Development of Risk-Based Ambient Air Quality Standards in the Russian Federation on the Basis of Risk Assessment Procedures Harmonized with International Approaches

Nina V. Zaitseva, Pavel Z. Shur, Nina G. Atiskova

***Abstract*—**Nowadays harmonization of sanitary and hygienic standards of environmental quality with international standards is crucial part of integration of Russia into the international community. Harmonization of Russian and international ambient air quality standards may be realized by risk-based standards development. In this paper approaches to risk-based standards development and examples of these approaches implementation are presented.

***Keywords*—**Harmonization, health risk assessment, evolutionary modelling, benchmark level, nickel, manganese.

I. Introduction

CURRENTLY there is an active process of integration of Russia into the international community, one of the priority directions of which is rapprochement of health legislation, and in particular, harmonization of sanitary and hygienic standards of environmental quality with international standards.

Today the risk assessment is a key element in establishment of standards concerning safety of environment objects and also it has to be carried out with application of structured approach including hazard identification, exposure assessment, assessment of "dose-response" relationship and risk characteristic [1], [2].

In compliance with, for example, Canadian Environmental Quality Guidance [1], the development of risk-based standards is carried out with respecting the following principles: implemented ambient air standards shouldn't pose the risk to the public health; the development of standards should be carried out for the real exposure scenario; critical health effect should be established considering the most sensitive population groups; the developed standards should be reasonable and real for implementation.

On the territory of the Russian Federation as hygienic standards of ambient air pollutants the maximum single and the average daily maximum allowable concentrations are used,

but they don’t fully reflect the lifelong impact and can't be used within the health risk assessment, where the values taking into account the safety of lifelong impacts are required.

Nina V. Zaitseva, Pavel Z. Shur, and Nina G. Atiskova are with FBSI «Federal Scientific Center for Medical and Preventive Health Risk Management Technologies», 82 Monastyrskaya St., Perm, 614045, Russia (phone: +7(342)237-25-34; fax +7(342)237-25-34; e-mail: atiskovanina@mail.ru).

Appropriate standards for the Russian Federation, application of which is possible in the field of health risk assessment, can be obtained as a result of the establishment of risk-based standards with annual averaging.

II. General Approaches to Risk-Based Standards Development

According to internationally recognized health risk assessment methodology on the stage of hazard identification in accordance with a variety of criteria, the selection of priority-oriented pollutant for risk-based ambient air standard establishment is performed.

Developed criteria for determining the priority-oriented ambient air pollutants for chronic inhalation exposure conditions include the existence of differences in the values of standards used in Russian Federation and abroad; data on the toxicity and hazards of chemicals, including the carcinogenic potential; the presence in international and national lists of priority ambient air pollutants; data on the prevalence in objects of environment [3].

At the stage of exposure assessment the quantitative establishment of agent admission into the organism in real exposure conditions is carried out [2].

The next stage of health risk assessment procedure is the evaluation of “exposure – response” dependence. It involves the conclusive set of relationship between exposure and the risk of organs and body systems functional disorders considering degree of their disturbances [2].

In the course of non-cancerogenic health risk assessment of chemicals the binary mathematical models can be used. They are listed in methodical guidance and recommendations of the major international organizations (WHO, OECD, etc.), and are contained in the published scientific researches (EPA, ATSDR, etc.). In the absence of “exposure – response” models the results of special epidemiological researches can be used.

The threshold principle in "exposure-response" dependences modelling within evaluation of non-cancerogenic risk is laid out. According to this principle the negative health effects or responses are appeared starting from a benchmark level.

During the research the number of hypotheses about the relationships between the different exposure levels and development of health effects are considered. The population group which is under the study exposure level is considered as a control and that which is above the investigated exposure level as an experimental. Each hypothesis is verified by odds ratios (OR), on the value of which the mathematical models of dependence "concentration of chemical in the ambient air - the odds ratio" are based. As a benchmark level of pollutant in the ambient air the value corresponding to the upper 95% confidence boundary of the resulting model was accepted.

