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**HEALTH RISK ANALYSIS IN THE TASKS OF IMPROVING SANITARY AND EPIDEMIOLOGICAL SURVEILLANCE IN THE RUSSIAN FEDERATION****G.G. Onishchenko<sup>1</sup>, A.U. Popova<sup>2</sup>, N.V. Zaitseva<sup>3</sup>, I.V. May<sup>3</sup>, P.Z. Shur<sup>3</sup>**<sup>1</sup>RF Government Apparatus<sup>2</sup>Federal service on customers' rights protection and human well-being surveillance, Russian Federation, Moscow, Vadkovsky pereulok, 18, building 5 and 7, 127994<sup>3</sup>Federal Budget Scientific Institution "Federal Scientific Center for Medical and Preventive Health Risk Management Technologies", Russian Federation, Perm, 82 Monastyrskaya St., 614045

**Abstract.** The main direction of improving the activity of the Federal Service on Customers' Rights Protection and Human Well-Being Surveillance at the present stage is the implementation of a risk-oriented model, which involves the use of health risk assessment methods for solving a wide range of functional tasks of the Service, classification of supervised objects depending on the degree of threat and risk of harm to life and health of citizens and a differentiated approach to the conduction of regulatory and supervisory activities with concentration on efforts on objects forming unacceptable health risks; introduction of risk assessment methodology in the system for sanitary regulation, systematic approach to the information analysis provision of tasks on the assessment and health risk management, including within the framework of public health monitoring, accounting of indicators of economic efficiency of supervisory activities and health risk management measures.

**Key words:** Rospotrebnadzor, risk assessment, risk-oriented activity model.

Today the Russian Federation is actively becoming part of the global integration processes including those associated with the World Trade Organization, Organization for Economic Cooperation and Development, Customs Union, etc. This suggests the development of innovative manufacturing methods, expansion of the areas of circulation of the new types of products, raw materials, increased mobility of the population which is related to the emergency of new threats and hazards to public health [2, 3].

The analysis of strategic risks to the sustainable development of the Russian Federation reveals that the top areas of focus include risks associated with reduction in the living standards, decrease in the production capacity of the country (including the productive forces, i.e. the population involved in the production of gross domestic product), and uneven socio-economic development of the regions [1].

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To ensure national security, preserve and strengthen the nation's health along with providing favorable conditions for economic activities in all the RF regions, the federal government pays special attention to the development of a new conceptual basis for the state policy based on the risk management theory and system<sup>1</sup>. This is explained primarily by the fact that the probabilistic nature of threats, the combination of which is a random variable each time, requires new approaches and tools to evaluate, predict and validate the mitigating measures.

The tasks associated with the development of a risk-prone activity model are faced by the Federal Service for Supervision of Consumer Rights Protection and Human Welfare as well.

Implementation of the Decree of the President of the Russian Federation №797 dated May 15, 2008 "On Necessary Measures to Eliminate Administrative Barriers to Business" furthered the adoption of a number of federal laws that had a significant impact on the supervisory and inspection activities of the government at all levels: №294-FZ dated December 26, 28 "About Protection of the Rights of Legal Bodies and Individual Proprietors During the Performance of State and Municipal Control (Supervision)"; №99-FZ dated May 4, 2011 "About Licensing of Separate Types of Activity"; №242-FZ dated July 18, 2011 " On Introduction of Amendments to Individual Legislative Acts Concerning the Performance of State and Municipal Control (Supervision)"; №210-FZ dated July 27, 2010 "On the Organization of Provision of the State and Municipal Services"; № 8-FZ dated February 9, 2009 "On Providing Access to Information on the Activities of Government Bodies and Bodies of Local Self-Government".

The most recent developments include an improved system of procedural activities conducted by the control and inspection authorities; a new notification procedure to notify of inception of certain types of economic activity; a new revision of the legislation on licensing of certain activities, reduced frequency of scheduled inspections; a developed methodological and normative framework to improve the quality and delivery (performance) of the state and municipal services (functions) [4, 7].

