

Qualitative Environmental Health Impact Assessment in Veles, Republic of Macedonia

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1. Introduction

The environment in which people live, work and play is an important determinant of health and well being, but the extent of its importance in developed economies is difficult to quantify. The non-communicable diseases present the biggest burden to public health analyzed by direct cost to the society as well as to the governance from aspect of disability adjusted life years (DALY) indicator. Due to fact that more and more citizens are elderly and because of that are more exposed to non-communicable diseases and disability, the needs for data, which will reflect the life quality, including the influence of environmental risk more precisely is essential. The summary measure of the population health and the methodology for the burden of diseases estimation nowadays is extraordinary indicators for the public health policy development as well as for actions needs for its reduction. The total burden of most frequent diseases in the Republic of Macedonia: circulatory, malignant and respiratory are estimated to 60,7% to DALY from all cause mortality, which is different than the percentage from the year of life lost, i.e. 52,4, respectively (Kendrovski& Gjorgjev, 2004).

The most common diseases in the Republic of Macedonia – heart and circulatory diseases, cancer, respiratory diseases, injuries and non defined symptoms – have many causes which are often interconnected; including genetics, the condition people are in (via diet, exercise etc.), and the environmental circumstances to which they are exposed. Identifying cause-and-effect relationships is therefore very difficult, especially if the impact of the environment on health is delayed, or is the product of many, perhaps small, environmental factors acting together. The country has a few environmental hot spots, characterized by high levels of pollution (air, water and soil), due to emissions from industrial facilities. According the Second National Environmental Action Plan there is a direct correlation between the air pollution and human health based on a number of research works performed in the period 1997-2002. The positive correlation was found between the monthly average concentrations of the black smoke and SO₂ and the increased respiratory morbidity for the children at the age 0-6 and 7-14. The air pollution problem is more acute in the winter period due to the effects of temperature inversion and climate circumstances in the country; this is supported by the 32% of all sold drugs being under the respiratory diagnosis, as reported by the Pharmacy Information System. Air pollution affects approximately 60% of the population, in particular those living in the cities of Skopje, Veles, Bitola and Tetovo. In regard to the industry sector, obsolete equipment and non-existent modern technologies

result that this sector represents a major air polluter. The main pressure on environment (in particular air quality) originates from the metallurgy sector (until 2003 the lead and zinc smelter MHK Zletovo in Veles and ferro-alloy SILMAK in Jegunovce, Maksteel, MAKSTIL, FENI Industries-Kavadarci), and the chemical industry- refinery OKTA, OHIS chemical complex and TITAN cement factory. Until closure of MHK Zletovo in 2003, the lead and zinc smelting plant located in Veles operates a single absorption sulphuric acid plant with no additional treatment of the exhaust gas leading to an emission quantity of about 2100 t/y of SO₂. Additional 1800 t/y of SO₂ and 2.5 tpa of lead have been emitted through the ventilation system and the fugitive sources. In Veles a significant correlation has been found between the emissions of lead, zinc and cadmium as well as SO₂ in the air and the health of inhabitants. The higher concentration of the lead in the blood was registered and it has been connected with occurrence of cancer, respiratory diseases, miscarriages and birth defects. The direct correlation has been found by the medical experts between the particulate matters with small dimensions (PM_{2.5}) in the form of dust originated by the REK Bitola Power Plant and health problems with respiratory system at adults as well as bronchia at the children age. Although there are no any study in Macedonia presenting the direct correlation between the lead from mobile sources and human health, the medical experts uses the series of publications worldwide that confirms the harmful effect of lead (NEAP 2, 2005).

There is a serious lack of data and information on exposures, effects and biological models that connect them. Therefore considerable uncertainty surrounds many issues of concern, such as air pollution, noise, water contamination, waste, climate change, chemicals (including endocrine disruptors and antibiotics), ionising and non-ionising radiation.

Risk and hazard are two distinct, but interrelated, concepts. A hazard represents a chemical, physical, or biological substance that has the potential to produce harm to health if it is present in the environment and comes into contact with people. The hazardous properties of an environmental agent are defined according to the nature and severity of its harmful consequences. Fortunately, many hazards can be either contained or avoided, so not every potential environmental hazard poses an actual health risk. A risk, in turn, is defined as the likelihood of adverse health effects arising from exposure to a hazard in a human population, which is conceptually expressed as the product of two factors: the probability of exposure and the severity of the consequences.

Environmental health risk assessment is an essential element in environmental management and an important condition in precise priority-setting to the necessary actions for its sanitation. At present there are not sufficient scientific data available for a large number of health-related environmental hazards representing risk on human health. In addition, even with the best possible information available on the nature and level of pollutants in the environment and about population exposure to different pollutants, environmental health risk assessment may not be complete because of difficulties in analyzing the complexity of possible interactions in the case of multiple exposures. Even more complex is the assessment and comparison of costs and benefits of health risk elimination. This is partly because environmental health risk assessment is still limited in its effectiveness by the inadequacy of the information available, especially on exposure. In addition, even with the best possible information, an environmental health risk assessment may not be complete because of difficulties in analysing the complexity of possible interactions in the case of multiple exposures (NEPC,1999)

2. Health Risk Assessment Methodologies

In the context of environmental health, the risk management process can be organized into several distinct activities. The three core activities that constitute the essential decision-making steps in the risk management process are each involved in examining different aspects of the risk problem:

2.1 Risk estimation

The use of science-based risk information and analytical methods to characterize the nature and extent of environmental health risks in the human population;

2.2 Risk evaluation

Consideration of the economic, social, political, and legal factors that influence a decision to adopt a particular course of action to reduce health risks - in some risk frameworks, the quantitative economic analysis of the benefits and costs of risk reduction is combined with results of the risk estimation process, so that a risk assessment may subsume part or all of risk evaluation;

2.3 Risk control

The selection of options and the commencing of actions intended to reduce risk to an acceptable or tolerable level; this activity is often referred to as risk management, but the term risk control is more specific and better reflects the objectives of the activities it denotes. Risk assessment is the process of estimating the potential impact of a chemical, physical, microbiological or psychosocial hazard on a specified human population or ecological system under a specific set of conditions and for a certain timeframe. Risk assessment is intended to provide complete information to risk managers, specifically policymakers and regulators, so that the best possible decisions are made. There are uncertainties related to risk assessment and it is important to make the best possible use of available information.

