## PREVENTIVE MEDICINE: **URGENT ASPECTS OF RISK ANALYSIS**

Universal Decimal Classification (UDC) 614.3

## PROBLEMS AND PROSPECTS FOR MAINTAINING THE REGISTER OF SANITARY AND EPIDEMIOLOGICAL OBJECTS OF SURVEILLANCE FOR THE TASKS OF THE TRANSITION TO RISK-ORIENTED MODEL OF ACTIVITY

N.V. Zaitseva<sup>1</sup>, I.V. May<sup>1</sup>, D.A. Kiryanov<sup>1</sup>, S.V. Babina<sup>1</sup>, A.S. Kriga<sup>2</sup>, E.L. Ovchinnikova<sup>2</sup>, V.A. Bondaryov<sup>3</sup>, E.A. Golovanova<sup>3</sup>, A.S. Sboev<sup>4</sup>, L.N. Akimova<sup>4</sup>

<sup>1</sup> FBSI "Federal Scientific Center for Medical and Preventive Health Risk Management Technologies",

Russian Federation, Perm, 82, Monastyrskaya St., 614045,

<sup>2</sup>Administration of Rospotrebnadzor in Omsk region,

Russian Federation, Omsk, 98, St. 10 years of October, 644991,

<sup>3</sup> Administration of Rospotrebnadzor in Lipetsk region, Russian Federation, Lipetsk, St. Gagarina, 60a, 398002,

<sup>4</sup> Administration of Rospotrebnadzor in Perm region, Russian Federation, Perm, 50, St. Kuibysheva, 614016

The article describes the approaches to the formation of regional databases of the objects of sanitary-epidemiological surveillance for the tasks of sequential evaluation of each object having the potential risk to the citizens of the affected areas of these objects, e.g. workers, consumers of products or services. The basic structure of the information system is demonstrated. The system is oriented to be used together with the DBMS MS Access. The system performs the manual quiding function for the register and implements the calculation algorithm of the health risk indicators and classification of the objects of surveillance. Approaches to the formation of the system have been tested in Perm, Lipetsk, Kaluga, Omsk regions as part of a pilot project of the Federal Service on Surveillance for Consumer rights protection and human well-being.

The problems of the registers' formation are in the fact of scares operational entering of the significant amount of information, that has been accumulated in Administration offices of Rospotrebnadzor, but do not exist in the form of electronic databases. The relevant issue is the development of guidance documents to ensure unified approaches to the registers' formation and risk calculation in relation to population census under the influence of various activities.

Key words: objects of surveillance, risk-oriented model, registers, information system.

Transition to the risk-oriented model of activity of the Federal Service for Consumer Rights Protection and Human Well-Being Surveillance is performed increasing the openness of service for business so-

Δ

in accordance with strategic changes in the state management system [1, 2, 5] and is accompanied by

<sup>©</sup> Zaitseva N.V., May I.V., Kiryanov D.A., Babina S.V., Kriga A.S., Ovchinnikova E.L., Bondaryov V.A., Golovanova E.A., Sboev A.S., Akimova L.N., 2015

Zaitseva Nina Vladimirovna- Fellow of the Russian Academy of Sciences, MD, Professor, Director (e-mail: znv@fcrisk.ru; tel. +7 (342) 237-25-34).

May Irina Vladislavovna- DSc, Professor, Deputy Director for Research (e-mail: may@fcrisk.ru; tel. +7 (342) 237-25-47). Kiryanov Dmitry Aleksandrovich- PhD in Engineering, Head of Department of Systems and Processes Mathematical Modeling (e-mail: kda@fcrisk.ru; tel. +7 (342) 237-18-04).

Babina Svetlana Vladimirovna- Head of the Information and Computing Systems and Technologies Laboratory (e-mail: bsv@fcrisk.ru; tel. +7 (342) 237-18-04).

Kriga Alexandr Sergeevich- Head of the Administration of the Federal Service on Surveillance for Consumer rights protection and human well-being in Omsk region, chief sanitary officer in Omsk region (e-mail: rpn@55.rospotrebnadzor.ru; tel. +7 (3812) 32-60-32).

Ovchinnikova Elena Lvovna- Deputy Head of Department for surveillance organization and activity provision for Administration of Rospotrebnadzor in Omsk region (e-mail: el-omsk@yandex.ru; tel. +7 (3812)32-60-20).

