PREVENTIVE HEALTHCARE: TOPICAL ISSUES OF HEALTH RISK ANALYSIS

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Research article

DEVELOPING THE METHODOLOGY FOR HEALTH RISK ASSESSMENT WITHIN PUBLIC MANAGEMENT OF SANITARY-EPIDEMIOLOGICAL WELFARE OF THE POPULATION

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The article focuses on generalizing Russian scientific and methodical developments aimed at updating and supplementing the health risk assessment methodology. This methodology is a key component in tackling tasks related to providing sanitary-epidemiological welfare of the population. Russian approaches to risk assessment are shown to have a significant peculiarity, which is a wide use of methods of multidimensional statistical analysis, mathematical modeling, fuzzy logic, and their combinations. The most significant Russian scientific innovations include development of qualitative risk assessment, non-carcinogenic health risks included; severity of health disorders taken into account in risk assessment; methodical support for assessing integral risks under exposure to heterogeneous environmental factors. Russian experts suggested and developed an idea that it was possible to model evolution of risks and their growth under changing exposures. Approaches to assessing risks evolution under long-term exposure to variable factors made it possible to solve a whole set of applied hygienic tasks. In addition to establishing qualitative characteristics of non-carcinogenic risks under exposure to chemicals, methods for assessing risks under exposure to environmental noise, certain lifestyle factors and factors related to work process have also been substantiated and implemented.

Progressive development of the health risk assessment methodology ensured operative, smooth and effective transitions of control and surveillance activities performed by Rospotrebnadzor onto a fundamentally new control platform that relies on the risk-based model.

Obviously, analytical opportunities offered by the health risk assessment methodology are extensive. Development of methodical grounds in hygiene and epidemiology as well as design of applied algorithms and approaches to risk assessment and management based on the fundamental methodology should involve several trends. We should extend our knowledge on mechanisms of health disorders under exposure to heterogeneous environmental factors and work-related ones; hygienic standardization needs improvement; we should apply situational modeling and prediction of sanitary-epidemiological welfare under changing or preset conditions; we should provide substantiation for the strategic and tactical regulatory actions aimed at managing threats and risks. The experience accumulated in developing the health risk assessment methodology in variable spheres should be considered a starting point for creating new risk assessment and risk management technologies. They should give an opportunity to solve any tasks related to providing sanitary-epidemiological welfare of the population in the Russian Federation.

Keywords: public health, risk assessment, sanitary-epidemiological welfare.

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The Order by the RF President "On the National Security Strategy of the Russian Federation" issued on July 02, 2021 No. 400[1] declares the preservation of the country population and development of its human potential to be the top priority and the most vital task. In both the nearest and remote future, efforts taken by public authorities at any level should be focused on finding solutions to the issue. Accordingly, it is necessary to build and implement new public administration models based on the best available world practices and scientific developments [1, 2]. A key component in public health preservation and development of human potential is sanitary-epidemiological welfare of the population. Providing it makes it necessary to rethink certain managerial criteria and mechanisms [3].

At the contemporary stage of the society development, it is hardly possible to make the environment absolutely harmless for public health since this requires extremely high economic costs. Awareness of the fact predetermined creation of a new paradigm for safety of environmental factors for people. Key postulates in this new system of ideas and views are human health as the top priority among other elements in everyday life and the non-zero risk concept [4].

At the end of the 20th and the beginning of the 21st century, the world expert society formulated fundamental postulates of health risk analysis (such as the necessity to separate risk assessment and risk management) [5–8], determined principles and key stages in risk assessment [9] with a system of indicators for such assessment [7], and established approaches to informing about risks [10].

Russia was quick to get involved into mastering this new methodology for assessing and managing public health risks under exposure to environmental factors. Model studies were accomplished in cooperation with American colleagues in the Moscow region, Perm, Samara, the Sverdlovsk region, Angarsk, and some other cities and regions in the country [11, 12]. Risk assessment practices were expanded and generalized. New approaches were considered vital and significant and this was confirmed by an interdepartmental document signed by the RF Chief Sanitary Inspector and the RF Chief State Inspector on Environmental Protection. The document was entitled "On application of the health risk assessment methodology to manage environmental quality and public health in the Russian Federation"[2].

Initially, health risk assessment was in the highest demand within the system of social-hygienic monitoring when it came down to management of sanitary-epidemiological welfare in the country. Application of the new methodology became the most significant and even revolutionary change in the system of social-hygienic monitoring since its creation. The aforementioned document was truly strategic in its essence and its implementation led to several effective practical decisions. They expanded the sphere where the methodology for health risk assessment could be applied and reinforced analytical capabilities of monitoring quite substantially [13–16].

When the risk assessment procedure was included into the most vital document of the sanitary service in the country entitled "the Sanitary Rules and Norms SanPiN 2.1.1.1200-03. Sanitary protection zones and sanitary classification of enterprises, constructions and other objects", it became the extremely important step in integrating the risk assessment methodology into the system of public administration tools. The Sanitary rules imperatively demanded "*a reduction in effects produced by pollution on ambient air (chemical, biological, and physical) down to levels established by the existing hygienic standards, and for enterprises belonging to the hazard category I or II, both down to levels established by the existing hygi-*

[1] O Strategii natsional'noi bezopasnosti Rossiiskoi Federatsii: Ukaz Prezidenta RF ot 02.07.2021 № 400 [On the National Security Strategy of the Russian Federation: The RF President Order issued on July 02, 2021 No. 400]. *GARANT: information and legal support*. Available at: https://base.garant.ru/401425792/ (August 30, 2022) (in Russian).

[2] Ob ispol'zovanii metodologii otsenki riska dlya upravleniya kachestvom okruzhayushchei sredy i zdorov'ya naseleniya v Rossiiskoi Federatsii: Postanovlenie Glavnogo gosudarstvennogo sanitarnogo vracha RF № 25 ot 10.11.1997, Glavnogo gosudarstvennogo inspektora RF po okhrane prirody № 03-19/24-3483 ot 10.11.1997 [On application of the health risk assessment methodology to manage environmental quality and public health in the Russian Federation: The Order by the RF Chief Sanitary Inspector No. 25 dated November 10, 1997, The RF Chief State Inspector on Environmental Protection No. 03-19/24-3483 dated November 10, 1997]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/420276120 (August 30, 2022) (in Russian).

enic standards and to levels of acceptable risks for population health" [3]. The document made it possible to involve large business and experts on spatial planning and urban development as stakeholders in risk assessment and analysis of its results [17, 18].

At the same time risk assessment within social-hygienic monitoring and design of sanitary protection zones was accomplished in accordance with approaches and criteria that were mostly developed abroad and fixed in trustworthy international documents.