3. Methods

Retrospective epidemiological method was used in order the following four distinct and essential components of the risk assessment paradigm to be addressed:

- (1) Hazard identification - identification of the inherent capability of a substance to cause adverse effects by sides;
- (2) Assessment of dose-response relationships involves characterization of the relationship between the dose of an agent administered or received and the incidence of an adverse effect;
- (3) Exposure assessment is the qualitative and/or quantitative assessment of the chemical nature, form and concentration of a chemical to which an identified population is exposed from all sources (air, water, soil and diet);
- (4) Risk characterization is the synthesis of critically evaluated information and data from exposure assessment, hazard identification and dose-response considerations into a summary that identifies clearly the strengths and weaknesses of the database, the criteria applied to evaluation and the validation of all aspects of methodology, and the conclusions reached from the review of scientific information (EPA,1992).

The logical consequence of the process of assessment of potential risk is the application of the information to the development of practical measures (risk management) for the protection of human health. All available studies, articles and reports related to defined hotspots in the Republic of Macedonia from 2000 to 2007 are included in assessment. The migration pathways and sensitive receptors are as following:

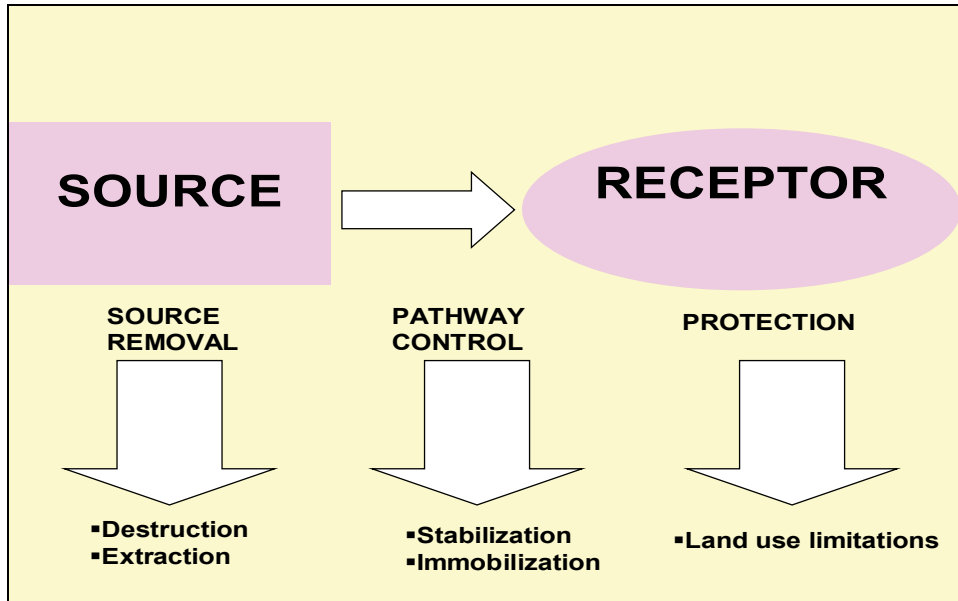


Fig. 1. Contaminated land management

The Figure 1 showed the principles of contaminated land management as general approach for the identification of sources of contamination and associated hazards.

3.1 Advantage of Various Methods

Many organisations are now actively involved in Environmental Risk Assessment, developing methodologies and techniques to improve this environmental management tool. Such organisations include OECD, WHO and ECETOC. One of the major difficulties concerning the use of risk assessment is the availability of data and the data that is available is often loaded with uncertainty (WHO,1994). The risk assessment may include an evaluation of what the risks mean in practice to those effected. This will depend heavily on how the risk is perceived. Risk perception involves people's beliefs, attitudes, judgements and feelings, as well as the wider social or cultural values that people adopt towards hazards and their benefits. The way in which people perceive risk is vital in the process of assessing and managing risk. Risk perception will be a major determinant in whether a risk is deemed to be "acceptable" and whether the risk management measures imposed are seen to resolve the problem. The procedures, methods and techniques for regulatory risk assessment of chemicals in the EU is described in both legislation and supporting Technical Guidance Documents. Implementation is supported by the European Chemicals Bureau, part of the Joint Research Centre, in Ispra.

Most methodologies for human health risk assessment of chemicals are based on the NAS model. A number of methodologies exist due to differences in the toxic mechanisms exerted by different classes of chemical and the toxicological end-point being assessed. The end-point being assessed could be death, or a specific pathological condition relating to exposure to a chemical. When attempting to assess the risks from an immuno-suppressant toxin, specific end-points may be difficult to determine, as may be the role of other agents and stressors on the body. This will lead to risk assessment methodology for immuno-suppressants being different from assessments for irritants for instance. All human health risk assessments of chemicals include hazard identification, dose-response assessment, exposure assessment and risk estimation/characterisation. If the assessment is site-specific, then a release assessment would be required in the absence of good data of environmental levels or to account for non-routine, accidental releases.

