HEALTH RISK ASSESSMENT AND MANAGEMENT AS AN EFFECTIVE TOOL TO SOLVE ISSUES TO ENSURE THE HEALTH AND EPIDEMIOLOGICAL WELL-BEING OF THE RUSSIAN FEDERATION POPULATION

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Abstract. The Russian Federation continues to develop legislative, scientific, methodological and information bases, harmonized with international requirements and approaches, for the methodology of assessing health risks from exposure to hazardous environmental factors. Health risk assessment methods included in the social and environmental health monitoring system have been validated and proven to be effective, are used in many Russian regions to justify health and environmental measures to protect public health, workers' health as well as in product safety analysis, etc. Taking into account risk parameters, we developed national environmental health standards of the concentrations of chemical substances in the environment, we justified the position of the Russian Federation on the content of residual hazardous impurities in food, and we justified ambient air quality monitoring programs during the Universiade in Kazan and the Olympic Games in Sochi. The country is developing methodical and laboratory basis for social and environment health monitoring as a foundation for exposure assessment; new approaches to the determination and mathematical modeling of "dose-effect" relationships, to risk classifications, including those used in exposure to factors of various origin, and to the application of risk assessment results in management decision making in the field of ensuring health and epidemiological well-being, are being validated.

Keywords: risk assessment, risk management, practical application.

Currently the Russian Federation is facing intense inclusion in global integration processes, accelerated development of innovative industries, and the emergence of new health threats and hazards; the local governments are working on the strategic projects to preserve public health, reduce mortality rates, increase life expectancy, and create conditions and incentives for the generation of healthy lifestyles [1-5].

Under such conditions, the Federal service on customers' rights protection and human well-being surveillance (hereafter the Service) is working on the practical application of effective knowledge-based management tools for sanitary and epidemiological situations. These contemporary efficient tools that support decision-making at all levels include a methodology for the analysis of health risks associated with environmental exposure. The methodology uses reliable quantitative assessment criteria and helps bring the Russian sanitary and hygienic standards and requirements in accordance with the international standards acknowledged in the European Union, the United States, Canada and other countries with due regard to risk parameters.

While developing national regulatory, procedural documents and implementing practical work on the analysis and prediction of sanitary and hygienic situations, the specialists of the Service departments and agencies have already taken into consideration the information from the Directives of the European Union Commission, Technical regulations, and European Directives on the general product safety and other documents that govern the assessment procedures for the health risks associated with various adverse factors.

1 Translated by Ksenya Zemnlyanova
The Russian legislative framework follows the global trends with the account of the accumulated positive national experience and hygiene practices. Thus the Federal Law No. 52 of March 30, 1999 - “On the sanitary and epidemiological well-being of the population” provides for the prediction of social, economic and health-demographic implications of applying regulations, the criteria for which are based on the principle of public health safety. Under the health legislation, hazardous enterprises must perform risk assessment activities while designing sanitary protection zones (Sanitary Regulations and Standards SanPiN 2.2.1/2.1.1.1200-03 “Sanitary protection zones and sanitary classification of enterprises, buildings and other facilities”). The description of the risk assessment procedures for chemical hazards, and the criteria for acceptable (permissible) risk are given in the Regulations 2.1.10.1920-04 “Guidelines for human health risk assessment from environmental chemicals”. In the field of radiation safety, legally defined indicators are used to determine the limits of individual risk of stochastic effects occurrence...” etc. (standards of radiation safety-99). The system of occupational risk assessment and the basic principles of occupational risk management have been developed (Regulations 2.2.1766-03 “The occupational health, safety and risk assessment guidelines Organizational and methodological foundations, principles and assessment criteria”). The occupational hazard assessment methodology developed by the Russian scientists is based on the recommendations made as a result of the implementation of international projects in Russia and the EU EuropeAid 119764/C/SV/RU “Rapprochement of the legal framework for occupational safety and health” as well as current recommendations of the International Organization of Labor Protection, which recommended “... to determine a risk assessment procedure as a preliminary stage of job evaluation, to develop the minimum risk assessment criteria.” A concept of the labor protection system reform has been developed for the period until 2025, and major steps to modernize the labor and compulsory social insurance have been taken on the basis of a systematic approach to a whole range of issues related to the improvement of working conditions and health of employees. Additionally, a comprehensive system of occupational risk management is being developed; it is based on the identification of all the workplace hazards, their quantitative evaluation, record-keeping, and monitoring of the ongoing changes with the subsequent registration of the relevant dependencies between labor conditions and health of employees on the basis of the measurement of individual occupational hazards for employees.