However, Russian scientific approaches relied on much wider use of certain methods from the very beginning. These methods include multidimensional statistical analysis (multiple regressions, factor analysis, neural networks etc.) and mathematical modeling; the methods and their combinations are quite common for assessing relationships within the "environment – health" system, establishing reasons and conditions for functional disorders of various organs and systems or analyzing the structure of threats and risks for health [19–21]. Russian experts have developed new approaches to application of health risk assessment to prove damage to human health as well as to conjugation of exposure assessments and health risks with vector maps of specific territories and settlements based on geoinformation systems [22–24].

An important trend in the methodology development involves increasing reliability and correctness when assessing population exposure to harmful factors. Thus, there are new approaches to assessing air pollutant exposure based on conjugating calculated and field data suggested in the work [25]. This makes it possible to simultaneously consider specific spatial distribution of pollutions over a given territory and actual contents of chemicals in ambient air that are registered at environmental or social-hygienic monitoring posts. Risk assessment results, combined with such mathematical processing procedures as factor and / or cluster analysis, allow determining specific zones within settlements that have similar risk levels and the same harmful factors, spotting out priority ones among such zones, and then determining reasons and sources of unacceptable health risks at later stages. Figure 1 provides an example map showing spatial distribution of risks over a given territory. Such approaches are extremely vital and interesting especially now when management of industrial emissions is in transition to principles of quoting[4].

It is important that development and practical application of the risk assessment methodology substantially increased the demand for results of social-hygienic monitoring. Thus, for example, according to E.E. Andreeva, A.V. Ivanenko with colleagues [26, 27], several vital managerial actions were taken in Moscow due to the improved system of social-hygienic monitoring and constant and systemic communications with decision-makers about results obtained by assessing health risks for people living in a megacity and exposed to harmful environmental factors. These actions resulted in positive medical and demographic trends, obvious stabilization or even a decrease in population incidence authentically associated with exposure to harmful environmental factors and a decline in frequency of severe diseases (perinatal pathology and congenital malformations, etc.).

S.V. Kuzmin with colleagues [28] show that more extensive use of the risk assessment methodology in the Sverdlovsk region ensured a substantial growth in the number of managerial decisions taken by regional and municipal authorities or by management of specific economic

[3] SanPiN 2.1.1.1200-03. Sanitarno-zashchitnye zony i sanitarnaya klassifikatsiya predpriyatii, sooruzhenii i inykh ob"ektov / utv. postanovleniem Glavnogo gosudarstvennogo sanitarnogo vracha RF ot 25 sentyabrya 2007 goda № 74 [Sanitary Rules and Norms SanPiN 2.1.1.1200-03. Sanitary protection zones and sanitary classification of enterprises, constructions and other objects (approved by the Order by the RF Chief Sanitary Inspector No. 74 dated September 25, 2007)]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/902065388 (August 30, 2022) (in Russian).

[4] O provedenii eksperimenta po kvotirovaniyu vybrosov zagryaznyayushchikh veshchestv i vnesenii izmenenii v otdel'nye zakonodatel'nye akty Rossiiskoi Federatsii v chasti snizheniya zagryazneniya atmosfernogo vozdukha: Federal'nyi Zakon ot 26.07.2019 № 195-FZ (prinyat Gosudarstvennoi Dumoi 17 iyulya 2019 goda, odobren Sovetom Federatsii 23 iyulya 2019 goda) [On accomplishing the experiment on quoting emissions of pollutants and making alterations into specific legal acts of the Russian Federation regarding reduction of ambient air pollution: The Federal Law issued on July 26, 2019 No. 195-FZ (approved by the State Duma on July 17, 2019, approved by the Federation Council on July 23, 2019)]. *KonsultantPlus*. Available at: http://www.consultant.ru/document/cons_doc_LAW_329955/ (August 30, 2022) (in Russian).

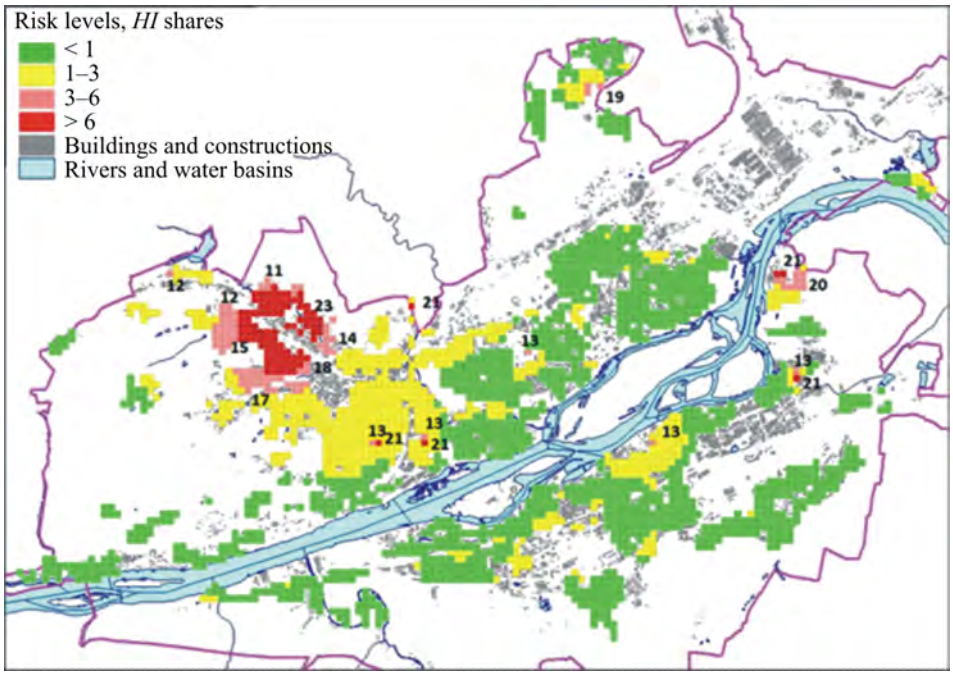


Figure 1. Zoning of a city territory as per levels of public health risks. Identification of zones with unacceptable risks of diseases of the immune system under exposure to ambient air pollution

entities and aimed at providing sanitary-epidemiological welfare of the population. Situations when consumers' rights were violated were settled according to pre-trial procedures by 1.3 times more frequently. A share of claims made by Rospotrebnadzor to defend unidentified individuals and satisfied by courts grew by 1.2 times.