In this case, removal of administrative barriers to economic activity shall not lead to a decrease in the reliability and effectiveness of supervision over the sanitary law and validity of measures aimed at reducing mortality, morbidity, increasing life expectancy and creating favorable living conditions [9]. This is all the more significant that the data on sanitary-hygienic and health demographic indications in Russia in 2013 and a number of previous years indicates

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<sup>1</sup> Strategic plan to improve the effectiveness of the control and supervisory performance of the federal and local government in 2014-2018.

remaining problems related to poor environmental quality and, correspondingly, associated with this quality indicator of public health in the country.

So, for example, while the atmospheric air quality in the urban and rural areas was overall improving (in 2013 as compared to 2012, a significant decrease was registered in the share of nonstandard samples of the atmospheric air in terms of suspended substance, carbon oxide, hydrogen sulfide, hydrogen chloride, benzene, toluene, etc.), over 30 administrative territories of the 13 RF regions registered the level of pollution at 5 MPC daily average and higher for benzo (a) pyrene, formaldehyde, nitrogen dioxide, carbon black, phenol and other impurities. In 2013, air pollution caused roughly 18 thousand deaths from diseases of the respiratory and circulatory systems as well as new growths; and almost 4 million additional cases of diseases of the respiratory, circulatory, and endocrine systems, new growths, eye diseases, blood diseases and perinatal pathologies suffered by children and adults, including working-age population. For instance, morbidity of respiratory organs in the population at large was associated with the respiratory diseases in 27 of the RF regions. This have been said, in several regions, harmful chemical impurities cause from 1.5 to 25 thousand cases of respiratory diseases per 100 thousand population. Among the priority regions are Irkutsk, Chelyabinsk, Samara regions, Perm Krai, Orlov region, etc.

The situation with the drinking water is still alarming: the share of drinking water samples that do not meet the hygienic standards in terms of sanitary and chemical indicators averages 16.4% in the Russian Federation, in terms of microbiological indicators – 4.2%, and parasitological – 0.1%. These numbers are lower as compared to the previous years but they still exceed those in the economically developed countries.

Infections are caused by microbes. Higher levels of chrome, arsenic, nickel, bromide, molybdenum, manganese, ferrous iron, strontium, nitrates, nitrites, chloroform, etc, in drinking water contribute to an unfavorable effects from the digestive system, kidney, cardiovascular system, hormonal and immune systems, central and peripheral nervous system. The priority risk areas include Rostov region (nickel), Trans-Baikal region (nitrites), Lipetsk, Voronezh, Rostov, Kemerovo, Orenburg region, the Republic of Khakassia, Buryatia (nitrates), Murmansk (chloroform), etc.

In general, in the Russian Federation, dust and gas emissions, wastewater discharges, accumulated waste, noise pollution, electromagnetic interference caused by the local industrial enterprises and transport, waste management and other activities have resulted in increased, including unacceptable, risk to public health. In 2013, those risks resulted in more than 55 thousand deaths and 20 million cases of disease. Of those, about 52 thousand deaths and 6

million cases of disease concerned the working-age population.

Incapacity for work of economically active population due to death, disease or patient care has led to reduced gross domestic product<sup>1</sup> and lower overall government revenues. In 2013, economic losses totaled approximately 193 billion roubles.

In order to reduce federal medico-demographic and economic losses and to improve the quality of life, the executive government implements contemporary science- and technology based management methods.

Risk assessment as a tool that provides information and analytical data to support executive decisions at different levels is widely used in the activities of the Federal Service for Supervision of Consumer Rights Protection and Human Welfare as well (see Figure).

Thus, improvements to the control and supervisory activities of Rospotrebnadzor require risk assessment when classifying the supervised sites depending on the level of threat and the risk of harm to the life and health of citizens. The results of the risk assessment, which takes into account the epidemiological state of the object, the likelihood of violations of the law, the scope and severity of health effects allow one to implement a differentiated approach to supervisory activities with a focus on the sites that present unacceptable health risks.

Based on the assessment of the supervised sites using a series of health disorder probability indicators (including complaints about uncomfortable lifestyle), the level of negative exposure effects, the size of the population group under exposure, and characteristics of the affected population (children, the employed, pensioners, etc.), we can break the sites into the following categories:

- extremely high health risk (hazard);
- high health risk (hazard);
- moderate (average) risk (moderate hazard);
- low risk.

