

UDC 614.3:342.9

## SCIENTIFIC APPROACHES TO THE CLASSIFICATION OF ECONOMIC ENTITIES IN TERMS OF HEALTH RISKS FOR THE PURPOSES OF CONTROL AND SUPERVISORY ACTIVITIES

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*The article suggests approaches to the classification of economic entities involved in economic activities that are subject to sanitary-epidemiological and product safety requirements. The risks presented by the entity is determined by the possibility of violation of the sanitary legislation, severity of consequences of the violation for public health, and amount of people (employees, consumers) under exposure. The risk is assessed on the basis of available information. The risk assessment method for all the economic entities is transparent and reproducible.*

*The article identifies four classes of hazard in terms of potential health risks (extreme hazard, high hazard, moderate (average) hazard and low hazard). The class of hazard determines the frequency and amount of planned supervisory activities. Reconnaissance assessment of potential risk for 6400 subjects of sanitary-epidemiological supervision in Perm Krai showed that almost 70% of economic entities are not sources of high and average health risks. There is no need for close supervision of such entities; instead, the focus can be moved to the entities of high and extreme hazard. The article also describes the criteria that can be used to increase or decrease the frequency of planned inspections.*

*The suggested approaches are aimed at stimulating the economic entities to follow the current legislation.*

**Key words.** risk of harm, sanitary and epidemiological supervision, classification of the subjects of supervision

Increased health risks and hazards is a global process typical of Russia. Stochastic appearance and launch into circulation of newly synthesized chemicals, the emergence and spread of new species and strains of microorganisms, expanded range of the physical factors of public exposure, economic globalization and the opening of borders for goods and human resources - all this has negative consequences for public health [5, 9,10].

In this situation, the Federal Service for Supervision of Consumer Rights Protection aims to prevent and mitigate the negative impact on public health created by the economic activities.

The Decree of the RF President of May 15, 2008 №797 "On Emergency Measures to Eliminate Administrative Restrictions When Exercising Entrepreneurial Activities", a number of amendments

Popova A.Yu., Zaitseva N.V., May I.V., Kiriyanov D.A., Sboev A.S., 2014

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added and planned to the RF Federal Laws №294-FZ of December 26, 2008 “On Protection of Rights of Legal Entities and Individual Entrepreneurs When Exercising State Control (Supervision) and Municipal Control”; №242-FZ of July 18, 2011 “On Making Changes to Some RF Legislative Acts on State Control (Supervision) and Municipal Control”; №210-FZ of July 27, 2010 “On Provision of State and Municipal Services” – stipulate, among other things, the introduction of health assessment and management methodology tailored to specific economic activities into the system of state supervision. The importance of such activities is emphasized in the draft Concept of improving the effectiveness of inspection and enforcement activities of state bodies and local self-government in 2014-2015 [3].

Following the federal policy, the Federal Service for Supervision of Consumer Rights Protection and human well-being sets an objective to introduce risk-based supervision into the activities aimed at providing sanitary and epidemiological well-being of the population and consumer right protection aimed at:

- Ensuring the proportionality of the control and supervisory activities to the level of public health and property damage risk;
- Focusing the supervisory efforts on the entities that present the biggest health risk (to the public, employees, and consumers) and decreasing the number of inspections at the entities of low risk;
- Rational and effective use of the funds allocated for the supervision over the execution of the state function;
- Improving the quality of the environment, workplace conditions, and product safety by preventing the violations of the sanitary legislation by the entities that present the biggest health risk;
- Stimulating the subjects of supervision to follow the legislative requirements by the incentive of decreased frequency of planned inspections;
- Increasing the efficiency of control and supervisory activities aimed at providing sanitary and epidemiological well-being [5-7].

To achieve the above objectives, methodological approaches to the classification of the economic entities were developed using the criteria of potential public health risk. The classification of the economic entities, in its turn, serves as a basis for determining the frequency of planned inspections and scheduling the inspections for the coming year with the account for the resources at Rosпотребнадзор and expenses on the supervisory activities.