Still, the most significant issues in public administration[5], including those related to sanitary-epidemiological welfare of the population, required substantial development of approaches stipulated by foreign methodical documents:

– declining quality of human potential in the country and insufficient human resources;

– ineffective public administration as regards reducing loads on businesses together with preserving proper protection of guarded social values;

– global climate change that poses potential threats for public health and living environment;

– growing variable environmental threats and hazards for public health due to wide use of harmful (including highly toxic) chemicals, their accumulation in the environment; new chemicals, biological agents and drugs being developed and implemented though their effects on people and the environment have not been studied enough; growing prevalence of antimicrobial resistance;

– growing intensity of physical environmental factors, noise, and electromagnetic radiation, especially on urbanized territories;

– many objects of accumulated environmental damage being located in close proximity to settlements, recreation zones, or agri-

[5] Edinyi plan po dostizheniyu natsional'nykh tselei razvitiya Rossiiskoi Federatsii na period do 2024 goda i na planovyi period do 2030 goda (utv. rasporyazheniem Pravitel'stva RF ot 01.10.2021 № 2765-r) [The Unified Plan on achieving national goals of the Russian Federation development for the period up to 2024 and for the planned period up to 2030 (approved by the RF Government Order dated October 01, 2021 No. 2765-r)]. *GARANT: information and legal support*. Available at: https://base.garant.ru/402929258/ (August 30, 2022) (in Russian); O natsional'nykh tselyakh i strategicheskikh zadachakh razvitiya Rossiiskoi Federatsii na period do 2024 goda: Ukaz Prezidenta RF ot 07.05.2018 g. № 204 [On national goals and strategic tasks of the Russian Federation development for the period up to 2024: the RF President Order dated May 07, 2018 No. 204]. *Prezident Rossii*. Available at: http://kremlin.ru/acts/bank/43027 (June 25, 2020) (in Russian); Ob Osnovakh gosudarstvennoi politiki Rossiiskoi Federatsii v oblasti obespecheniya khimicheskoi i biologicheskoi bezopasnosti na period do 2025 goda i dal'neishuyu perspektivu: Ukaz Prezidenta RF ot 11 marta 2019 g. № 97 [On the basics of the RF state policy in the sphere of providing chemical and biological safety for the period up to 2025 and beyond: The RF President Order dated March 11, 2019 No. 97]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/553849979 (June 25, 2020) (in Russian).

cultural land spots; such objects tend to be polluted heavily as a result of former economic activities that took place at them in the past, etc.

It is noteworthy that the Russian scientific and methodical base for health risk assessment was largely well-prepared to be used in public administration when all the aforementioned issues were first set. Over the period starting from 90ties last century, certain postulates were developed, provided with methodical support and prepared for implementation in practical activities. These provisions further developed the theory of health risk analysis, first of all, health risk assessment.

There are several Russian scientific innovations in the field. The most interesting ones are:

– development of quantitative health risk assessment, non-carcinogenic health risks included;

– severity of health disorders taken into account within health risk assessment;

– methodical support provided for assessing integral risks associated with variable functional disorders in the body under exposure to heterogeneous environmental factors;

– health risk assessment methodology applied to estimate combined exposure to environmental factors and harmful working conditions.

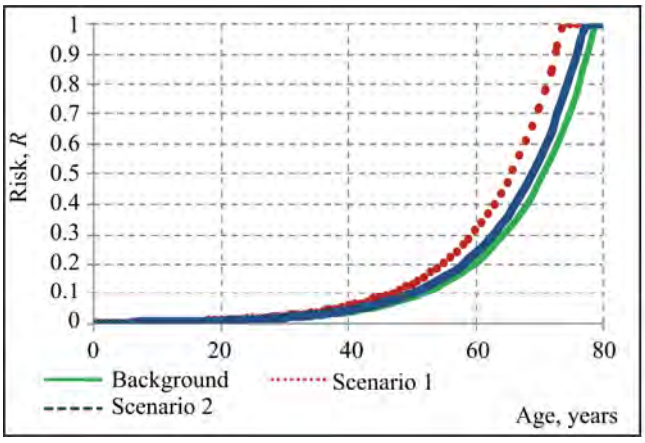
When developing quantitative risk assessment, Russian experts suggested and developed an idea that it was possible to model risk evolution and its growth under changing exposures [29, 30]. This approach was based on coordinated use of statistical and analytical models describing negative health outcomes caused by exposure to harmful environmental factors. Within this suggested approach, the human body was considered an open system consisting of a finite multitude of target organs that were tightly connected with each other and interacted with external factors. Risk evolution models were based on mathematical models that were repeatedly proven by experiments and epidemiological studies and were described in relevant research works. To implement the idea, differential calculus was needed. Essentially this new tool developed the risk assessment methodology and made it possible to perform numerical (virtual) experiments under preset exposure scenarios that involved any combination of harmful factors. Later the developed methodical approaches were applied to solve a whole set of managerial tasks.

Thus, the evolution model that described accumulating risks of functional disorders of various organs and systems was applied to substantiate a hygienic standard for ractopamine, an antibiotic used as a silage additive for farm animals, in foods [31]. The issue was associated with the necessity to give grounds for the opinion expressed by Russian hygienists who believed ractopamine should be strictly prohibited in any food. This was not in line with the *Codex Alimentarius* Decision stipulating allowable ractopamine contents from 0.01 to 0.09 mg/kg in various meat and meat products[6].

Russian hygienists used evolution modeling and made an effort to predict ractopamine accumulation in the body. This allowed them to prove that a maximum permissible daily dose taken as a basis for establishing maximum permissible level of ractopamine was within 0–1 μg/kg of body weight, that is, it did not differ authentically from zero and could not be used as a ground to establish hygineic standards for ractopamine contents in meet products (Figure 2). Basic postulates of the methodology were applied to substantiate maximum pertmissible levels of tetracycline antibiotics [32]. To do that, several models were used to describe how imbalance was developing in gut microbiota resulting in digestive diseases, dermatitis, or food allergy (Figures 3 and 4).

Overall, we have this available Russian methodology for health risk assessment harmonized with methodical approaches applied worldwide. Use of this methodology to substantiate hygienic standards has already become a considerable advantage in upholding the sovereign standards existing in Russia and the EAEU member states in discussions held by such international organizations as the FAO, WHO etc. Without doubt, this advantage will be retained in future.

[6] Joint FAO/WHO Food Standard Programme Codex Alimentarius Commission. 35th Session. Rome, Italy, July 2–7, 2012, pp. 87–120.



$$R_{t+1} = R_t + (\alpha \cdot R_t + \beta \cdot D)C$$

Recurrence equation showing accumulating risks of functional disorders of the cardiovascular system (non-carcinogenic risk)

R_{t+1} is a risk of disorders at the moment t+1;
R_t is a risk of disorders at the moment t;
α is a coefficient for risk evolution due to natural causes;
β is a coefficient for ractopamine effects;
C is a time empirical coefficient (C = 0.00274 for daily averaging);
D is a ractopamine dose [µg/kg].