3.2 Risk and Constrains of Various Methods

Risk assessments may assess individual or population risks. Individual risks may be for the average (i.e. typical) individual or the highly exposed or particularly susceptible individual and the risks may be estimated for various duration of exposure (e.g. per year or per lifetime) or for different locations. Individual risk can only be assessed for a hypothetical individual with assume characteristics. Assessing the risk for any real individual will be frustrated by the fact that risk predictions for an individual can never be validated by experience. Any real individual will either experience the negative outcome or will not. Neither of these results can validate any risk prediction other than a probability of one or zero. Population risk may relate to the number of adverse health effects (eg. fatalities, cancers, or illnesses) in a population over a specified period of time or the rate of adverse effects for a given location or sub-population .

The UNEP/ILO/WHO International Programme on Chemical Safety (IPCS), in collaboration with the US Environmental Protection Agency (US EPA), the European Commission (EC), the Organization for Economic Cooperation and Development Cooperation, and other international and national organizations developed a working partnership to foster the integration of assessment approaches to evaluate human health and ecological risks. The overall goal of this project was to promote international understanding and acceptance of the integrated risk assessment process. Three specific objectives were identified to meet this goal: 1) enhance understanding of the benefits of integration, 2) identify and understand obstacles to integration, and 3) engage key scientific organizations to promote discussion of an integrated approach to risk assessment

A generic framework and associated documentation were developed to communicate how an integrated risk assessment could be conducted. Recognizing the similarities in risk assessment frameworks currently in use internationally, the integrated risk assessment framework is based on US EPA's framework for ecological risk assessment and its associated terminology (EPA, 1998). Ecological risk assessment frameworks have greater general applicability than do human health frameworks (or those environmental frameworks derived directly from human health frameworks) in that they 1) were developed to deal with a range of environmental stressors beyond toxic chemicals, 2) must describe the nature and role of the environment in the risk assessment process, and 3) must explicitly identify the endpoint to be assessed. Further, a well-developed body of concepts and terminology exist in the literature treating ecological risk assessment that

supports integration. The integrated framework consists of three primary assessment phases. During the first of these, *Problem Formulation*, the overall goals, objectives, scope, and activities of the assessment are delineated. The *Analysis* step consists of data collection and modelling exercises to characterize exposure in time and space, and to define the effects on humans and ecological systems resulting from exposure. The methods appropriate for the Analysis step may be stressor-specific, but also depend upon the nature of the systems identified to be at risk. Exposure and effect information are synthesized as estimates of risk in the *Risk Characterization* step. Ideally, these estimates are quantitative with respect to the level of risk expected under different exposure scenarios, although only qualitative estimates of risk may be possible in some circumstances. The integrated risk assessment framework treats the relationships among risk assessment, risk management, stakeholder input, and data collection activities in a general parallel and concurrent manner. Essentially, risk characterisation is a summary of the data compiled in the risk assessment process including the uncertainties associated with each stage and the presentation of a risk estimate.

3.3 Parameters and Indicators for Choosing a Methodology

Risks can be managed in many ways. They can be eliminated, transferred, retained or reduced. Risk reduction activities reduce the risk to an "acceptable" level, derived after taking into account a selection of factors such as government policy, industry norms, and economic, social and cultural factors. It is important to note that although risk assessment is used extensively in environmental policy and regulation it is not without controversy. This is also true for risk management. There are various criteria for assessing risk assessment including: The logical soundness of the method is eg. its justification based on theoretical arguments or scientific knowledge, and the validity of the underlying methodological assumptions.

Completeness - (e.g. whether it can address all aspects of the problem and the degree to which it excludes issues because they are hard to accommodate).

Accuracy - (e.g. the precision reflected in the confidence level associated with the results; biases resulting from undue weight given to specific interests or considerations; and the sensitivity of results to untested or untestable assumptions).

Acceptability - (e.g. compatibility with existing processes; whether it is viewed as rational and fair; the level of understanding for all parties affected by it; and the confidence and familiarity of those who will use it).

Practicality - (e.g. the level of expertise, time and input data required).

Effectiveness - (e.g. usefulness of results; range of applicability across different risks and problem areas; the generalisability of the conclusion to other problem areas; and effectiveness and efficiency of linkage with other types of methods).

The level of risk can be described either qualitatively (ie by putting risks into categories such as 'high', 'medium' or 'low' as we used in our study as matrix showed in Figure 2) or quantitatively (with a numerical estimate). Current risk assessment methods do not enable accurate quantitative estimates of risk for low levels of exposure to environmental hazards. Numerical estimates of risk will rarely be feasible because of variability in the agent and population and limitations in toxicological and exposure data which will be reflected in the uncertainty assessment, but a degree of quantification may be possible for some components such as data collection and exposure assessment.

	Contaminant Hazard Factor	Receptor Factor	Migration Pathway		
			Evident	Potential	Confined
Contaminant Hazard •Significant (H) •Moderate (M) •Minimal (L)	Significant	Identified	HHH	HHM	HHL
		Potential	HHM	HMM	HML
		Limited	HHL	HML	HLL
Migration Pathway •Evident (H) •Potential (M) •Confined (L)	Moderate	Identified	HHM	HMM	HML
		Potential	HMM	MMM	MML
		Limited	HML	MML	MLL
Receptors •Identified (H) •Potential (M) •Limited (L)	Minimal	Identified	HHL	HML	HLL
		Potential	HML	MML	MLL
		Limited	HLL	MLL	LLL

Fig. 2. Qualitative environmental health risk matrix

Regarding human health, the assessment was focused on exposure routes, both direct and indirect. For each of the two sites we established what exposure routes exist and what routes are significant. We also established the number and type of people that may be affected to a significant extent, depending upon location, age and profession. Finally, using an expert judgement method the conclusions are based of principles used during a qualitative risk assessment for each of 2 hotspot sides.