Health risk analysis is included in the Federal Law No. 184 of 27 December 2012 - “On Technical Regulation”, the development of a methodological framework for the assessment of health risks in circulation of products (goods) has been initiated”.

In general, over the past two years, the Federal Service has approved and recommended the introduction of over a dozen of documents aimed at assessing the health risks associated with exposure to environmental hazards. These guidelines include the following documents: “Evaluation of health risks associated with long-lasting regular low-dose technogenic radiation” (Guidelines 2.1.10.3014-12 ), methodological recommendations “Assessment of risks and damages from climate change resulting in increased disease incidence and death rates in groups of at-risk population (Guidelines 2.1.10.0057-12 ), “Integrated assessment of the risk of bacterial intestinal infections transmitted by water” (Guidelines 2.1.10.0031-11 ), “Assessment of health risks from exposure to road traffic noise” (Guidelines 2.2.10.0059-12 ), documents on the
assessment of health risks associated with electromagnetic radiation, lifestyle factors, problems of economic risk assessment and damages, etc.

Several projects have been developed including guidelines, assessment methods and execution procedures including the following: a methodology for an integrated assessment of the workplace environment with the account for the exposure to various hazardous factors; a method for calculating the likelihood of a full loss of the ability to work depending on the workplace environment; a method for measuring individual occupational risk depending on the conditions and state of health; a method of calculating an integral indicator of the occupational hazard level in the organization; procedure for identifying hazards and assessing injury risks in a hazardous workplace including a hazard classifier (catalogue); a system of regulations and standards “Documented procedures and standards of the organization and conduct of work evaluation and assessment of occupational risks”.

In recent years, health risk assessment methods included in the system of public health monitoring have been tested and proved to be effective; they have been used to solve many sanitary assessment issues and justify the sanitary measures of different levels. This process was facilitated by the establishment of the System of Accreditation bodies to assess risk on the basis of the Federal State Budget Institution (FSBI) “Federal Hygiene and Epidemiology Center”. The system played a crucial role in the training of highly qualified personnel in the field of risk assessment in the RF; it included best risk assessment practices and strengthened the intra- and inter-agency cooperation while solving a set of sanitary and hygienic problems.

In 2011, the Russian Federation had 48 organizations accredited by the National Accreditation Board and representing almost all the Federal Districts: Central (Moscow city; Moscow, Voronezh, Lipetsk, Kursk, and Yaroslavl Regions), North West (St. Petersburg city, Vologda), Volga District (Nizhny Novgorod, Republic of Tatarstan, Bashkortostan, Udmurtia; Saratov, Kirov, Orenburg Regions, Perm Krai), Ural (Sverdlovsk and Chelyabinsk Regions), Siberia (Kemerovo Region, Altai Krai and Krasnoyarsk Krai; Novosibirsk, Irkutsk, Omsk Regions), South (Krasnodar Territory, Volgograd and Rostov Regions), the North Caucasus and the Far Eastern Federal Districts (Stavropol Krai and Sakhalin Region, respectively).

The number of risk assessment has been steadily growing totaling 280-300 projects per year (in 2006 - 120 projects). Due to existing legal framework, most studies focus on the justification of the size of sanitary protection zones. However, some studies are aimed at assessing the risk associated with the use of drinking water, food products, living in the territories with contaminated soils, etc. An important fact here is that the results of such risk assessment studies set grounds for the activities of the Service itself, public authorities, local governments, and business entities.

For example, the risk assessment data obtained in the course of an air pollution study in Moscow was used to develop proposals for the 2011 Program of Social and Economic Development of the North-Eastern Administrative District of the city and for the six projects of organizing sanitary protection zones for the local enterprises by 2013.

The Federal service on customers’ rights protection and human well-being surveillance in Kemerovo used the results of the risk assessment studies to develop proposals on the health risk assessment Region prepared proposals for the Administration of Kemerovo Region and
municipal administrations on the improvement of water supply and drainage systems in the municipality “Mezdurechensky city district”, according to the Measures to protect the rights of consumers and ensure sanitary and epidemiological well-being of the population of Novokuznetsk in 2011-2013 (the program included measures to improve the city air quality, water supply, and sanitation of the river Tom’).