Figure 2. Results obtained by modeling health risk evolution under various exposure scenarios

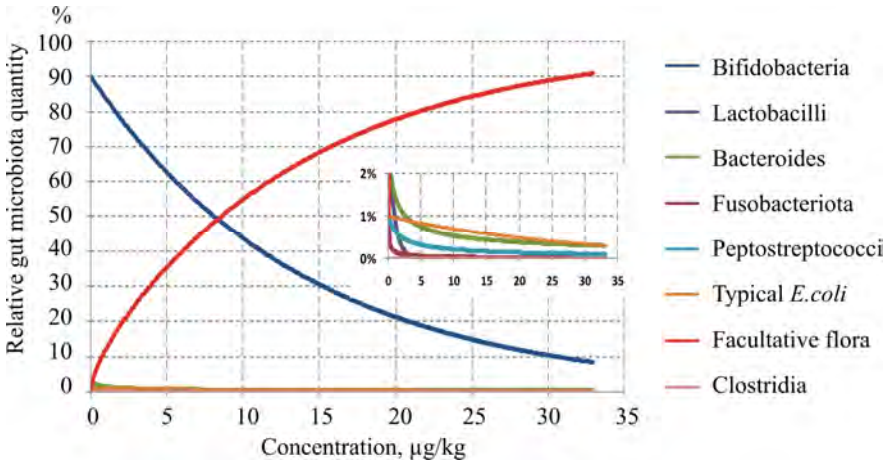


Figure 3. Dependence of relative gut microbiota abundance (%) on tetracycline concentration

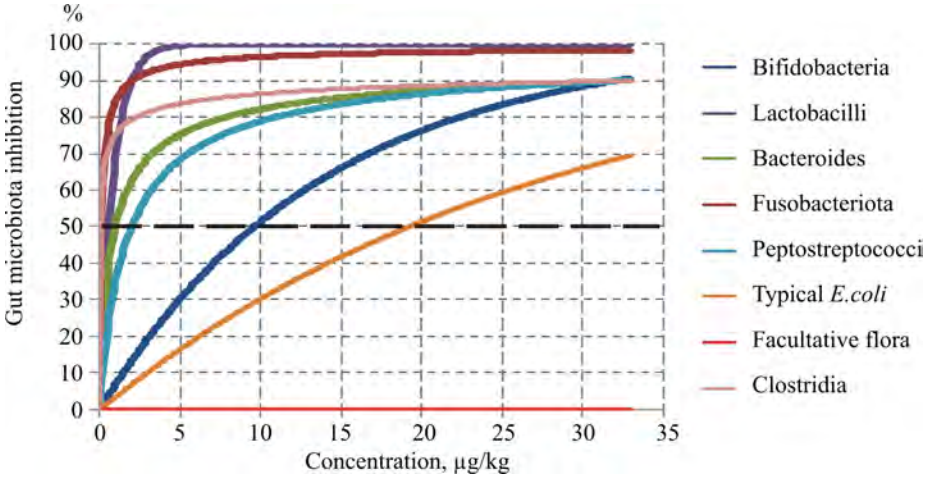


Figure 4. Models describing relationships between tetracycline concentrations and inhibition of growth for various bacteria

Efforts are being taken to develop practical use of the methodology for health risk assessment to solve tasks associated with hygienic standardization and establishing improved hygienic standards for concentrations of certain chemicals in the environment. Thus, a new type of maximum permissible concentrations has been developed and implemented, namely, maximum permissible concentrations of pollutants in ambient air with yearly averag-

ing ($MPC_{av.an.}$)[7]. Such MPC are substantiated with health risk criteria and they ensure acceptable (permissible) risks regarding both non-carcinogenic (HQ ≤ 1) and carcinogenic ($CR \leq 1 \cdot 10^{-4}$) effects [33, 34]. The methodical approaches applied to substantiate $MPC_{av.an}$ of chemicals in ambient air are fully harmonized with international approaches to developing hygienic standards, including reference concentrations used as indicators in risk assessment. By now, the Sanitary Rules and Norms SanPiN 1.2.3685-21 "Hygienic standards …"[7] contain average annual MPC for 72 chemical pollutants in ambient air. Conformity with these standards ensures life-time absence of unacceptable health risks for population, sensitive groups included.

Studies with their focus on effects produced by working conditions on workers' health have become another important trend in scientific development of the methodology for health risk assessment. This is due to a substantial contribution made by diseases associated with working conditions to losses of economic activity that were considerably higher than similar losses caused by occupational incidence [35].

A lot of attention is also given to developing methods for quantitative assessment of occupational risks as a function of likelihood and severity of negative health outcomes in workers. Experts have suggested methodical approaches to assessing health risks for workers considering cause-effect relations between health disorders and work and using epidemiological studies for such assessment [36].

Results of semi-quantitative (as per categories of working conditions, indexes of occupational diseases (I_{OD}) and work-related diseases (I_{WRD})) and quantitative risk assessment made it possible to substantiate new principles in determining a category of an occupational risk and analyzing its acceptability (Table).

As before, if a risk is assigned into "negligible" or "low" category, it means this risk is acceptable. Such an assessment fully correlates with the Guide "Human Health Risk Assessment from Environmental Chemicals" [8] where a risk level equal to $1 \cdot 10^{-3}$ is considered acceptable for occupational groups.

Table

Categories of occupational risks determined as per the results of its semi-quantitative and quantitative assessment

Category of working conditions	I_{OD}	I_{WRD}	Quantitative levels of occupational risks	Category of an occupational risk
Optimal – 1	Lower than 0.05	Lower than 0.05	Lower than $1 \cdot 10^{-4}$	Negligible risk
Permissible – 2	0.05–0.1	0.05–0.1	$1 \cdot 10^{-4}$–$1 \cdot 10^{-3}$	Low risk
Harmful – 3.1	0.1–0.2	0.1–0.2	$1 \cdot 10^{-3}$–$1 \cdot 10^{-2}$	Moderate risk
Harmful – 3.2	0.2–0.4	0.2–0.4	$1 \cdot 10^{-2}$–$3 \cdot 10^{-2}$	Average risk
Harmful – 3.3	0.4–0.6	0.4–0.6	$3 \cdot 10^{-2}$–$1 \cdot 10^{-1}$	High risk
Harmful – 3.4	0.6–0.8	0.6–0.8	10^{-1}–$3 \cdot 10^{-1}$	Very high risk
Hazardous – 4	Higher than 0.6	Higher than 0.6	$3 \cdot 10^{-1}$–1	Extremely high risk

[7] SanPiN 1.2.3685-21. Gigienicheskie normativy i trebovaniya k obespecheniyu bezopasnosti i (ili) bezvrednosti dlya cheloveka faktorov sredy obitaniya (utv. postanovleniem Glavnogo gosudarstvennogo sanitarnogo vracha RF ot 28 yanvarya 2021 goda № 2) [Sanitary Rules and Norms SanPiN 1.2.3685-21. Hygienic standards and requirements to providing safety and (or) harmlessness of environmental factors for people (approved by the Order by the RF Chief Sanitary Inspector No. 2 dated January 28, 2021)]. *KODEKS: electronic fund for legal and reference documentation.* Available at: https://docs.cntd.ru/document/573500115 (August 30, 2022) (in Russian).