The federal regulatory measures in regards to the sites of various hazard levels provide for ongoing state supervision over the sites in the extremely high health risk (hazard) category, routine inspections at the recommended frequency of once or twice a year at the sites in the high risk category, routine inspections at the recommended frequency of once every two or three years at the sites in the moderate health risk (hazard) category. Sites in the low risk category do not require routine inspections as set by the federal regulatory measures. At the same time,

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<sup>1</sup> Methodology for calculating economic losses caused by population mortality, morbidity and disability; approved by the Regulation of the Ministry of Economic Development, Ministry of Health and Social Development, Ministry of Finance, and Rosstat of Russia №192/323n/45n/113 of April 10, 2012.

public complaints about health, unsatisfactory living conditions or other manifestation of nonconformance with the state sanitary and epidemiological requirements and standards can serve as a trigger for supervisory actions in regards to the sites of any risk category.

Introduction of the risk assessment methodology into the system of hygienic standardization is a challenging goal in Russia.

The need to modify the principles of hygienic standardization is explained by the growing number of risk factors, the regulation of which is limited due to time and financial factors. For example, according to the International Program on Chemical safety, from 2 to thousand new chemical substances are synthesized and put into circulation annually. Over 4 thousand substances require immediate hygienic assessment. Registration of the substances occurring and put into production annually require significant acceleration and increased expenditure on research to substantiate the hygienic standards although it is hard enough to justify the expenditures on the full spectrum of hazardous environmental factors. In the international practice, the feasibility of full-scale research projects is the subject of individual development programs, the criteria for selecting those factors are fixed in legislation. Risk evaluation allows for the use of in vitro and in vivo experiments to justify the level of harm and hazard of the standardized factor which significantly reduces the cost of research and time of the result.