In 2011, Lipetsk region conducted a study aimed at the assessment of health risks associated with the quality of the underground source of drinking water in Matyrsky village. The study showed that the cancer risk value for arsenic was at 1.45 E-04; chrome – 4.89 E-05; beryllium, lead, cadmium - 4.96 E-06; 3.31 E -06 and E-06 1.51, respectively. The total cancer risk level in the residential area is at 2.03 E-04 which is considered to be impermissible and calls for the implementation of health and sanitary measures. The study results were used to plan additional studies of the underground water quality in Matyrsky village aimed at measuring the amount of arsenic, lead, cadmium, nickel and chromium. Currently, the plan is being implemented.

The impact of environmental factors on the health of the population of municipalities of Sverdlovsk region was assessed for the period of 2008-2010. It was determined that 83% of the population in the region (or more than 3568 thousand people) live in the conditions of complex chemical load. It was revealed that the biggest chemical impact on the population comes from drinking water, contaminated soil, air and food products. The total economic damage from the increased disease incidence in the region reached 25 666 772.16 rubles, including 17 381 980.57 thousand rubles from the disease incidence in the adult population, and 8284 791.6 thousand rubles - in children. The local authorities developed a 2015 program to minimize the health risks associated with environmental factors. Previous assessment studies of the exposure related to food products was analyzed and summarized.

The risk assessment activities carried out in the past in preparation for the Olympic Games in Athens (2004), Beijing (2008) and London (2012) were used in preparation for the Summer Universiade in Kazan in 2013 and the 22nd Olympic Winter Games 2014 in Sochi to determine the main air pollutants subject to sanitary and epidemiological control. The following elements were taken into account to address the exposure: breathing patterns in athletes when involved in high physical activities, weather conditions, sporting venues, the layout of sporting and recreation facilities, street and road network design, the intensity and structure of traffic flows in the period of mass sporting events, and modes of operation of manufacturing enterprises. These activities will guarantee a safe and healthy environment for the residents and visitors of the cities that host major sporting events. They also put the Russian Federation in compliance with the highest international sanitary and epidemiological standards.

A risk assessment methodology is used to protect public health in the Russian Federation when it comes to the quality of imported food products. Due to the fact that the use of a risk assessment methodology in the European Union is mandatory when it comes to the justification of the maximum permissible levels (MPL) of chemicals in food products, especially xenobiotics (the PRIMO model); in case of disagreement with the MPL values, the data on the scientific substantiation of alternative amounts (with the results of the health risk assessment) are to be submitted to the Codex Alimentarius Commission. For example, research institutes of the
Federal Service and the Russian Academy of Medical Sciences have analyzed scientific data including those from the USA and European scientific communities, on the issues of tetracycline and ractopamine MALs. So the position of the Russian delegation, expressed at the 35th session of the Codex Alimentarius Commission was developed; it stated that the permissible daily intake of ractopamine is not sufficiently proved and can not be used to set the maximum permissible levels of ractopamine in meat and by-products. Risk assessment studies have shown that consumption of food products containing ractopamine in animal tissues at the permissible level in accordance with the assessment method recommended by Codex Alimentarius will result in impermissible levels of risk of functional disorders and cardiovascular diseases (hypertension, atherosclerosis, ischemic heart disease). This results in an increase in cardiovascular diseases and reduction in life expectancy in the Russian Federation (heart and vascular diseases in the RF are the causes of more than half of the deaths in the population). On the basis of the findings, the Federal Service on customers’ rights protection and human well-being surveillance continues defending its position on the content of ractopamine in food and plans future work on the harmonization of the maximum permissible levels of potentially hazardous substances in food, as part of a joint action plan of the Federal Service and the Epidemiology Directorate of the European Commission’s Health and Consumer Protection.

The results of the application of the risk assessment methodology which involves some elements of epidemiological analysis and diagnosis of a stressed sanitation situation, were used for the development of a number of healthcare technologies recommended for practical application. For example, in some regions, a 3-staged organizational and functional model was developed and successfully put into operation to provide groups of ill children with specialized medical care; this includes children with the environmentally modified course of respiratory diseases (allergic bronchitis, bronchial asthma), digestive disorders (gastro-duodenal disorders, hepatobiliary system), diseases of the cardiovascular and nervous systems, and the sensory organs (vegetative-vascular dystonia, dysfunction of the nervous system), skin diseases (atopic dermatitis, alopecia, etc.), musculoskeletal diseases (osteomyelitis, osteoporosis), endocrine system (endemic goiter, obesity etc.), etc.