Bondarev Vladimir Aleksandrovich- Head of the Administration of the Federal Service on Surveillance for Consumer rights protection and human well-being in Lipetsk region, state chief sanitary officer in Lipetsk region (e-mail: admin@48.rospotrebnadzor.ru; tel. +7 (4742) 27-47-65).

Golovanova Elena Alekseevna- assistant Head (e-mail: golovanova ea@48.rospotrebnadzor.ru; tel. +7 (4742) 27-47-65).

Sboev Alexandr Sergeevich- Head of the Administration of the Federal Service on Surveillance for Consumer rights protection and human well-being in Perm region, state chief sanitary officer in Perm region (e-mail: urpn@59.rospotrebnadzor.ru; tel. +7 (342) 239-35-63).

Akimova Lyudmila Nikolaevna- Deputy Head of the Administration of the Federal Service on Surveillance for Consumer rights protection and human well-being in Perm region, (e-mail: urpn@59.rospotrebnadzor.ru; tel. +7 (342) 239-35-63).

ciety, citizens, public associations, governmental and local authorities [5, 11].

Both the replacement of the control and surveillance paradigm and the openness of the federal controlling bodies are provided by the draft of the Federal Law "On the basics of the state and municipal control and surveillance in the Russian Federation". The document declares that the selection of the objects of state and municipal control and surveillance and determination of the frequency of measures shall be carried out based on the assessment of degree of the potential hazard of objects. The draft of the law establishes the requirements to accounting, documenting and analysis of the results of control and supervisory measures, ensuring the transparency and subordination in relation to the activity of controlling bodies.

Therefore, the controlling bodies as well as Rospotrebnadzor are faced the task of justified and transparent selection of priorities during the control performance. Herewith the control and supervisory actions shall finally ensure the effective management in relation to minimizing the risks to the life and health of population.

The draft law provisions implementation requires the creation and maintenance of the industry-specific risk registers, development of algorithms, standards, regulations and guidances on the conduction of control and supervisory measures based on the risk approach.

The guidelines "Risk-oriented model of control and supervisory activity in the field of sanitary and epidemiological well-being. Classification of the types of activity and economic entities under the potential risk of infliction of harm to the health of human in order to organize the planned control and supervisory measures" [4] approved by the Order of the Head No. 1302 dd. December 26, 2014 in their fundamental provisions and approaches completely meets the planned changes in the legislation. Most likely, the document will require some revision in order to bring it to compliance with normative act of higher level (it can include the terminological updating of document, introduction of supplements to the classification of entitites according to the adopted provisions of the law, etc.). However, the main methodical approaches are determined already and they require the clarification and testing only.

The first step in the implementation of approaches is the formation of regional registers for legal entities (LE) and individual entrepreneur (IE) the activity of which is subejected to the state sanitary and epidemiological control (surveillance) and

control in the field of consumer rights protection. Such registers in the one or another form already exist at the administrations of Rospotrebnadzor in the constituent entities of the Federation. In some regions the registers contain several hundreds of LE and IE (Nenets Autonomous Area, Chukot Autonomous Area), in other - several dozens of thousands (Moscow, Moscow region, Saint-Petersburg, Rostov region, etc.). Herewith, as a rule, the lists of economic entities are formed based on the tax service data which has the required passport information of LE and IE. Some regions montly update the databases from the tax service. For example, the electronic bases of the supervision objects in Omsk region consisting as of the 1<sup>st</sup> of May 2015 of 11588 legal entities and individual entrepreneurs are updated in such manner. In Sverdlovsk region the exchange with data between the tax service and Rospotrebnadzor administration in relation to the lists of taxpayers is performed quarterly. The databases at the Perm Territory are updated annually, etc.

Mainly, the registers contain the codes of region (according to the codes of the Federal Tax Service) in which the surveillance object carries out its activity; taxpayer identification numbers; names of LE or IE; codes of the types of economic acticity (Russian Classification of Economic Activities), both the main and additional; legal and postal addresses and other general data. The other information is accumulated by the separate regions according to the existing practice and used program tools, including the ones developed for internal use.

In addition, the risk-oriented model of the service activity requires the significant extention of the content of databases on the legal entities and individuals subjected to control (surveillance). First of all, it relates to the data which allow for assessing the profile of risk for the object and the number of population exposed ti hazardous factors specific for this activity.