In addition, for the purposes of "exposure-response" assessment the multiple evolutionary models can be used, reflecting the influence of chemicals complex on the risk of progression of various health problems according to the age and duration of exposure, and taking into account the processes of accumulation of functional disorders in the organism due to the natural causes.

Establishment of chemical agent risk-based standard in ambient air is carried out using benchmark level and the value of uncertainty factor (UF).

The value of uncertainty factor is determined taking into account the potential impact of several factors on the evaluation accuracy. When choosing the component of uncertainty factor value it is recommended to consider the intraspecies variation; distribution of data obtained under the conditions of relatively short exposure on the longer expositions; impact on the developing organism; extrapolation from one exposure route to another, transition from the minimal to full database, etc [2].

At the stage of risk characterization the assessment of health risk acceptability in conditions of using the developed ambient air quality standard is carried out.

III. Implementation of Risk-Based Standards Development Approaches in the Russian Federation

Within the development of risk-based ambient air quality standards in the Russian Federation on the basis of a harmonized with international approaches the health risk assessment procedure on the stage of hazard identification based on the mentioned above selection criteria, nickel and manganese were included in the list of priority for establishing the ambient air risk-based standards.

For exposure assessment the estimated data of industrial city ambient air pollution in residence of each child, approximated by the results of instrumental studies were used. The range of ambient air nickel concentrations on the residence territory of studied group vary from 0.0000067 to 0.000073 mg/m^3; manganese – from 0.000014 to 0.00022 mg/m^3.

Derivation of ambient air benchmark levels of nickel and manganese was conducted by the results of cross-sectional study. 382 children aged 3 to 7 years old, living in industrial city were examined. Health status evaluation of the studied group was carried out using long-term data about seeking medical care.

As the health effects for " ambient air nickel concentration - odds ratio" relation modelling were considered the several nosologic units from five disease chapters of ICD-10 (II - neoplasms, III - disease of the blood, blood-forming organs and certain disorders involving the immune mechanism; VI - diseases of nervous system; X - respiratory diseases; XII - diseases of skin and subcutaneous tissue), selected in accordance with target organs and systems for chronic inhalation nickel exposure [4], as well as several laboratory tests.

It was developed and evaluated 32 models of "ambient air nickel concentration - odds ratio" relation. The most adequate for research tasks were models for some respiratory diseases and laboratory tests. The obtained benchmark levels of nickel in ambient air were 0.00002 mg/m^3 for asthma (J 45.0); 0.00003 mg/m^3 for vasomotor rhinitis (J 30.0); 0.00002 mg/m3 for chronic tonsillitis (J 35.0); 0.00002 mg/m3 for percent of phagocytosis increase; 0.00002 mg/m3 for phagocytic number increase; 0.00002 mg/m3 for superoxide dismutase blood level decrease; 0.00004 mg/m3 for serotonin blood level decrease.

As the health effects for the ambient air manganese benchmark level establishment were considered several nosologic units from three disease chapters according to ICD-10 (V - mental and behavioral disorders; VI - diseases of nervous system; X - respiratory diseases), corresponding to the critical organs and systems for manganese chronic inhalation exposure [5]. In addition, as the manganese is a proven allergen, in the course of modeling of "ambient air manganese concentration - odds ratio" relation it was taken into account the appropriate health effects, including donozological [5], [6].

It was developed and evaluated 29 “ambient air manganese concentration - odds ratio” relation models. The most adequate for research tasks were models and values of benchmark levels for sleep disorders (G 47) - 0.00009 mg/m^3; atopic dermatitis (L 28.0) - 0,00008 mg/m^3; increase of absolute number of eosinophils - 0.0002 mg/m^3, increase of total IgE level - 0.00004 mg/m^3.

According to the criterion of the lowest benchmark level as ambient air nickel benchmark level under the chronic exposure can be considered the value 0.00002 mg/m^3, ambient air manganese benchmark level under the chronic exposure – 0.00004 mg/m^3.