[8] Guide R 2.1.10.1920-04. Human Health Risk Assessment from Environmental Chemicals (approved and implemented by the Order of G.G. Onishchenko, the RF Chief Sanitary Inspector and the First Deputy to the RF Public Healthcare Minister on March 5, 2004). *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/1200037399 (August 30, 2022) (in Russian).

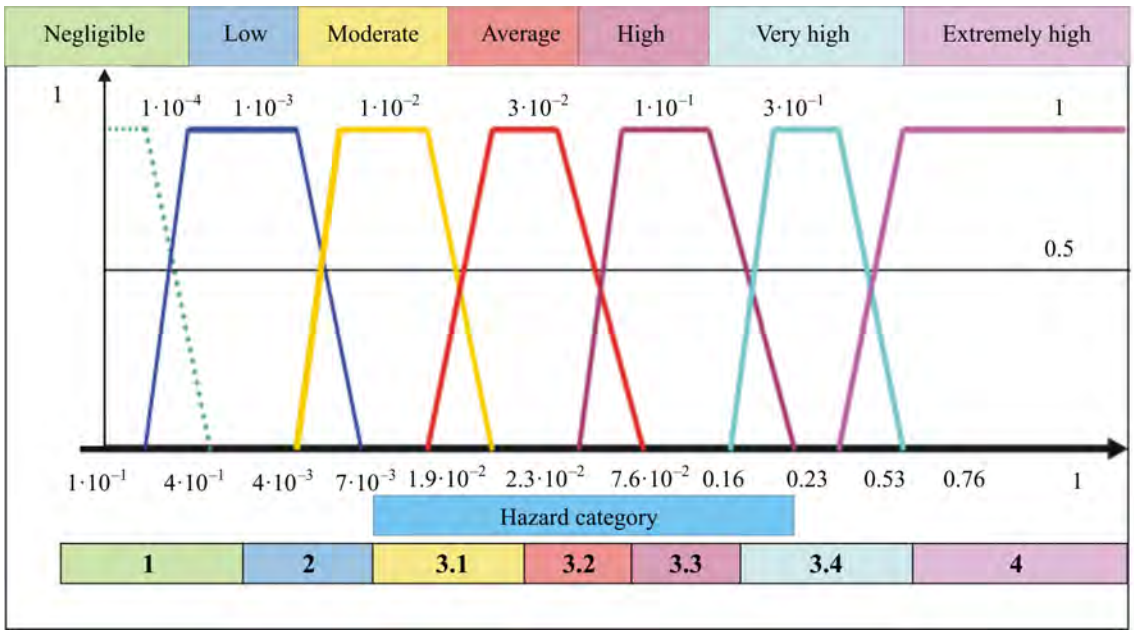


Figure 5. Graphic image of the scale showing trapezoid fuzzy numbers to determine an occupational risk category

Methods for assessing and predicting personified occupational risks are being developed to optimize occupational risk prevention. Such personified assessment considers age and work records of each worker. Results obtained by determining a category of a personified occupational risk can be clarified by applying probabilistic estimates, for example, the fuzzy set theory (Figure 5).

This method has great potential when it is used to create occupational risk groups for priority targeted medical and prevention activities given the predicted increase in risk levels.

An approach to risk assessment based on evolution models has turned out to be interesting, new and relevant when considering noise as a harmful environmental factor[9]. In contrast to models based on relative risk assessment or probit analysis, this approach offers to assess aggregated risks of cardiovascular disorders, disorders of the nervous system and the hearing organs. The assessment integrates both Russian and foreign data on how these effects are developing in dynamics against natural ageing of the body. Finding a solution to the system of recurrent equations made it possible to identify periods when exposure to noise was harmless (periods of acceptable risk) as well as to predict moments when a risk moved on to a fundamentally new level (a low risk became moderate; a moderate risk became high; etc.) [37]. Such assessments are in high demand by experts and ensure clear understanding when it can be or must be time to take sanitary-hygienic, technical, technological, or any other actions aimed at protecting population.

Studies that address assessment of risks associated with effects produced on health by lifestyle factors are also an interesting and promising new trend in the development of the risk assessment methodology [38]. A formalized social survey was included into the risk assessment algorithm. This stage in risk assessment was aimed at identifying risk factors and selecting those posing the highest threats, quantitative indicators considered, as well as estimating "factor – effect" relationships and

[9] MR 2.1.10.0059-12. Otsenka riska zdorov'yu naseleniya ot vozdeistviya transportnogo shuma (utv. rukovoditelem Federal'noi sluzhby po nadzoru v sfere zashchity prav potrebitelei i blagopoluchiya cheloveka Glavnym gosudarstvennym sanitarnym vrachom RF G.G. Onishchenko 23 marta 2012 g.) [The Methodical Guidelines MR 2.1.10.0059-12. Assessment of health risks caused by exposure to transport noise (approved by G.G. Onishchenko, the RF Chief Sanitary Inspector and the Head of the federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing on March 23, 2012)]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/1200095849 (August 30, 2022) (in Russian).

obtaining quantitative or semi-quantitative risk characteristics.

"Factor – effect" relationships were obtained for certain lifestyle factors (active and passive smoking, alcohol abuse, unhealthy diets) on the basis of evolutionary deterministic models that described relationships between lifestyle factors and both specific and aggregated health outcomes. These models were built based on the results of meta-analysis that covered foreign and domestic empirical studies (including those performed by the World Health Organization (WHO), the International Agency for Research on Cancer (IARC), the US National Center for Health Statistics (NHANES)). The methodology was applied to assess risks associated with "traditional" lifestyle factors (smoking, alcohol abuse, poor physical and motor activity, and unhealthy diets) and we should note that previously such risks were predominantly assessed with "odds ratio", a statistical indicator. In addition to these factors, the suggested methodology also involved semi-quantitative assessment of risks associated with irresponsible medical and hygienic behavior, use of drugs and nonnarcotic psychoactive substances. Experts introduced a method to give score estimates to a risk-creating potential of specific components in the aforementioned factors. The method should be used when calculating separate and integrated indexes of health disorders probability. The approaches were fixed in the methodical document issued by Rospotrebnadzor[10] and implemented into practical activities performed by regional offices of the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing (the Krasnoyarsk region, Arkhangelsk region, Irkutsk region, Voronezh region, etc.) [39–41].

The development of the methodology for health risk assessment also entailed providing scientific grounds for transition in spreading results of health risk assessment. This transition was from one-side informing of stakeholders (population, local authorities, economic entities etc.) about risk assessment results to a dialogue-based risk communication model. New approaches are based on transparency, trust, and mutual understanding; they ensure "communication between equals" and a partner dialogue. This corresponds to the contemporary concept of consensus-oriented public relations, which is very popular now in developed countries. These approaches have been fixed in several methodical documents approved by the Head of the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing[11].