The variety of the types of acticity which are subjected to the sanitary and epidemiological supervision at one LE or IE as well as the availability of territorially separated property complexes where these types of activity are carried out complicates the maintenance of registers. It is necessary to have clear terminological definition of the object of supervision in order to "combine" with it the hazard and risk factors and the population exposed to them.

The draft of considered federal law proposes to understand under the objects of the state control and surveillance " the individuals and legal entities; the property, including the production facilities - territories, buildings, premises, structures, equipment, devices, materials, transport vehicles, cargos carried by them and other similar objects, used by the legal entities and individual entrepreneurs during the conduction of their activity, the activity of individuals and legal entities; the results of activity of individuals and legal entities, including the products..., hazardous in relation to inflicting the harm to the life and health of people ... ". Such definition to some extent complicates the register maintenance procedure formalizaton. For example, the legal entity which itself is the object of surveillance shall include the different types of activity to which the special mandatory requirements are presented as well as the seprate property complexes (buildings, structures, etc.). Accordingly, the register shall have the branched hierarchical structure which considers the specific features of surveillance in the field of sanitary and epidemiological well-being.

Within the pilot project provided by the order No. 1302 for the tasks of classification under the potential risk of damage to health it is necessary to work out the procedure for forming the registers of objects which carry out their activity at the territory of region (constitutent entity of the Russian Federation) and are subjected to the surveillance by the bodies of the Federal Service for Consumer Rights Protection and Human Well-Being Surveillance. The register represents the aggregate of combined tables and consists of five main parts:

- passport information of LE and IE (surveillance objects of "upper level" which in the guidelines approved by the order No. 1302 are called as "the objects of surveillance") which includes the data on the place of registration, codes characterizing the types of economic activity, forms of ownership. etc.;

-passport information (in aggregate or separately) of the territorially distinguished property complexes, buildings and facilities of the certain LE or IE carrying out the same type of activity – surveillance objects of "lower level"; - special information which contains the data on the results of control and supervisory activity in relation to the objects of surveillance – both for the objects of upper level in general and separately for the objects of "lower level"; data on the number of population exposed to the object of surveillance and results of calculation of the level of risk and classifications of the objects of surveillance.

It is possible to form the main tables of the surveillance objects register in MS Excel formats. The tables contain the fields (columns) for entering the data of the first four parts of the register – sheets "Subject", "Object", "Surveillance", and "Number". In this case the filling out of register is associated with necessity to control the integrity of data.

More proper but at the same time more complex equivalent to the provided pattern is the use for filling out the surveillance objects register the specially developed structures of data organized in the form of linked tables. The practical solutions on the storage system organization can be different and can be oriented to the information system used in the region.

The structure which represents the aggregate of normalized tables of data and reference books linked to them is proposed as the one of the data organizing solutions (see figure).

The structure of data consists of four logical information blocks:

1) reference information block (reference books of territories; forms of the entrepreneurial activity organization; departmental classification; reference book of the types of legislation; table for the relationship of object with the types of activity under the form 1-14 "Data on the results of federal state surveillance by the territorial bodis of Rospotrebnadzor");

2) block of main data on the objects and subjects of surveillance (table for storing the general data on the surveillance object of "upper level", table for storing the general data on the surveillance object of "lower level");



Fig. Layout for organizing the data in the surveillance objects register

3) block of data on the violations detected during the audits with breakdown under the articles of sanitary and the customer rights protection legislation as well as on the results of laboratory tests (table with data on the violations of the articles of legislation; table with data on the last audit; data on the laboratory tests);

4) block "population under impact" (tables for storing the data on the number of population under impact, with distinguishing the data on the number of employees; consumers of goods and services; population under the impact of contaminations of atmospheric air, water, soils).

The entering of data in the provided structure requires the development o special program tools both for automatic initial entering (through "pouring" of data from the tax service registers) and for furher manual entering. Currently, the Federal Scientific Center for Medical and Preventive Health Risk Management Technologies develops the information system oriented to the use of database management system MS Access which performs the functions of the manual maintenance of data in the register. The algorithm for calculation of the health risk indicators and the surveillance objects classification will be implemented within the system.