4. Results-Side Specifics Risk Assessment

The Municipality of Veles is located in the central part of the Republic of Macedonia and covers approximately 465 square kilometres, supports a population of over 55.000 inhabitants, making it the 8th largest municipality in the country. Established in 1973, MHK Zletovo was a lead and zinc smelter employing 1,100 workers. Each year it was uses lead and zinc concentrates to produce 30,000 tons of lead, 60,000 tons of zinc and 250 tons of cadmium, as well as smaller quantities of silver-gold and copper dross, and bismuth alloy. The process was producing 100,000 tons per year of sulphuric acid as a by-product. The same company also was owned and operates a nearby fertilizer plant. The smelter emits into the atmosphere large quantities of sulphur dioxide, and dust bearing lead, zinc and cadmium. MHK Zletovo-Veles during its activities has operated as the country’s smelter and refinery for the production of lead, zinc and associated metals. About 45% of the feedstock was came from domestic lead and zinc mines (Sasa- Makedonska Kamenica,

Zletovo-Probistip, and Toranica-Kriva Planca); the balance was imported concentrate. The zinc refinery had a production capacity of 14.000 Mg/yr and the lead refinery a capacity of 40.000 Mg/yr. (UNEP, 2000)

4.1 Hazard Identification

The identification of the inherent capability of a substance to cause adverse effects. The purpose of hazard identification is to evaluate the weight of evidence for adverse effects in humans based on assessment of all available data on toxicity and mode of action:

Lead - is a very toxic element, causing a variety of effects at low dose levels. Brain damage, kidney damage, and gastrointestinal distress are seen from acute (short-term) exposure to high levels of lead in humans. Chronic (long-term) exposure to lead in humans results in effects on the blood, central nervous system (CNS), blood pressure, kidneys, and Vitamin D metabolism. Children are particularly sensitive to the chronic effects of lead, with slowed cognitive development, reduced growth and other effects reported. Reproductive effects, such as decreased sperm count in men and spontaneous abortions in women, have been associated with high lead exposure. The developing fetus is at particular risk from maternal lead exposure, with low birth weight and slowed postnatal neurobehavioral development noted. Human studies are inconclusive regarding lead exposure and cancer.

Cadmium- The main sources of cadmium in the air are the burning of fossil fuels such as coal or oil and the incineration of municipal waste. The acute (short-term) effects of cadmium in humans through inhalation exposure consist mainly of effects on the lung, such as pulmonary irritation. Chronic (long-term) inhalation or oral exposure to cadmium leads to a build-up of cadmium in the kidneys that can cause kidney disease. Cadmium has been shown to be a developmental toxicant in animals, resulting in fetal malformations and other effects, but no conclusive evidence exists in humans. An association between cadmium exposure and an increased risk of lung cancer has been reported from human studies, but these studies are inconclusive due to confounding factors. Animal studies have demonstrated an increase in lung cancer from long-term inhalation exposure to cadmium. EPA has classified cadmium as a Group B1, probable human carcinogen. Zinc is essential for the function of more than 300 enzymes, including alkaline phosphatase, alcohol dehydrogenase, Cu, Zn-superoxide dismutase, carboxypeptidase, delta-aminolevulinic acid dehydratase, carbonic anhydrase, ribonucleic acid polymerase, and reverse transcriptase. Zinc is also involved in DNA and RNA synthesis and cell proliferation. Zinc coordinates with cysteine and histidine residues of certain peptides and produces a tertiary structure which has an affinity for unique segments of DNA in promoter gene regions, including zinc finger protein domains, the most common zinc motif, and the zinc thiolate cluster. Other physiological roles of zinc include enhancement of the affinity of growth hormone for its binding receptors, modulation of synaptic transmissions by interacting with specific sites on ionotropic neurotransmitter receptor proteins, and induction of metallothionein (ACGIH, 1999; U.S. Department of Health and Human Services, 1993; WHO, 2004).

4.2 Assessment of Dose-Response Relationships

It involves characterization of the relationship between the dose of an agent administered or received and the incidence of an adverse effect:

For lead the acute effects are as follows:

- Death from lead poisoning may occur in children who have blood lead levels greater than 125 $\mu\text{g}/\text{dL}$ and brain and kidney damage have been reported at blood lead levels of approximately 100 $\mu\text{g}/\text{dL}$ in adults and 80 $\mu\text{g}/\text{dL}$ in children.
- Gastrointestinal symptoms, such as colic, have also been noted in acute exposures at blood lead levels of approximately 60 $\mu\text{g}/\text{dL}$ in adults and children.
- Short-term (acute) animal tests in rats have shown lead to have moderate to high acute toxicity.)

The chronic Effects (Non-carcinogen) are as follows:

- Chronic exposure to lead in humans can affect the blood. Anaemia has been reported in adults at blood lead levels of 50 to 80 $\mu\text{g}/\text{dL}$, and in children at blood lead levels of 40 to 70 $\mu\text{g}/\text{dL}$.
- Lead also affects the nervous system. Neurological symptoms have been reported in workers with blood lead levels of 40 to 60 $\mu\text{g}/\text{dL}$, and slowed nerve conduction in peripheral nerves in adults occurs at blood lead levels of 30 to 40 $\mu\text{g}/\text{dL}$.
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- Children are particularly sensitive to the neurotoxin effects of lead. There is evidence that blood lead levels of 10 to 30 $\mu\text{g}/\text{dL}$, or lower, may affect the hearing threshold and growth in children.
- Other effects from chronic lead exposure in humans include effects on blood pressure and kidney function, and interference with vitamin D metabolism.
- Animal studies have reported effects similar to those found in humans, with effects on the blood, kidneys, and nervous, immune, and cardiovascular systems noted.