It is noteworthy that progressive development of the risk assessment methodology taking place in 1990–2010 ensured operative, smooth, and effective transition of control and surveillance activities performed by Rospotrebnadzor onto a fundamentally new control platform that relies on the risk-based model. The old concept of control that previously stipulated unified frequency of inspections that should be performed at all economic entities at least once every three years[12] was replaced

[10] MR 2.1.10.0033-11. Otsenka riska, svyazannogo s vozdeistviem faktorov obraza zhizni na zdorov'e naseleniya (utv. Rukovoditelem Federal'noi sluzhby po nadzoru v sfere zashchity prav potrebitelei i blagopoluchiya cheloveka Glavnym gosudarstvennym sanitarnym vrachom RF G.G. Onishchenko 31 iyulya 2011 g.) [The Methodical Guidelines 2.1.10.0033-11. Assessment of health risks associated with impacts exerted on public health by lifestyle-related factors (approved by G.G. Onishchenko, the RF Chief Sanitary Inspector and the Head of the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing on July 31, 2011)]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/1200111974 (August 30, 2022) (in Russian).

[11] MR 2.3.2/2.3.7.0123-18. Sistema informirovaniya o riskakh ostatochnogo kolichestva antibiotikov v pishchevykh produktakh (utv. Rukovoditelem Federal'noi sluzhby po nadzoru v sfere zashchity prav potrebitelei i blagopoluchiya cheloveka, Glavnym gosudarstvennym sanitarnym vrachom RF A.Yu. Popovoi 1 marta 2018 g.) [The Methodical Guidelines MR 2.3.2/2.3.7.0123-18. The system for informing about risks associated with residual contents of antibiotics in foods (approved by A.Yu. Popova, the RF Chief Sanitary Inspector and the Head of the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing on March 1, 2018)]. *Biblioteka normativnoi dokumentatsii*. Available at: https://files.stroyinf.ru/Data2/1/4293736/4293736537.htm (August 30, 2022) (in Russian).

[12] O zashchite prav yuridicheskikh lits i individual'nykh predprinimatelei pri osushchestvlenii gosudarstvennogo kontrolya (nadzora) i munitsipal'nogo kontrolya: Federal'nyi zakon ot 26.12.2008 № 294-FZ [On protecting rights of juridical persons and private entrepreneurs when accomplishing state control (surveillance) and municipal control: The Federal Law issued on December 26, 2008 No. 294-FZ]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/565415215 (August 30, 2022) (in Russian).

with a new one stating that frequency of inspections should correspond to actual risks of health harm created by a specific economic entity[13]. This replacement fully corresponded to goals and tasks the sanitary service in the country had to achieve and tackle.

Algorithms and methods with their aim to assign objects under sanitary-epidemiological surveillance into specific risk categories [42] facilitated substantial development of approaches to risk-based surveillance. They conformed to all the provisions fixed in the Federal Law "On protecting the rights of juridical persons and private entrepreneurs when performing state control …" that was valid at that moment.

The algorithm for risk assessment and assigning objects under surveillance into specific risk categories was based on two fundamental principles:

– a risk of health harm occurs when an object under surveillance violates the sanitary legislation;

– violation of the legislation that regulates sanitary-epidemiological welfare results in deteriorating quality of the environment (including lower safety of goods and services) and associated likelihood of health disorders in population, workers, or consumers.

A key idea in this innovative approach was an effort to avoid expert score estimates that were accepted by many federal authorities when they differentiated objects under surveillance as per risk categories.

It was offered to calculate a potential risk of health harm when determining a risk category of an object under surveillance $R_i\,(l)$ in full conformity with the classical definition of a risk as a combination of a probability that the sanitary legislation would be violated *p(l)* and severity of negative health outcomes (*u(l)* as an indicator describing health harm):

$$R_i\,(l) = p(l) \cdot u(l) \cdot M_i\,. \qquad (1)$$

The approach was based on analyzing long-term statistical data on the results of control and surveillance activities performed both at the federal level and in specific RF regions. A probability that the sanitary legislation would be violated was estimated as 95 % percentile of the distribution of regional relative frequency of violations detected during one inspection.

An indicator that described health harm when the sanitary legislation was violated at objects under surveillance was determined by performing system analysis of cause-effect relations in the "frequency of law violations – prevalence of health disorders" system. Targeted science-intensive studies accomplished specifically to solve issues related to creation of a model for risk-based control made it possible to obtain more than a thousand authentic relationships. These relationships confirmed that violations of the mandatory sanitary-epidemiological requirements produced negative effects on population mortality and incidence. Health disorders were differentiated as per their severity in accordance with the documents issued by the World Health Organization [43]. Severity for a group of diseases was calculated considering the structure of each category of nosologies in the Russian Federation over the last three years separately for children, adults of working age, and people older than working age. A scope of impacts exerted by an object under surveillance was considered a unique value typical for activities performed by a specific object under surveillance; this value was determined by a number of people influenced by a given object.

Such an approach to determining a risk category of an object under surveillance was quite new in the country and a practice when Rospotrebnadzor considered negative health outcomes in population was fundamentally different from those accepted by other surveillance authorities. The algorithm and assessment procedures were fixed in the methodical

[13] O gosudarstvennom kontrole (nadzore) i munitsipal'nom kontrole v Rossiiskoi Federatsii: Federal'nyi zakon ot 31 iyulya 2020 goda № 248-FZ [On the state control (surveillance) and municipal control in the Russian Federation: The Federal Law issued on July 31, 2020 No. 248-FZ]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/565415215 (August 30, 2022) (in Russian).

guidelines[14] where objects under surveillance were assigned into six different categories (starting form objects that caused an extremely high risk down to those with low risks) and were differentiated accordingly as per frequency and contents of scheduled control activities.

We should note that experts from the Higher School of Economics analyzed approaches to creating models of risk-based control accepted by different authorities and concluded that "*... the system for risk assessment used within sanitary-epidemiological surveillance is the only one assessment methodology that relies on a qualitative mathematical apparatus. This makes it possible to determine quantitative values of risks...*"[15]. These approaches were tested in pilot regions and then in the country as a whole and, as a result, it was determined that the share of objects that could create "extremely high risks" or, in other words, objects that were subject to the most strict (annual) control amounted to approximately 0.5–3.0 % of the total number of objects under surveillance in the country (depending on a region). Typically, such objects supplied drinking water to large cities or densely populated territories; they could also be industrial enterprises of the 1st or 2nd category according to the sanitary classification located within settlements or food-producing enterprises with high production outputs etc. From 4 to 9 % of objects under surveillance were classified as objects with high risks and they were subject to control every two years. From 20 to 40 % of all the registered objects under surveillance were determined as objects with low risks and any scheduled control activities were not mandatory for them. Thus, several years after the risk-based model was implemented into practice, scheduled surveillance was established to be unnecessary for approximately 54 % of transport infrastructure objects; approximately 44 % of objects rendering communal, individual and social services; approximately 33 % of industrial enterprises; etc. Overall, since 2017 a volume of scheduled inspections went down by 20 % in the country.