As of now, the filling out of fields reflecting the number of population exposed to the one or another type of activity of the object of surveillance is the most difficult during the formation of register. It is necessary to have the information on the density of population residing at the certain territories – to assess the number of population exposed to the atmospheric contaminations; on the coefficient of water demand – to assess the number of population exposed to the water collection and treatment facilities; on the duration of provision of the one or another service; on the specific demand for food and non-food commodities, etc. Forming the reference books for practical use during the health damage risk assessment is one of the most important directions of activity of the scientific organizations of Rospotrebnadzor which provide the methodical support for the risk-oriented surveillance system and one of the tasks of the pilot project. It should be noted that the conduction by the specialized scientific organizations of targeted studies to form the reference materials for correct risk assessment is the common global practice [8–10]. Also the relevant domestic data are considered [3, 6, 7]. Herewith, the uncertainties during the assessment of risk are decreased significantly and respectively the reliability of results and managing decisions taken under them is increased.

The testing of described approaches allowed for forming the registers of surveillance objects oriented to the further health damage risk assessment in Omsk, Lipetsk, Kaluga and Perm regions.

The results of testing of the formed registers in the tasks on calculating the health damage risk and classification of objects evidence that the correctly formed registers (databases) provide the widest possibilities for analysis.

The most important task – distinguishing the objects of extremely high and high damage infliction risk – is solved. The preliminary results for the specified regions evidence that the objects of extremely high risk make up not more than 0.4% of the total number of accounted surveillance objects (mainly these include the legal entities engaged in the collection and treatment of drinking water supplied to the population through large surface water intakes, as well as the objects engaged in the waste water removal).

About 1.5% of surveillance objects are preliminary classified as the objects of high risk (in this class – the objects for collection and treatment of water, waste water removal, production enterprises, large food products retail trade facilities, etc.).

The maintenance of register for the objects of lower level (separate, territorially distinguished property complexes - branches, separate subdivisions, trade outlets, etc.) for the tasks of planning allows for distinguishing those complexes which are subjected to the priority inspection conducted in relation to the separate legal entity or individual entrepreneur. Thus, among the individual territorially separated objects of Novogor-Prikamye LLC at the Perm Territory 4 objects were classified as the objects of high risk in relation to the infliction of damage to health (risks during the collection and treatment of water calculated under the proposed methods was from  $9.4 \cdot 10^{-2}$  to  $3.6 \cdot 10^{-3}$ ), other – as the objects of moderate or low risk ( $R < 1.10^{-3}$ ). Therefore, namely these objects were determined as priority for inclusion into the field inspections.

The assessment and classification of risks formed during the performance of the different types of activity by the one object of surveillance allowes for determining the content of supervisory measures and field of sanitary surveillance. The table contains the results of assessing the risks formed by the one surveillance object in relation to the different groups of population.

Results of calculation for the damage infliction risk from economic entity carrying out several types of activity at the territory of region

|                      | Type of population under impact |   |   |                       |
|----------------------|---------------------------------|---|---|-----------------------|
| Type of activity     | Employees                       | Population exposed to<br>the atmospheric air<br>contamination | Population exposed to the factors of natural and drinking water | Consumers of products |
| Water collection and | 2,22E-05                        | 5,92E-04  | 1,31E-01  |                       |
| treatment            | (III class)                     | (III class)   | (I class)   | -                     |
| Water distribution   | 2,98E-04                        | I   | 1,14E-02  | _                     |
|                      | (VI class)                      |   | (II class)  |                       |
| Waste water removal  | 8,47E-04                        | 6,12E-04  | 5,47E-03  |                       |
|                      | (III class)                     | (III class)   | (II class)  | -                     |
| Catering             | 1,06E-06                        | _   | _   | 5,09E-05              |
|                      | (IV class)                      |   |   | (IV class)            |

It can be seen that the highest potential risks are formed in relation to population. The object is subjected to the environmental sanitation surveillance with maximally allowed frequency in the form of field inspections with laboratory support. The surveillance of occupational and nutrition hygiene shall be carried out with lower frequency and use of the other forms of inspections.

The processing of interregional and federal registers of surveillance objects will allow for obtaining the quantitative health damage risk characteristics during the performance of the different types of activity that certainly will allow for determining the most effective risk management measures using the control and surveillance methods.