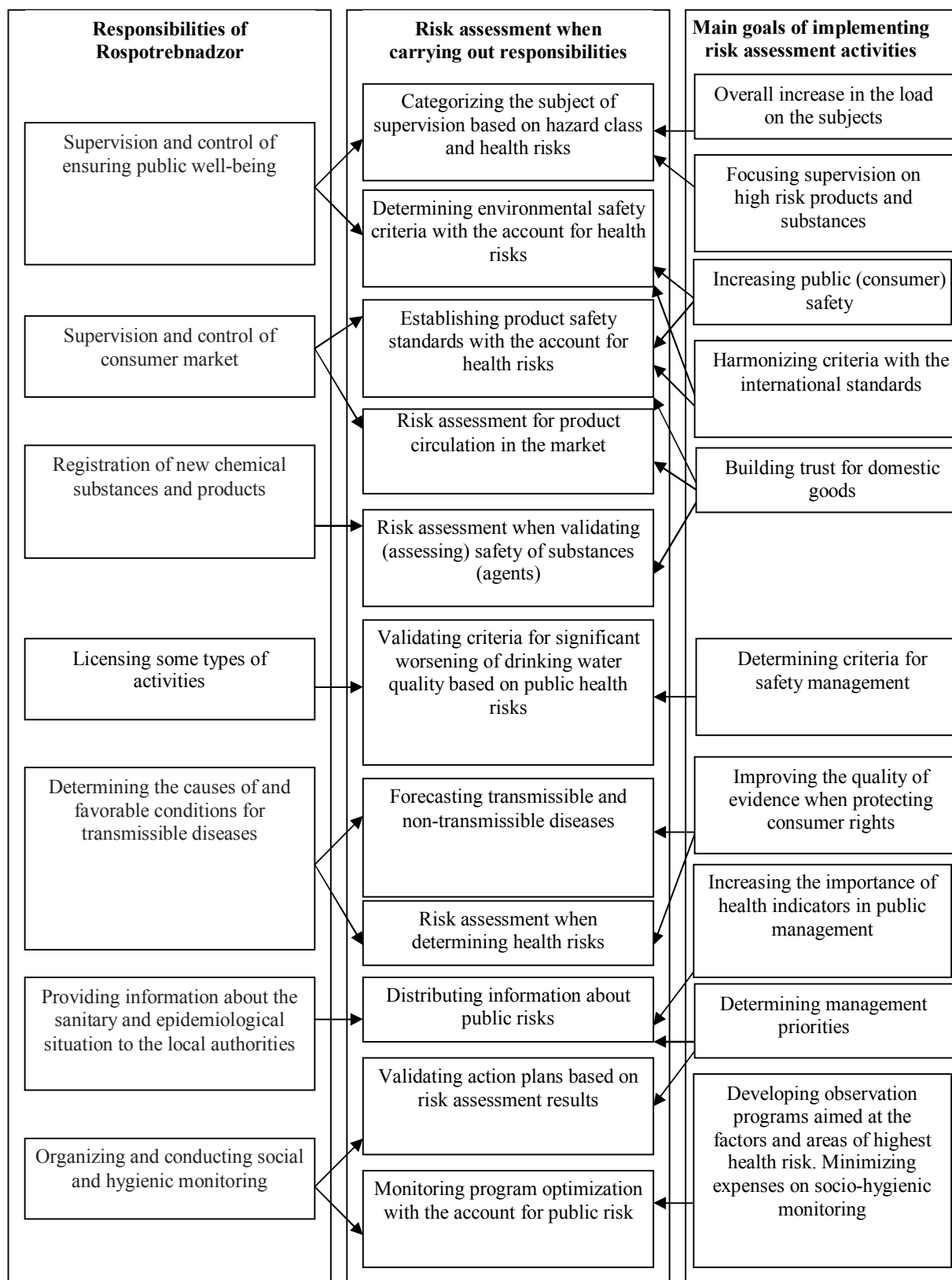


Figure. Place and objectives of health risk assessment under the authority of the Federal Service for Supervision of Consumer Rights Protection and Human Well-being

The methodology of health risk assessment helps remove some limitations associated with the use of the principle of separation of the objects of the sanitary control in the hygienic standardization. The development of hygienic standards for individual factors and environmental objects does not fully take into account the combined impact of environmental factors. For example, in Russia, the combined effect coefficient set for 56-binary and 3-5 component mixtures of atmospheric pollutants does not exhaust all the possible combinations that requires new approaches to the assessment process. We should take into account that the health risk assessment methodology involves the use of 'exposure-effect' threshold models, specifically, when assessing the risks associated with noncancer chemical factors as well as, in some cases, the risk associated with the physical and microbiological factors. This allows us to set the safety criteria with the account for the given level of risk acceptance.

Complex and diverse problems can be solved with the use of a risk assessment methodology in terms of supervision of the consumer market.

The international legislation including the General Product Safety Directive (2001/95/EC) and the Regulation (EC) No 178/2002 that lays down the general principles and requirements of food law makes provisions for health risk assessment at the projecting, manufacturing, quality assurance, and market circulation stages. As a result, through a system of regulatory documents, EU puts on the manufacturers, distributors, and importers the responsibility to conduct product risk assessment and take measures to mitigate consumer health risks at all stages of a product's lifecycle.

The procedure of product assessment against the established requirements involves taking into account the results of health risk assessment and depends on the hazard class of a product. The responsibility of the competent authorities to conduct supervision and oversight with the account for consumer health risks is also formalized in legislation. In the event of revealing unacceptable risks, it is important to notify the manufacturers, the authorities, and the community about the risks. At the same time, the EU law, the US law and the WTO legal framework require that the product safety standards be validated with due account for the results of scientific health assessment research (risk-based standards) or reviewed upon obtaining new research data on health risks. Still product compliance with the safety standards does not prevent the member states from taking the due measures to organize commercial distribution or recall if despite the indicated compliance, the product turns out to be hazardous<sup>3</sup>.

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<sup>3</sup> General Product Safety Directive (2001/95/EC).

The Russian Federation, autonomously and within the Customs Union legislation, is trying to harmonize the local and international approaches to safety assessment. For example, the product risk safety approach used by the Customs Union is regulated by the top level documents: the Agreement on Coordinated Policy in the Field of Technical Regulation, Sanitary and Phytosanitary Measures (as amended May 19, 2010) and the Uniform Sanitary and Epidemiological and Hygienic Requirements for Products Subject to Sanitary and Epidemiological Supervision (control) (as amended by Decisions of the Customs Union Commission № 341 of 17.08.2010, № 456 of 18.11.2010, № 571 of 02.03.2011).