The Reproductive/Developmental Effects are as follows:

- Studies on male lead workers have reported severe depression of sperm count and decreased function of the prostate and/or seminal vesicles at blood lead levels of 40 to 50 $\mu\text{g}/\text{dL}$. These effects may be seen from acute as well as chronic exposures.
- Occupational exposure to high levels of lead has been associated with a high likelihood of spontaneous abortion in pregnant women. However, the lowest blood lead levels at which this occurs has not been established. These effects may be seen from acute as well as chronic exposures.
- Exposure to lead during pregnancy produces toxic effects on the human fetus, including increased risk of preterm delivery, low birth weight, and impaired mental development. These effects have been noted at maternal blood lead levels of 10 to 15 $\mu\text{g}/\text{dL}$, and possibly lower. Decreased IQ scores have been noted in children at blood lead levels of approximately 10 to 50 $\mu\text{g}/\text{dL}$.
- Human studies are inconclusive regarding the association between lead exposure and other birth defects, while animal studies have shown a relationship between high lead exposure and birth defects.

Human studies are inconclusive regarding lead exposure and an increased cancer risk. Four major human studies of workers exposed to lead have been carried out; two studies did not find an association between lead exposure and cancer, one study found an increased incidence of respiratory tract and kidney cancers, and the fourth study found excesses for lung and stomach cancers. However, all of these studies are limited in usefulness because

the route(s) of exposure and levels of lead to which the workers were exposed were not reported. EPA considers lead to be a Group B2, probable human carcinogen. Human exposure to lead occurs through a combination of inhalation and oral exposure, with inhalation generally contributing a greater proportion of the dose for occupationally exposed groups, and the oral route generally contributing a greater proportion of the dose for the general population. The effects of lead are the same regardless of the route of exposure (inhalation or oral) and are correlated with internal exposure, as blood lead levels. For this reason, this fact sheet will not discuss the exposure in terms of route but will present it in terms of blood lead levels.

For cadmium the acute effects are as follows:

- Acute inhalation exposure to high levels of cadmium in humans may result in effects on the lung, such as bronchial and pulmonary irritation. A single acute exposure to high levels of cadmium can result in long-lasting impairment of lung function.
- Cadmium is considered to have high acute toxicity, based on short-term animal tests in rats.

The chronic Effects (Non-carcinogen) are as follows:

- Chronic inhalation and oral exposure of humans to cadmium results in a build-up of cadmium in the kidneys that can cause kidney disease, including proteinuria, a decrease in glomerular filtration rate, and an increased frequency of kidney stone formation.
- Other effects noted in occupational settings from chronic exposure of humans to cadmium in air are effects on the lung, including bronchiolitis and emphysema. Chronic inhalation or oral exposure of animals to cadmium results in effects on the kidney, liver, lung, bone, immune system, blood, and nervous system. The Reference Dose (RfD) for cadmium in drinking water is 0.0005 milligrams per kilogram per day (mg/kg/d) and the RfD for dietary exposure to cadmium is 0.001 mg/kg/d; both are based on significant proteinuria in humans. The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious noncancer effects during a lifetime. It is not a direct estimator of risk, but rather a reference point to gauge the potential effects. At exposures increasingly greater than the RfD, the potential for adverse health effects increases. Lifetime exposure above the RfD does not imply that an adverse health effect would necessarily occur.

The Reproductive/Developmental Effects are as follows:

- Limited evidence exists for an association between inhalation exposure and a reduction in sperm number and viability in humans.
- Human developmental studies on cadmium are limited, although there is some evidence to suggest that maternal cadmium exposure may result in decreased birth weights.
- Animal studies provide evidence that cadmium has developmental effects, such as low fetal weight, skeletal malformations, interference with fetal metabolism, and impaired neurological development, via inhalation and oral exposure.
- Limited animal data are available, although some reproductive effects, such as decreased reproduction and testicular damage, have been noted following oral exposures.

Several occupational studies have reported an excess risk of lung cancer in humans from exposure to inhaled cadmium. However, the evidence is limited rather than conclusive due to confounding factors. EPA considers cadmium to be a probable human carcinogen (cancer-causing agent) and has classified it as a Group B1 carcinogen.

Regarding the zinc there are no reports on the possible carcinogenicity of it and compounds per se in humans. Case studies have been used to evaluate the effects of zinc administered for therapeutic reasons. There are reports which compare zinc levels in normal and cancerous tissue. Studies of occupational exposure to zinc compounds have also been conducted, but have limited value because they do not correlate exposure with cancer risk. Either zinc deficiency or excessively high levels of zinc may enhance susceptibility to carcinogenesis, whereas supplementation with low to moderate levels of zinc may offer protection. For example, zinc deficiency enhanced carcinomas of the esophagus induced by methylbenzyl nitrosamine but retarded the development of cancer of the oral cavity induced by 4-nitroquinoline-N-oxide. Thus, zinc's modifying effect on carcinogenesis may depend both on the dose of zinc and the identity of the carcinogen being affected. The mutagenicity of zinc, particularly in *Salmonella typhimurium*, appears to depend greatly on the chemical form. (CaEPA, 1997,1999; IARC, 1979)