The performed studies resulted in the justification of a number of tasks which shall be solved immediately. These tasks include:

- the development and documenting of requirements to the accounting of the numbe of violations during the conduction of inspections if these violations are registered at the territorially separated property complexes (in the different buildings and structures) of one legal entity or private entrepreneur;

- justification and documenting of unified approaches to determining the number of population under impact, including the specific weakly developed as of now approaches to the assessment of population exposed to the activity of waste removal, activity of distribution centers, pharmacies, etc.;

- unification of correlation of the codes of economic activity which are subjected to the sanitary and epidemiological surveillance with classification used in the statistical reporting of the Federal Service for Consumer Rights Protection and Human Well-Being Surveillance (in particular, with form 1.14);

 working out the approaches to the registration of violations of requirements of technical regulations and assessment of risks of damage to consumers associated with these violations;

– development of recommendations on improving the classification of industrial objects within the statistical reporting of Rospotrebnadzor since the existing is not enough for forming risk profiles and correct classification of surveillance objects.

## References

1. Kontrol'no-nadzornaja dejatel'nost' v Rossijskoj Federacii. Analiticheskij doklad. 2013 [Control and surveillance activity in the Russian Federation. Analytical report. 2013]. Moscow: MAKS Press, 2014. 272 p.

2. Koncepcija povyshenija jeffektivnosti kontrol'no-nadzornoj dejatel'nosti organov gosudarstvennoj vlasti i organov mestnogo samoupravlenija na 2014–2018 gody. Proekt [Concept of the increase of the control and surveillance activity in the system of central and local authorities on 2014-2018 years. Project]. Available at: <a href="http://www.gosbook.ru/node/79006">http://www.gosbook.ru/node/79006</a>.

3. Lim T.E., Bek A.V., Alikbaeva L.A. Ocenka vozdejstvija na naselenie Sankt-Peterburga zagrjaznenij pochvy kancerogennymi veshhestvami. [Assessment of the impact of soil contamination by carcinogens on the population of St. Petersburg]. *Profilakticheskaja i klinicheskaja medicina*, 2013, no. 2 (47), pp. 11–15.

4. O vnedrenii Metodicheskih rekomendacij v «pilotnyh» territorial'nyh organah Rospotrebnadzora [On the implementation of Recommendations in the "pilot" territorial bodies of Rospotrebnadzor]. Available at: <u>http://rospotrebnadzor.ru/privat/?ELEMENT\_ID=2847</u>.

5. Ob osnovah gosudarstvennogo i municipal'nogo kontrolja i nadzora v Rossijskoj Federacii. Proekt Federal'nogo zakona [On the bases of state and municipal control and supervision in the Russian Federation. Draft Federal Law]. Available at: <u>http://www.nsopb.ru/events/1220.php</u>.

6. Novikov V.M., Lagutov V.V., Sazykina T.G., Gorlinskij Ju.E., Nikol'skij O.A., Pavlenko V.I. Ocenki vozdejstvija na naselenie i okruzhajushluju sredu vremennyh hranilishh radioaktivnyh othodov na territorii RNC «Kurchatovskij institut» [Assessment of the exposure of the temporary storage of radioactive waste in the RRC "Kurchatov Institute" on people and environment]. *Atomnaja jenergija*, 2005, vol. 99, no. 2, pp. 152–159.

7. Ilivanov Ju.D., Pavlov Ju.M., Talanov V.I., Nazarova A.A. Pit'evaja voda i zabolevaemost' zlokachestvennymi novoobrazovanijami moche-vydelitel'noj sistemy [Drinking water and the occurrence of malignant neoplasms in urinary system]. *Kazanskij medicinskij zhurnal*, 2007, vol. 88, no 1, pp. 81–82.

8. Arnold C.G., Sobal J. Food practices and nutrition knowledge after graduation from the expanded food and nutrition... *Journal of Nutrition Education*, 2000, vol. 32, no 3, pp. 130–138.

9. Bremmer H.J., van Veen M.P. Children, s Toys Fact Sheet. To assess the risks for the consumers. RIVM report 612100112/2002.

10. Guidelines for the study of the Dietary Intakes of Chemical Contaminants / WHO. Geneva: WHO Offset Publication, 1985, № 87, 104 p.

11. Hampton P. Reducing administrative burdens: effective inspection and enforcement. Available at: www.hm-treasurear.gov.ru/hampton.