Businesses stated that the results were in line with their expectations; however, public values were not sacrificed in the process. Annual surveillance activities are performed exactly at those objects that can create the highest health risks [44].

This system is dynamic and "alive"; there are mechanisms for systemic review of risk assessment results. The latter is due to the developing legislative base, changes in violations of the mandatory sanitary requirements and "law-obedience" of economic entities all over the country.

The applied approaches turned out to be even in higher demand after the Federal Law "On state control (surveillance)" No. 248-FZ came into force on June 01, 2021. This law determines not only "activity" but also "production facilities" and "products" as objects under surveillance.

The risk calculation model was a universal one and this allowed developing an algorithm for determining hazard categories of products distrib-

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[14] MR 5.1.0116-17. Risk-orientirovannaya model' kontrol'no-nadzornoi deyatel'nosti v sfere obespecheniya sanitarno-epidemiologicheskogo blagopoluchiya. Klassifikatsiya khozyaistvuyushchikh sub"ektov, vidov deyatel'nosti i ob"ektov nadzora po potentsial'nomu risku prichineniya vreda zdorov'yu cheloveka dlya organizatsii planovykh kontrol'no-nadzornykh meropriyatii (utv. i vved. v deistvie Rukovoditelem Federal'noi sluzhby po nadzoru v sfere zashchity prav potrebitelei i blagopoluchiya cheloveka, Glavnym gosudarstvennym sanitarnym vrachom RF A.Yu. Popovoi 11 avgusta 2017 g.) [The Methodical Guidelines MR 5.1.0116-17. The risk-based model for control and surveillance activities in the sphere of providing sanitary-epidemiologic well-being. Ranking economic entities, types of activities, and objects under surveillance as per potential risks of damage to health for organizing scheduled control and surveillance activities (approved and implemented by A.Yu. Popova, the RF Chief Sanitary Inspector and the Head of the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing on August 11, 2017)]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/555601296 (August 30, 2022) (in Russian).

[15] Plaksin S.M., Zuev A.G., Knutov A.V., Maksimova S.I., Polesskii E.A., Semenov S.V., Trifonov V.A., Chaplinskii A.V., Shabala Yu.I. Kontrol'no-nadzornaya deyatel'nost' v Rossiiskoi Federatsii: Analiticheskii doklad 2015 [Control and surveillance activities in the Russian Federation: Analytical report 2015]. Moscow, The analytical center of the RF Government, 2016, pp. 58 (in Russian).

uted on the consumer market and to fix it in the methodical guidelines issued by the Service[16].

Actual frequency of cases when mandatory requirements to product safety were violated, severity of outcomes caused by these violations and a number of consumers who used this or that product were considered in full conformity with the previously developed conceptual approaches. The methodology was flexible and objective and therefore different from subjective expert estimates typical for most classifications of consumer products as per risks of damage to health accepted abroad.

In addition, the methodology gave an opportunity to consider changing parameters of probability that mandatory requirements to product safety would be violated, severity of consequences and volumes in which this or that product was consumed. This made it even more relevant and provided a unified methodical ground for creating federal and regional registers of products assigned into different categories as per health risks they could cause.

The structure of these categorized registers was different in different regions (Figure 5) and this made it possible to spot out local priorities and adjust regional control and surveillance over products for the sake of providing safety for people living in a given region [45, 46].

Undoubtedly, the risk-based model of control and surveillance activities has good prospects for further development. A quite actual and relevant task is to create "risk profiles" of objects under surveillance as a systematized description of a risk area created by a typical object, risk indicators, and priority factors [47]. This will make it possible to raise predictive significance of risk assessment substantially, make control activities more targeted and reduce financial expenses necessary to perform them, laboratory tests included.

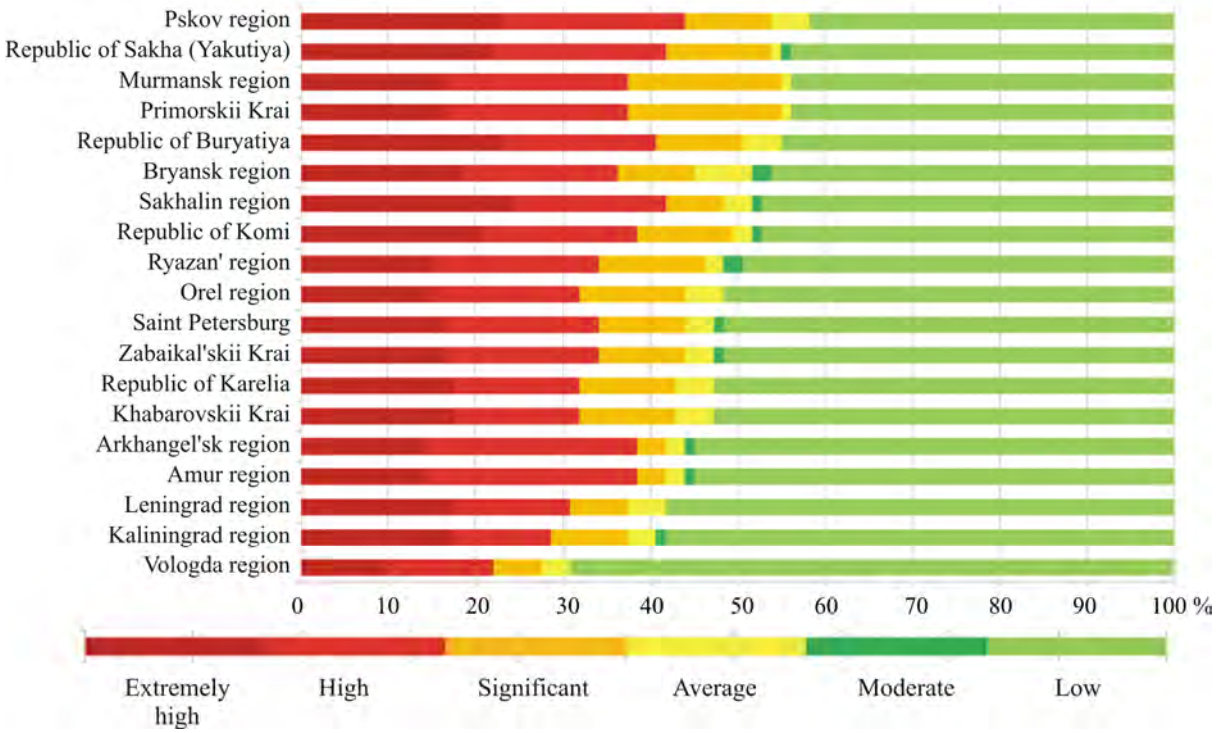

Figure 5. Comparative analysis of the structure of risk categories identified for foods distributed in the RF regions: a fragment (2021)

[16] O vnedrenii Metodicheskikh rekomendatsii «Klassifikatsiya pishchevoi produktsii, obrashchaemoi na rynke, po risku prichineniya vreda zdorov'yu i imushchestvennykh poter' potrebitelei dlya organizatsii planovykh kontrol'no-nadzornykh meropriyatii»: Prikaz Rospotrebnadzora ot 18.01.2016 № 16 [On implementation of the Methodical guidelines "Classification of foods distributed on the market as per health risks for consumers and risks of consumers' financial losses for organization of scheduled control and surveillance activities": The Order by Rospotrebnadzor dated January 18, 2016 No. 16]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/420332234 (August 30, 2022) (in Russian).