A wide range of studies is carried out in the field of occupational and work-related risk assessment. Today such activities are very important since the death rate of the working population in Russia exceeds the rate in the European Union by 4.5 times [6]. It has been determined that the launch of new technologies at some enterprises led to a decrease in occupational diseases; as a result, the without clear biological markers of mixed (professional and age) genesis are most frequent. Such diseases of subclinical cases are typical of long-time employees (over 20 years of employment) who have a variety of identified age-related health problems. Therefore, it is important to determine an average employment risk threshold in relation to the parameters of hazardous occupational factors, outside of which there is a risk of “professionally caused” (induced) diseases. This issue is of current interest also because many employees exposed to occupational hazards that significantly exceed the maximum permissible level, despite the known average employment risk threshold, continue working in the hazardous environment putting their health at risk. This is unacceptable, that is why today awareness of the health risks to different age groups is at high priority than ever.
In general, it should be noted that the departments and scientific institutions of the Federal service on customers’ rights protection and human well-being surveillance have accumulated a significant knowledge database about the negative effects arising under the impact of combined hazardous environmental factors [7, 8]. At that, applied risk analysis studies including such activities as hazard identification, exposure assessment, assessment of “dose-response” relationship, risk specification, assessment of uncertainty, management and distribution of information about risks are carried out.

Some studies, for example, are aimed at studying the parameters of component and compositional content of dust particulate emissions from major manufacturing enterprises with the release of fractions of PM 10, PM 2.5, these data are extremely important for the assessment of the exposure to employees and the general population. The data are relevant to the implementation of the approval procedures by the Federal Service in relation to maximum permitted emissions of enterprises and producing organizations.

Some methodical approaches were developed to justify the permissible risk levels for non-communicable diseases and related economic losses, as safety criteria for long-term planning. The methods and criteria for the assessment of direct and long-term effects from exposure to adverse environmental factors have been developed.

Many studies are aimed at the assessment of risks to the employees and the general population associated with nanoparticles and nanomaterials [9], the reason for this is a rise in modern laboratory facilities set up by the authorities and organizations of the Federal Service and increased popularity of knowledge-based centers of collective use - the RAS and the RAMS.

Connection between the two processes is very important: risk assessment and development of methods of generating health risk evidence, which is a database of health decrease cases (by in-depth epidemiological and biomedical researches). In this situation, an important activity requiring constant support is development of modern laboratory centers (based at the National Research University of the Federal Service), focused on exploration and development of innovative chemical analysis, cellular, cytogenetic, proteomics, metabolomics, and other high-tech methods of fine diagnosis of the state of health, incase of human exposure to hazardous environmental factors. It should be noted that in recent years the mechanisms of toxic chemical impact in many cases have been identified with genic-effects and relevant metabolites. In many cases, controlled cellular and subcellular studies may be expensive, but the arbitrage value of the data is extremely high. In this regard, risk assessment procedures allow for a significantly reduction in the search for both for impact factors and possible violations of health of the population under the risk; besides it can save both time and money to collect evidence on health hazards. Approaches used in risk assessment can also identify specific sources and causes of environmental pollution and determine the pollution rates for various pollutants and hazards. In general, the current risk assessment methodology (which develops new methods of hygienic diagnostics) can support health services both with tools and actual data for proving the existence of a “environment – health” connection; it is available for pre-trial and judicial protections of favorable habitat rights of the citizens.

These approaches have already been put into practice. For example, in Perm Krai a health risk assessment study conducted in Krasnokamsk (the population is more than 80 thousand
people) and aimed at the assessment of health risks associated with consumption of hyper chlorinated drinking water revealed that the total individual cancer risk was by 4.6 times higher than the permissible level. It is important that the generation of the evidence on health issues resulting from environmental exposure was conducted with the use of contemporary chemical analytical methods for the identification of chemical substances in the biological substrates, cellular and sub-cellular methods of diagnosis of biochemical, immunological, cytogenetic status of the body, various mathematical modeling tools. Chloroform was identified as the main cause of an impermissible health risk; and during the controlled trial study chloroform was found in the blood of 98.8 % of the 243 examined children, when the comparison level was below the threshold of method definition. Moreover, carbon tetrachloride was detected in the blood of all the tested children; 97.9% - dichlorobrommethane. Every other child consuming water from the centralized water supply system had dibromochloromethane and/or 1.2- dichloroethane in blood. So the studies have proved the presence of a cause-effect relationship (p <0.05) between the levels of contaminants in the blood of children with indicators of cell damage and reducing the liver function of protein synthesis, an imbalance of the oxidation-reduction processes, reduced non-specific resistance and the development of intoxication, changes in cellular (phagocytosis, T-lymphocytes) and humoral (immunoglobulins and cytokines) immunity, all the signs are associated with an increased incidence and severity of diseases for the tested patients. The results are used in the preparation of the following documents and measures: the decision of the Chief State Sanitary Doctor of Perm Krai to prohibit the use of drinking water in Krasnokamsk, as it is not compliant with the safety requirements; data for a legal complaint of the Federal Service (Rospotrebnadzor) against the company, that supplies the population with drinking water; the decision to take measures to find an alternative source of water supply.