However, the uncertainties associated with the presence in the ambient air of investigated territory the range of contaminants have synergistic effect with nickel and manganese, the essential impact on the reliability of epidemiological study results used in establishing of benchmark levels is assumed.

In order to minimize the uncertainties it was conducted the modelling of risk evolution, which is considered one of the most appropriate methods to solve the problems of prognosis and assessment of the probable environmental exposure on the health of population. Within the present study the modelling of risks evolution for the health was carried out using the linear no-threshold model, calculation of the coefficient reflecting the factor influence effect on the rate of risk accumulation, and establishment of nickel and manganese concentrations in the ambient air, corresponding to the value of the given risk of less than 0.05, estimated as acceptable risk level [7].

According to the results of mathematical modelling of health risk evolution for asthma as a specific response for chronic inhalation exposure of nickel and atopic dermatitis, as a specific response for chronic inhalation exposure of manganese, the concentration at which the risk for population health is characterized as negligibly small, amounted to 0.00005 mg/m^3 as for nickel and for manganese.

The level of 0.00005 mg/m3 for nickel and manganese in the ambient air can be considered as benchmark level and can be used for subsequent establishment of risk-based ambient air quality standards.

Calculation of the final value of risk-based ambient air quality standards for nickel and manganese was performed using established benchmark level according to the results of evolutionary modeling and cumulative uncertainty factor [5].

For this study were considered the following uncertainty factors:

- Uncertainty factor, taking into account the interspecies extrapolation - 1, because we used benchmark level received by the results of epidemiological studies;
- Uncertainty factor, which takes into account the intraspecies variation - 1, because it was considered impact on the sensitive group (children of 3-7 years);
- Uncertainty factor associated with the transfer of research results from the high levels of exposition to the low - 1, because the study was conducted under the conditions of actual exposition.

As a result, the value of ambient air quality standards for nickel and manganese, established on the basis of health risk assessment is 0.00005 mg/m^3. As the critical effects for nickel were suggested disorders of the respiratory system and for manganese - allergic reactions.

The results obtained are adequate to data of CalEPA for nickel and the data of US EPA for manganese.

IV. Conclusion

Thus, the main direction of harmonization of sanitary and hygienic environmental quality standards of the Russian Federation with the international standards is the development of risk-based standards, taking into account the annual averaging period using epidemiological methods of research. The developed approaches for establishing the risk-based standards have been approved on the example of establishment of the average annual MPC (maximum permissible concentration) for nickel and manganese in ambient air, and further is planned widely introduce them into practice of hygienic standardization improvement in the Russian Federation.

References

[1] Canadian Environmental Quality Guidance, Canadian Council of Ministers of the Environment, 2007.

[2] The Report of the Scientific Steering Committee’s Working Group on Harmonisation of Risk Assessment Procedures in the Scientific Committees advising the European Commission in the area of human and environmental health // First Report on the Harmonisation of Risk Assessment Procedures / Scientific Steering Committee, EU. – Brussels, 26-27 October 2000. – Part 1. – 173 p.

[3] Atiskova N.G., Shur P.Z., Romanenko K.V., Shljapnikov D.M., Sharaeva A.A. Forming a list of priority hygenic standards of ambient air ingredients for harmonization // Zdorov'e naselenija i sreda obitanija. 2013; 11: pp. 7-9. (Russian)

[4] Toxicological profile for nickel, U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, August 2005.

[5] Toxicological profile for manganese, U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, September 2008.

[6] Kagamimori S, Makino T, Hiramaru Y, et al. 1973. [Studies of effects on the respiratory organs of air pollution through dust consisting mainly of manganese] Nipon Koshu Eisei Zasshi [Japanese Journal of Public Health] 20:413-421. (Japanese)

[7] Methodical recommendations 2.1.10.0062- 12. Quantitative assessment of non-cancer risk on the basis of constructing evolutionary models» - 36p. (Russian)