4.3 Exposure Assessment

Is the qualitative and/or quantitative assessment of the chemical nature, form and concentration of a chemical to which an identified population is exposed from all sources (air, water, soil and diet); Hazardous waste generated in industry and mining create serious potential for soil and groundwater contamination and still is an important issue. Monitoring and regulation of industrial waste is inadequate. Evaluations are that at least this waste has contaminated 6.000 hectares in the country. There is no hazard assessment made on the risks these mine tailings impose on the soils, groundwater and surface water downstream. Neither the impact on public health through wind and water erosion is studied. Their potential danger is eminent and large. Hazard assessment of these hotspots is recommended, both to protect the water resources and the people. Hazard assessment of the hot spots is planned under the National Waste Management Plan. (NWMP, 2005) The UNEP did some hazard assessments for mine tailings in regard of their risk to soil, groundwater and surface waters downstream. (UNEP, 2001)

Regarding human health, the assessment is focus on exposure routes, both direct and indirect as well as establishes the number and type of people that may be affected to a significant extend.. Although the smelter was undoubtedly polluting the groundwater beneath it, the major source of soil and groundwater contamination is the disposal of more than 850,000 tons of solid waste containing heavy metals. This waste is deposited at a dump approximately one kilometer from the smelter. There has been no detailed investigation or monitoring of soil or groundwater contamination in the area, including private wells located downstream. Nevertheless, it is very likely that groundwater and nearby areas are being contaminated with heavy metals as a result of percolate from the dump. Due to the direction of groundwater flow, the private wells are probably being affected. Wastewater containing sulfuric acid and other pollutants is also a source of serious concern. During the activity, the MHK has a treatment plant that was designed to treat 135 m³ of effluent per hour. The plant, however, was generates 1,500 m³/hour of wastewater. The NEAP reported that cadmium, lead and zinc levels were 10-15 times higher in vegetables grown in Veles relative to control regions. As much as 4 to 10 times

the acceptable levels for lead and cadmium were found in spinach and lettuce due to soil contamination. According to the World Health Organization, blood lead levels in children of 100 to 150 $\mu\text{g}/\text{l}$ have been consistently reported as having a negative effect on measures of cognitive functioning, such as the psychometric intelligence quotient (WHO, 1993). The obtained results from Veles Study have shown slightly increased blood lead levels in randomly tested children (mean value 16,51 $\mu\text{g}/\text{dl}$), reflected correspondingly in the level of intelligence and graphomotor ability (randomly, $n=31$). In addition, the autonomous nervous system studied by peripheral biofeedback appeared to function normally, reacting adequately in stress situations. However, the EEG results have shown that only in two children the theta-beta ratio has normal values, while in others the obtained ratios correspond to increased attention deficit. Moreover, the two children from 31 with the highest theta-beta ratio showed pathological ADHD findings and also the highest blood lead levels ($> 20 \mu\text{g}/\text{dl}$). The suspected correlation between increased blood lead levels due to industrial pollution and changes in EEG, toward increased attention deficit in tested children has been confirmed, implying the need for corresponding health care and environmental response measures. Compared to other applied psychometric instruments, neurofeedback appeared to be the most sensitive and discriminative modality. Analyses of monthly morbidity reports produced by the Public Health Institutes show that both preschoolers (under 6 years of age) and schoolchildren (aged between 7 and 14 years) living in polluted cities, such as Skopje and Veles, have a higher (up to 2 - 3 times) level of morbidity from respiratory diseases (J00-J99) (excluding influenza and pneumonia (J10-J18)) than children living in relatively less polluted villages (RIHP,2007). The data for 2006 has showed the distribution of heavy metals in Veles as follows:

Hazard	Measuring point	Average yearly concentration (mg/m^3)	Minimum - maximum (mg/m^3)	(WHO,1999) Recommended Value (mg/m^3)
Pb	Nova Naselba	0.117 (361)	0.000-0.640	0.5
	Biro za Vrabotuvawe	0.125 (24)	0.000-0.200	
Cd	Nova Naselba	0.039 (361)	0.000-0.190	0.05
	Biro za Vrabotuvawe	0.006 (24)	0.000-0.026	
Zn	Nova Naselba	0.038 (361)	0.000-3.850	/
	Biro za Vrabotuvawe	0.251 (24)	0.000-0.501	

Source: RIHP, 2007

Table 1. Monitoring of air pollution in Veles during the 2006 for Pb, Cd and Zn

In accordance with results obtained from the Institute for Public Health, Veles- the average yearly concentration for Pb and Cd didn't exceed WHO recommended value. The average concentration of aero- sediment for heavy metals in Veles were for Pb-41,6(mg/m^3); Cd-0,92(mg/m^3) and Zn-121,1(mg/m^3) with higher values for Pb in measuring points: "Zdravstven Dom" and "Nova naselba" compared with "nas. Tunel" or the lowest value was detected in control area, i.e. village Ivankovci. The highest value for Cd were detected

in measuring points: “Biro za vrabotuvanje” and “Nova naselba”, and 10 times less in the control area (v.Ivankovci).

Veles/Month	Preschool children		Schools children	
	Urban	Rural	Urban	Rural
I	411.04	183.06	66.32	61.87
II	419.35	128.34	83.97	48.44
III	387.43	436.48	105.48	47.48
IV	435.32	142.02	71.07	35.01
V	420.69	203.26	63.6	23.фев
VI	564.68	226.06	45.04	25.42
VII	298.30	126.38	34.4	23.50
VIII	351.18	96.42	42.78	16.79
IX	464.92	115.96	77.86	18.23
X	517.46	118.57	66.09	29.26
XI	390.09	418.89	92.35	34.05
XII	555.70	137.16	110.68	43.17
Average	434.68	183.71	71.64	33.85

Table 2. The monthly rate (‰) of registered patient with respiratory diseases (J00-J99) without (J10-J18) among preschool and school children in Veles for 2006

The average monthly rate registered patient with respiratory diseases (J00-J99) without (J10-J18) among preschool and school children in Veles in 2006, shows that in urban area the rate is 2,5 higher than in rural area, especially in winter due to air pollution

