5	NA	8.5-38.5	NA	21.1-34.8	NA	NA	31
	2016	19.5-26.4	NA	11.5-39.9	NA	23.2-39.9	NA	NA	26
	2017	18.6-27.9	NA	7.5-38.8	NA	17.5-6.3	NA	NA	26
	2018	24.2-28.8	NA	23.5-38.9	NA	26.6-28.3	NA	NA	26
Manufacture of batteries	2014	37-57.8	89	12.0-12.9	3	10.7-11.7	2		
	2015	3.6-58.9	288	10.7-14.8	12	3.6-13.2	4		
Manufacture of car batteries	2014	32.09	277	15.34	10				
	2015	18.3	536	3.47	96				
	2016	17.1	543	4.71	94				
	2017	16.94	531	3.62	87				
	2018	16.04	524	3.54	90				
Manufacture of articles of metal wire	2014	4.0-45.0	97						
	2015	4.2-51.0	97						
	2016	2.4-31.7	97						
	2018	0.1-40.62	97						
	2019	0.6-54.5	97						

Table 4. Occupational lead poisonings reported in Romania (2011-2018)

Economic sector (NACE two digits code)*	No. of cases		Job title (ISCO-08 three digits code)**
	M	F	
Manufacture of basic metals (24)	6	1	Smelter, non-ferrous metals (812) Preparer, structural metal (721) Technician, metallurgy (311)
Manufacture of fabricated metal products, except machinery and equipment – ammunition (25)	1	2	Operator, machine tool (821)
Waste collection, treatment and disposal activities; materials recovery (38)	2	0	Operator, machine tool (821)

* NACE Rev.2 - Statistical classification of economic activities in the European Community

** ISCO-08 - International Standard Classification of Occupations

Interestingly, a previous Romanian study [5] showed that blood-lead level was less sensitive than cumulative blood lead index (CBLI) in predicting acute poisoning and highlighted the importance of $CBLI \geq 1,041 \mu\text{g} \cdot \text{years}/\text{dl}$ and air lead concentration $\geq 0.3 \text{ mg}/\text{m}^3$ in the occurrence of occupational poisoning. More and more data from international studies indicate a poor correlation between lead air concentration, blood lead levels and chronic effects (including genotoxicity and reprotoxicity).

In 2014, Safe Work Australia analyzed the relationship between blood lead (PbB) concentrations and lead air (PbAir) concentrations, the so called air slope factor (ASF) that reflects the incremental increase in PbB for each unit increase in air concentration. Safe Work Australia considered that: *“ASF is non-linear and the relative contribution of PbAir to PbB is greater at low air concentrations relative to high concentrations. The factors influencing ASF include, but are not limited to, particle size, solubility, personal versus area PbAir data, the temporal relationship of PbAir measurements with PbB measurements, accuracy of PbAir measurements for exposure, PbAir being total lead or respirable lead, smoking status, hygiene practice (i.e. likelihood of hand mouth interaction), length of employment, inter-individual variability in lead absorption, etc. Furthermore, although worker PbB levels are likely to primarily be the result of lead exposure in the workplace they also include a contribution from background lead exposure. Currently this background exposure mainly comes from lead in the diet but in the past when leaded petrol was widely used, lead in ambient air was a major contributor to background PbB”*. Safe Work Australia considered various ASFs and their merits and implications and suggested an airborne work exposure standard of $0.05 \text{ mg}/\text{m}^3$ to achieve a PbB level of $200 \mu\text{g}/\text{L}$.

Exposure to lead is associated with various health endpoints and the studies investigating the exposure-effect associations within those endpoints have used a variety of outcome markers ranging from early effect markers (for which the long-term predictive value is not fully understood) to clinical disease and mortality. The international and national bodies proposing occupational limit values use a biological limit value (BLV), more specifically blood-lead, as the relevant exposure metric. Those who also recommend an occupational exposure limit value (OEL) for workplace air quality, have derived an OEL that best corresponds to the established BLV. Lead is unique in this regard, since for most substances with a national or international BLV, the BLV is derived from the OEL instead.

With regard to OEL, in 2002 SCOEL noted that “Only part of the occupational exposure occurs by inhalation and a considerable portion is incorporated after oral ingestion. Lead ingestion varies as a function of personal hygiene of the individual and the overall cleanliness of the work environment. In consequence, the setting of an OEL for airborne lead is more difficult than for other compounds.”

ACGIH stated that various studies report that neurological and neurobehavioral effects and reproductive effects can be seen at PbB down to $200 \mu\text{g}/\text{L}$. ACGIH (2017) recommended a biological exposure index (BEI) of $200 \mu\text{g}/\text{L}$.

The German AGS did not derive an OEL for lead in the air. AGS considered the uncertainties inherent in establishing an airborne lead concentration limit to be so significant that a value of sufficient scientific quality could not be derived. AGS concluded on a BLV of $150 \mu\text{g}/\text{L}$ evaluated as being protective against most of the endpoints (such as immunotoxicity, cardiovascular effects, reproductive toxicity, genotoxicity and nephrotoxicity).

In the light of the most recent information regarding the reprotoxic effect of lead, in its recently published study, the European Commission assess a variety of options and generates evidence for a possible amendment of the current legislation (directives that address occupational exposure to Carcinogenic, Mutagenic and Reprotoxic substances - Directive 98/24/EC - Chemical Agents Directive, CAD and Directive 2004/37/EC - Carcinogens and Mutagens Directive, CMD) in order to lay down minimum requirements, in particular regarding occupational lead exposure [6].

Conclusions

1. In Romania, the workforce exposed to inorganic lead and its compound is about 1.3% of the total employed population. The main economic sectors are: the production of lead, the manufacture of batteries, the manufacture of thermal ceramic products (terracotta), the production of electric and electronic components, the manufacture of articles of metal wire, the production of dyes and additives for plastics, the recovery of lead from waste batteries, the waste collection and treatment of electrical and electronic equipment;

2. The lead concentrations in the workplaces air were between “not detected” and $0.22 \text{ mg}/\text{m}^3$. Values over the national binding limit were found in the manufacture of batteries, the manufacture of thermal

ceramic products (terracotta) and research;

3. The blood lead concentrations in the blood of male workers were greater than the binding values, in many sectors: production of lead, recovery of lead from waste batteries (recycling), manufacture of batteries, and manufacture of articles of metal wire;

4. The correlation between air concentration and blood concentration is influenced by various factors and is therefore not constant over various occupational settings;

5. Given that health effects have been linked to significantly lower blood lead levels, the BLV should be considered as the primary tool for protecting workers from lead toxicity. To control occupational airborne exposure, measurement of Pb concentrations in the air remains also important.

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