Over the past decade, risk assessment methodology has become much more complex due to the desire to bring it closer to the models which characterize the impact of environmental factors in the real world. There is a shift from the initial simplified methodical scheme which provides an isolated assessment of the impact of a factor (at the first stages it is mainly chemical data) taken from one environment to the study of integrated risks related to a variety of hazards, exposure ways, and duration of exposure. It should be noted that studies tend to take into account age and gender characteristics, mechanisms of evolution of risks, etc. Mathematical modeling techniques are becoming increasingly important as they are used in the calculation of exposure when identifying the “dose effect” relationships in the dynamic health risk assessment, etc.

However several aspects hinder the development of risk assessment methodology and its involvement in decision-making on the sanitary and epidemiological well-being of the population. Thus, the legislative and regulatory-procedural frameworks of risk assessment and management are obviously insufficient; the system of risk assessment terms, used in the current Russian legislation and other regulations, is poorly standardized and not fully harmonized with international documents, the problem is true for the concept of a reasonable (permissible) risk. Assessment of population exposure is often done without due regard to the duration of the impact of a factor with a given intensity; it leads either to the aggravation or to underestimation of the exposure level, and consequently, does not result correct conclusions about the risk. Development of methods and laboratory facilities for public health monitoring, as an information
framework for the assessment of population exposure, is required. The chemical analytical methods, applied for assessing the quality of the environment, do not often allow conducting quantitative measurement of impurities at the levels of reference concentrations or doses. In fact, there is almost no data on the regional characteristics of the exposure factors. There are no or few credible models describing relationships between environmental factors and health issues which are obtained in the framework of unified inter-regional epidemiological studies. In case of higher physical impacts (noise, electromagnetic radiation) the share of the studies on these effects increases very slightly. The impact of indoor environment factors on health is poorly studied. Projects aimed at the assessment of health risks associated with exposure to chemical, physical and biological factors are rather rare.

In order to consolidate the progress in the field of health risk assessment and to develop relevant methodology in the Russian Federation (regarding cross-disciplinarily), the following decisions and activities need to be considered:

- Improve the legislative, statutory and regulatory frameworks of public health risk assessment including technical regulation cases, taking into account the international obligations of the Russian Federation in connection with entering into a number of associations and unions; when assessing the safety of products and other dangerous objects, assessment methodology for risk factors of environment impact on human health becomes obligatory;

- Develop a methodological base and laboratory facilities for the environmental and health monitoring, as well as a framework for the assessment of population exposure (with a widening range of high-tech research methods) to ensure correct and timely assessment of population exposure levels;

- Expand the practice of organizing and conducting national epidemiological projects to identify the relationships between the impact factors and public health risks, which are stable and typical of the conditions of the Russian Federation;

- Develop a risk assessment methodology aimed at quantitative integrated risk assessment;

- Include the principles and methods of risk assessment in the system, regulating the impact of manufacturing enterprises and other facilities on the quality of the environment;

- Improve the quality of training in the field of risk assessment;

- Supply the Federal Service (Rospotrebnadzor) with tools that enable knowledge-based analysis within the current inspection and control activities;

- Intensify an international exchange of research results and increase the use of the Russian health risk assessment data in international scientific publications; and

- Include the public health risk assessment indicators related to human exposure to hazardous environmental factors in the criteria for the evaluation of local governments in the RF;

- Create a national information basis both for risk factors and responses (effects) to adverse impacts;

- Develop economic health risk evaluation with access to risk insurance systems for employees, working in hazardous conditions, and for all the population.

Legislative, methodological and informational support of the development of methodology for health risk assessment in the country and its application within the activities of
the Federal service on customers’ rights protection and human well-being surveillance will increase the efficiency of various legislative measures in the field of public sanitary and epidemiological safety; the above activities will set more reliable hygienic standards and safe levels of hazardous factors and help identify the most vulnerable population groups and justify preventive measures. These procedures ultimately contribute to the realization of the national policy on the maintenance of public health and improvement of the quality of life in the country.

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