Any “risk profile” of an object under surveillance, be it an activity, a production facility, or a product, should be substantiated and provided with quantitative description. This requires complete and systemically collected data on typical objects and tools for analyzing them. Given that, when Rospotrebnadzor’s Unified Information and Analytical System is implemented and filled with data, this can become a starting point for a new stage in the development and practical application of the risk assessment methodology within activities performed by the Sanitary Service in the country.

Overall, the methodology for health risk assessment is becoming more and more relevant in variable spheres related to providing sanitary-epidemiological welfare. Primarily, this is due to public health being declared a key value in the country and a top criterion to estimate effectiveness of the public administration. Thus, for example, a health risk is considered a component in substantiating lists of priority chemicals within the “Clean Air” Federal project[17]. Emissions of such priority chemicals should be reduced immediately and their concentrations in ambient air require mandatory control and monitoring.

A risk for public health and life expectancy at birth is among basic arguments to label an object of accumulated environmental health as being subject to immediate elimination within the “General cleaning” Federal project[18].

There are multiple variable objects of accumulated environmental damage located all over the country. They often tend to have existed without an owner for a long time and this leads to substantial changes in their initial conditions. All this required fundamentally new approaches to assessing public health risks. The task got even more complicated due to the necessity to accomplish it in a very short time and insufficient information database on essence and levels of exposure. The suggested approaches based on the fuzzy set theory made it possible to include both quantitative and qualitative variables into risk assessment procedures. These variables fully described each given object and hazards posed by its existence for public health [48]. To assess influence exerted by each indicator on public health, experts applied scales that graded a health hazard considering weight contributions made by separate indicators and a group of indicators as a whole (component risks of separate indicators and a group as a whole) to the aggregated health risk created by a given object. Experts strictly followed the principle that types and severity of potential functional disorders of critical organs and systems should be considered when examining impacts of pollution created by a specific object. These approaches were fixed in the methodical document issued by Rospotrebnadzor[19] and they are being applied when more than 190 objects of accumulated environmental damage located all over the country are now being assessed and assigned into a specific category.

Undoubtedly, a promising trend in the development of the risk assessment methodology is integration of risk assessment and epidemiological studies, data on actual population incidence in a given city and (if available) results of specialized biomedical studies

[17] Natsional'nyi proekt «Ekologiya» (utv. Minprirody Rossii) [“Ecology” National project (approved by the RF Ministry of the Environment and Natural Resources)]. *KonsultantPlus*. Available at: http://www.consultant.ru/document/cons_doc_LAW_394077/0b83e7b8d6b58016a40c77f7619b332b159d076e/ (August 08, 2022) (in Russian).

[18] Pasport federal'nogo proekta «General'naya uborka» [The profile of the “General cleaning” Federal project]. *Pravitel'stvo Rossii*. Available at: http://static.government.ru/media/files/DoFhF6zbaji5mAKgkefAjTssLoyUOyS.pdf (August 08, 2022) (in Russian); Ob utverzhdenii kriteriev i sroka kategorirovaniya ob"ektov, nakoplennyi vred okruzhayushchei srede na kotorykh podlezhit likvidatsii v pervoocherednom poryadke: Prikaz Ministerstva prirodnykh resursov i ekologii RF ot 4 avgusta 2017 goda № 435 [On Approval of the criteria and the term categorizing objects of accumulated environmental damage elimination of which is the top priority: The Order by the RF Ministry of Natural Resources and the Environment issued on August 4, 2017 No. 435]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/456089663 (August 24, 2022) (in Russian).

[19] MR 2.1.10.0273-22. Otsenka vozdeistviya ob"ektov nakoplennogo vreda okruzhayushchei srede na zdorov'e grazhdan i prodolzhitel'nost' ikh zhizni, v tom chisle s vozmozhnost'yu ekspress-otsenki (utv. Glavnym gosudarstvennym sanitarnym vrachom RF 20.01.2022) [The Methodical Guidelines 2.1.10.0273-22. Assessment of impacts exerted by objects of accumulated environmental damage on people’s health and life expectancy, express estimations included (approved by the RF Chief Sanitary Inspector on January 20, 2022)]. *KonsultantPlus*. Available at: http://www.consultant.ru/document/cons_doc_LAW_423034/ (August 24, 2022) (in Russian).

on those health disorders that are classified as dependent on pollution levels or influence exerted by risk factors.

It seems advisable to share risk assessment results and discuss them with economic entities; these discussions should cover all the detected discrepancies between declared emissions, calculated pollution levels and an actual sanitary-hygienic situation in a given city. In case it is impossible to make health risks acceptable due to technical and / or organizational insufficiency, medical and preventive activities are recommended as compensatory actions until the environment is made truly safe and qualitative [49, 50].

Overall, we should note that analytical opportunities offered by the methodology for health risk assessment are quite extensive. Development of methodical grounds in hygiene and epidemiology as well as design of applied algorithms and approaches to risk assessment and management based on the fundamental methodology should involve several trends. They may be as follows:

– extending our knowledge on mechanisms of health disorders under exposure to heterogeneous environmental factors and work-related ones together with assessing likelihood of their occurrence;

– improving hygienic standardization of environmental and work-related factors;

– situational modeling and prediction of sanitary-epidemiological welfare under changing or preset conditions (economic, social, environmental, etc.);

– estimating probabilistic socioeconomic losses due to exposure to risk factors;

– providing substantiation for the strategic and tactical regulatory actions aimed at managing threats and risks for public health;

– anticipatory development of procedures for assessing and managing health risks associated with potentially hazardous risk factors created by new technologies and products (nanotechnologies, new foods etc.);

– assessing effectiveness of all the regulatory actions aimed at minimizing harmful impacts on human health.

The experience accumulated in developing the health risk assessment methodology in variable spheres should be considered a starting point for creating new risk assessment and risk management technologies. They should give an opportunity to solve any tasks related to providing sanitary-epidemiological welfare of the population in the Russian Federation.

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