2004 (n=55)	Pb $\mu\text{gr}/\text{dl}$	Cd $\mu\text{gr}/\text{dl}$	Zn mg/l
Average	16.4	4.34	7.92
Maximum	46.70	13.30	10.20
Minimum	3.32	0.00	5.90
St. dev.	9	2.54	1.10
MPL	10 $\mu\text{gr}/\text{dl}$	9.5 $\mu\text{gr}/\text{dl}$	7 mg/l

Table 3. The monthly rate (‰) of registered patient with respiratory diseases (J00-J99) without (J10-J18) among preschool and school children in Veles for 2006

In accordance with investigation has been carried out in 2004 by the Republic Institute for Public Health the average value for Pb in blood samples among former employees (N=55) in MHK Zletovo was 64% higher than MPL as well as average Zn value for almost 15%. The Cd in blood samples is 4,34 $\mu\text{gr}/\text{dl}$ or twice less than MPL. During the same Study, 51 blood samples from mothers and 61 ones from newborns in Obstetric Clinic in Veles has been investigated for heavy metals, respectively. Even the average Pb value was less than MPL, it was reported that several mothers had high Pb contain in blood samples which posses high health risk for their newborns. Also several newborns with high Pb contain in blood samples was detected.

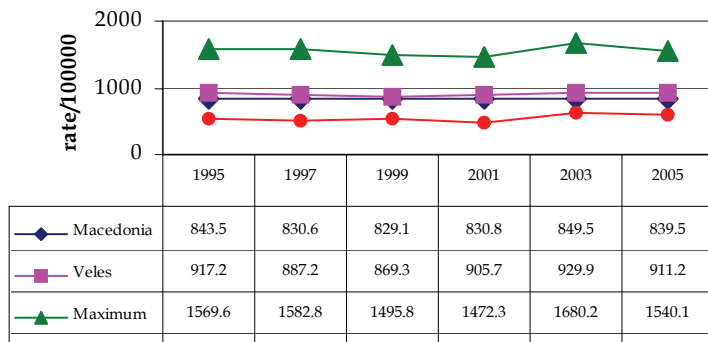


Fig. 3. General Mortality in the Republic of Macedonia, Veles Region and regions with lowest and higher mortality for the period 1995-2005

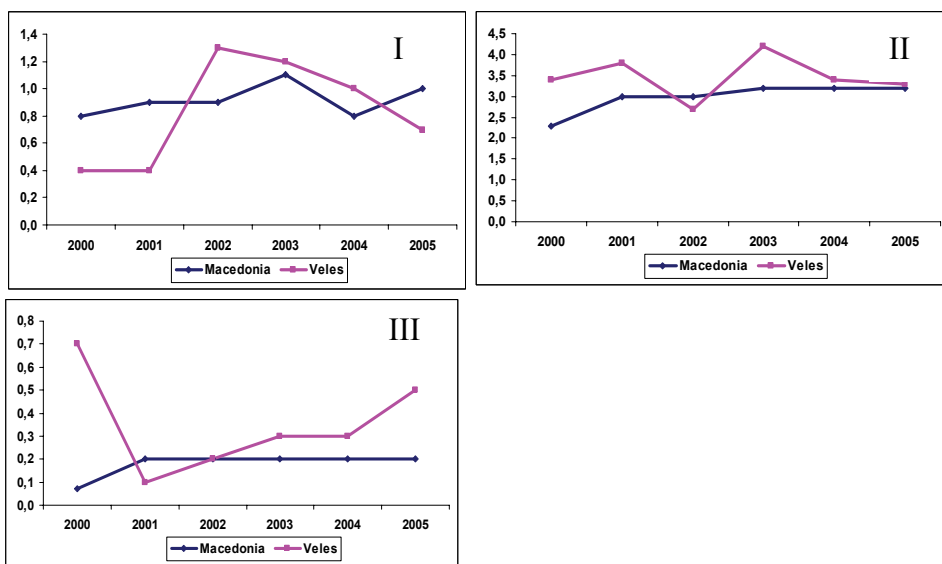


Fig. 4. Distribution of Mortality from malignant neoplasm of liver (I), lung and bronchial tubes (II), and kidneys (III) in the Republic of Macedonia and Veles Region for the period 2000-2005 (rate/10.000)

During the period 1995-2005 in Veles region has been registered higher general mortality rate per 100.000 than Macedonian average. Also, during the period 1995-2005 in Veles region has been registered higher mortality rate due to cancers per 100.000 than Macedonian average, especially for 2003 and 2005 (RIHP, 2006). The distribution of Mortality from malignant neoplasm of liver in the Republic of Macedonia and Veles Region for the period 2000-2005 (rate/10.000) has increasing especially in Veles in 2002 compared to 2000 and 2001. The distribution of Mortality from malignant neoplasms of lung and bronchial tubes in the Republic of Macedonia and Veles Region for the period 2000-2005 has showed higher values

for Veles region compared to average Macedonia value. The distribution of Mortality from malignant neoplasms of kidneys in the Republic of Macedonia and Veles Region for the period 2000-2005 has showed higher mortality rate per 10.000 compared to Macedonia (RIHP, 2006).