Clearly, with the account for the scale of product distribution, consumer characteristics known hazard classes, monitoring results, ‘refusals’ and violations of sanitary and hygienic requirements of the product circulation, the priority health risk assessment in the Customs Union and common economic space is required for the dairy products: poultry eggs, food products of animal origin (group 04 of the Commodity Nomenclature of Foreign Economic Activities of the Customs Union (HS TC)); fats and oils of vegetable or animal origin (group 15 FEACC TC); sugar and sugar confectionery (group 17 FEACC TC); alcoholic and non-alcoholic beverages and vinegar (a group of 22 CN FEA CU); toys, games and sports requisites; parts and accessories thereof (Chapter 95 CN FEA CU) and several other products.

Risk assessment methodology is necessary when establishing the causes of and conditions for infectious diseases and mass non-infectious diseases in the preparation of information and analytical materials addressed to public authorities and local governments in organizing and conducting social and hygienic monitoring. In all cases, the use of health risk assessment methodology increases the importance of health indicators in management decisions, helps the authorities determine the priority risk factors and the population groups at risk. This allows better decisions as to the sources of danger in the implementation of primary risk prevention and mitigation, and for the most vulnerable and exposed to the adverse effects of groups of citizens of the Russian Federation that require rehabilitative, compensatory or preventive health activities.

Wide introduction of risk assessment methodology in the activities of the Federal Service for Supervision of Consumer Rights Protection and Human Well-being involves optimization of the existing structural and functional model of the functioning of the service. This optimization can and should address the aspects of goal-setting, selection of performance indicators, modification of the structure of public services and functionality of individual service units. The process requires methodological support and ongoing personnel training in the field of risk assessment.



Currently, the risk-based model of activity is supported by relevant regulations and guidance documents of the Federal Service for Supervision of Consumer Rights Protection and Human Well-Being developed by Rospotrebnadzor agencies and organizations, Russian Academy of Medical Sciences, and the Ministry of Health and Social Development. The documents relate to the evaluation of health risks when exposed to chemical, biological and physical factors of the environment, including the working environment, also lifestyle, and products. To date, the Rospotrebnadzor agencies and organizations used more than 50 documents on various aspects of risk assessment and management.

In elaboration of the earlier research, in 2014, methodological approaches to the assessment of the economic losses avoided due to the activity of the Service were justified. The Service constantly inhibits the rate of additional deaths and illnesses of the population, as well as reduces the economic losses of the state, which would inevitably have taken place with a decrease in intensity and targeted control actions.

Developed under the auspices of the Eurasian Economic Commission, "Public Health Risk Assessment for Human Exposure to Chemical, Physical and Biological Factors to Determine the Safety Indicators for Products (goods)"<sup>4</sup> develops and supplements the international approaches to assessing the safety of products, allowing you to assess the overall risk associated with exposure to various factors inherent in goods, take into account the growth (evolution) of the risk in long-term use of products and the age characteristics of the consumer, consider the structure of risk allocation priorities, etc.

To conclude:

– Increased use of health risk analysis in the sanitary and epidemiological activities in the Russian Federation, the introduction of risk-oriented action model by Rospotrebnadzor unifies and enhances the quality of a wide range of tasks related to the responsibility of the Federal Service for Supervision of Consumer Rights Protection and Human Well-Being;

– Focusing on higher risk sites when carrying out control and supervisory activities guarantees improvements in the sanitary and epidemiological and, as a result, medical and demographic situation in the country;

– Risk assessment in supervision of product safety can detect items from the category of

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<sup>4</sup> Document drafted by: Federal Budget Scientific Institution "Federal Scientific Center for Medical and Preventive Health Risk Management Technologies (Perm, Russia), the Scientific Research Institute of Nutrition of the Russian Academy of Sciences (Moscow, Russia), Republican Scientific Practical Center of Hygiene (Minsk, Republic of Belarus), Kazan National Medical University named after S.D. Asfendiyarov of the Ministry of Health of the Republic of Kazakhstan (Almaty, Republic of Kazakhstan).

risky supply, install or remove restrictions on the use of products that enhances the credibility of domestic products, provides reliable protection for consumers;

– Development of risk-based quality standards for the habitat sites and products harmonizes the Russian system of hygienic standardization with the international requirements and standards;

– Differentiated measures of legal regulation of hazardous sites, justified selection of the regional, territorial, and local priorities and informed management decisions based on risk assessment results brings the Russian system of supervision closer to the best international practices in this field.

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