4.4 The Fertilizer Plant

The fertilizer plant was uses the sulfuric acid from the MHK Zletovo smelter and phosphate from Morocco to produce phosphoric acid and, in turn , mono-ammonium phosphate (MAP) and NPK fertilizer. The plant has closed in 2003 with the last reported producing of about 60,000 tons of fertilizer per year. Careless handling of raw materials and products was causing severe dust problems in the vicinity of the plant. Some areas are covered by deposits of up to several centimeters. According to studies carried out with support from the EU's Phare Programme, the plant's wastewater loadings of phosphorus and nitrogen were equivalent to those that would be generated by population centers of 4.6 million and 0.4 million people, respectively. Some diffuse soil and groundwater contamination can be expected on and around the plant facilities due to the use of impure raw materials containing heavy metals. (UN, 2002)

For each ton of phosphate produced, 5.5 tons of gypsum waste is generated. A mixture of 20 % gypsum and 80 % acidic process water (pH 2 - 3) was pumped to a special landfill that currently holds five million tons of gypsum waste. This waste was formerly deposited in the bottom of the valley, and sludge used to float directly into the Vardar River. It is now being deposited in the upper part of the valley, thereby reducing the direct risk to the Vardar. However, wastewater from the sludge dewatering process continues to drain into the river, and sludge can still be flushed into the river in flood conditions.

Our analyses from the gypsum special landfill have been carried out in the Republic Institute for Health Protection in June, 2007 showed higher natural radioactivity due to phosphate material and technological process.

5. Summary of Assessment Results

Large quantities of industrial waste are generated in the mining, metallurgical, fertilizer, and chemical industries, as well as in the coal-fired power plants. Most of the larger industries have their own industrial waste sites.

During the 3 week of June 2007 we investigated environmental health conditions in 2defined hotspots.

The Table shows distribution of hazards, possible health effects and potential number of excised people by hazardous sides.

Hazardous site	Hazards	Possible health effects	Potential number of excised people
Former Smelter Company Veles + Fertilizer company	Lead, nickel and cadmium contamination during past years of smelter company activities	Lead: toxic and carcinogenic effects in pregnant women and children; CNS damages	47.000 inhabitants

Table 4. The Distribution of hazards, possible health effects and potential number of excised people by hazardous sides

The defined health impacting hazards for Veles-Lead Smelter were as follows:

Toxic solid waste, airborne particulate matter and SO₂; Particulate matter: lead/zinc and iron oxides, As, Sb, Cd, Cu, metallic sulphates. Air emission for processes with few controls may be of the order of 30 kg Pb or Zn/t lead of zinc produced. Emissions of arsine, chlorine, and hydrogen chloride vapours and acid mists are associated with electro refining. Water effluents: Pb, Zn, As etc including dissolved and suspended solids, metals and oil and grease. Discard slag up to 0,7& lead/zinc up to 3 tons of solid waste per ton of lead/zinc produced.

	Contaminant Hazard Factor	Receptor Factor	Migration Pathway		
			Evident	Potential	Confined
Contaminant Hazard					
Significant (H)	Significant	Identified	HHH	HHM	HHL
Moderate (M)		Potential	HHM	HMM	HML
Minimal (L)		Limited	HHL	HML	HLL
Migration Pathway					
Evident (H)	Moderate	Identified	HHM	HMM	HML
Potential (M)		Potential	HMM	MMM	MML
Confined (L)		Limited	HML	MML	MLL
Receptors					
Identified (H)	Minimal	Identified	HHL	HML	HLL
Potential (M)		Potential	HML	MML	MLL
Limited (L)		Limited	HLL	MLL	LLL

Fig. 4. Qualitative risk assessment- Smelter Company- Veles

The key release or exposure vectors were as follows: to air (dust and smelter emission) and to water/groundwater Regarding human health, the qualitative assessment is focus on exposure routes, both direct and indirect as well as establishes the number and type of people that may be affected to a significant extend:

According to recent studies, emissions were having a significant impact on the health of the population. Increasing morbidity, especially from respiratory diseases, and frequent occurrence of lung cancers and anemia, have been noted in the local population and among factory workers. Children are especially affected. Workers have been observed to have experienced blood in urine, suggesting possible kidney disease. They have also had elevated concentrations of lead and cadmium in blood relative to control populations .Analyses of monthly morbidity reports produced by the Public Health Institutes show that both preschoolers (under 6 years of age) and schoolchildren (aged between 7 and 14 years) living in polluted cities, such as Veles, have a higher (up to 2 - 3 times) level of morbidity from respiratory diseases (excluding influenza and pneumonia) than children living in relatively

less polluted villages. The difference is particularly high in winter, when heating and climatic factors (including temperature inversion) contribute to an increase in air pollutants (especially SO₂ and black smoke). The health effects of particulate air pollution depend on particle size, composition and concentration, and can fluctuate with daily changes in PM₁₀ or PM_{2.5} levels. This is the particulate fraction of the greatest concern for health, as it penetrates the respiratory system. Particulate matter may have acute health effects, such as increased mortality, increased hospital admissions because of the exacerbation of respiratory disease, fluctuations in bronchodilator use, cough and peak flow reductions. According to the World Health Organization blood lead levels in children of 100 to 150 µg/l have been consistently reported as having a negative effect on measures of cognitive functioning, such as the psychometric intelligence quotient. The Institute of Occupational Health, Skopje in workers occupationally exposed to cadmium, has diagnosed kidney diseases. There is no official recording of the use of occupational carcinogens. There is insufficient information on dose-effect relations in some segments of the chemical industry. Obtained recent data for morbidity and mortality showed that even the factory has stop with operation in 2003, existing health risk among vulnerable population and former employees is still high. The eventual remediation of a smelter dump will have first of all direct environmental benefit and indirect one for citizens of Veles.

Environmental health risk assessment is an essential element in environmental management and an important condition in precise priority-setting to the necessary actions for its sanitation. Risk assessment is intended 'to provide complete information to risk managers, specifically policymakers and regulators, so that the best possible decisions are made'. There are uncertainties related to risk assessment and it is important to make the best possible use of available information. Environmental Health Risk Assessment provides a tool for appraising health risks in the broader process of Health Impact Assessment.

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