The level of health risk is determined based on the following principles:

- Health risk emerges when an economic entity violates the legislative requirements in the area of the sanitary and epidemiological well-being of the public and consumer right protection;
- Violations in the area of the sanitary and epidemiological well-being of the public and consumer right protection determine the probability of health risks to the public, employees, and consumers under exposure to the activities of the economic entity;
- Risk assessment is an objective and transparent procedure based on verified available data;
- The level of potential risk associated with the entities subject to the federal state sanitary and epidemiological supervision depends on the type of economic activities conducted by the entity. Public health risk assessment is carried out in regards to a specific type of activity of a legal entity or individual entrepreneur;
- On the basis of the conducted analysis, a classifier of risk entities is developed by the method of one-time reference of an economic entity (unit) to a certain risk group (statistical assessment of the risk levels);
- An economic entity is referred to a specific health risk class based on its most hazardous economic activity;
- The reference of an economic entity to a specific class of hazard serves as a basis for determination of the frequency of planned inspections; the differentiation of the units of supervision at the economic entity serves as a basis for planning the amount and content of the supervisory activities;
- Procedure and criteria used to refer an economic entity to a specific class of hazard in terms of health risks are consistent for all the legal entities and individual entrepreneurs regardless the type of economic activity or form of ownership;
- The reference of an economic entity to a specific class of hazard in terms of health risks at the regional level is carried out based on the results of control and supervisory activities for the period of at least 3 years, with the account for the available information about the entity (complaints, occupational diseases, acute poisoning, accidents, registered infectious diseases, population under exposure);
- Results of the sanitary and epidemiological audit are used to estimate/change the frequency of supervisory activities. The key principle of the classification is the fact that the risk of health damage emerges when an economic entity violates the leg-

islative requirements in the area of sanitary and epidemiological well-being of the population. Law violations determine the probability of damage to public health, the health of employees, and consumers under exposure.

The economic entities listed in the Uniform State Register of Legal Entities or the Uniform State Register of Individual Entrepreneurs and subject to the sanitary and epidemiological supervision and supervision in the sphere of consumer right protection are subject to the classification, with the account for their activities as listed in the Russian National Classifier of Economic Activities or the All-Russia Classifier of Services Rendered to the Public compared against the activity control form 1 "Information about the results of the state inspection by the local Rospotrebnadzor office".

Primary rating of an economic entity in terms of potential risk to public health is carried out on the basis of a comprehensive analysis, including expert analysis, of longitudinal statistical information on the situation in the RF in general and in some subjects in particular, using the following formula (1).

$$R = \mathring{a}_k (p_k \times u_k \times M), \quad (1)$$

where  $p_k$  – probability of violation of the sanitary legislation under the  $k$ -th article FZ "About the sanitary and epidemiological well-being of the population" and FZ "On protection of consumer rights" and other legislation on consumer rights protection;

$u_k$  – an indicator that describes the health hazard under the violation of the  $k$ -th article of the legislation;

$M$  – an indicator that describes the size of the population group under exposure to the activities of an economic entity (scale of exposure).

The probability of violation of the sanitary legislation ( $p_k$ ) is characterized by the frequency of violation of each ( $k$ -th) article of the sanitary legislation and legislation on consumer rights protection in the industries subject to the sanitary inspection, on the basis of the inspection results for at least 3 years, using the formula (2):

$$p_k = \frac{m_k}{n}, \quad (2)$$

where  $p_k$  – frequency of violations of the sanitary legislation or legislation on consumer rights protection under the  $k$ -th article for each of the economic activities;

$m_k$  – number of registered violations of the sanitary legislation or legislation on consumer rights protection under the  $k$ -th article for each of the economic activities;

$n$  – total number of inspections of a separate economic activity.

The frequency of violations of separate articles of the sanitary legislation (mean value and 95<sup>th</sup> percentile) in the Russian Federation is calculated on the results of the inspection activities of all the RF subjects for the last three years; it determines the current situation around compliance of the economic entities with the sanitary legislation and legislation on consumer rights protection.

For each separate economic activity, we identified the hazard factors associated with a specific type of violations of the sanitary legislation under the specific articles of the law № 52-FZ, and the law "On protection of the legal entities". For each type of hazard, we determined the type of health damage (type of diseases and/or cause of death) based on the analysis of the domestic and international relevant information sources and databases.

The calculation of a relative health damage caused by the violation of the sanitary legislation and legislation on consumer rights protection ( $u_k$ ) is carried out on the basis of a comprehensive analysis, including expert analysis, of the causal relationships between the frequency of the law violations and prevalence of health damages including the death rate and primary disease incidence, taking into account the severity of a health damage.

The calculations are made using the following formula (3):

$$u_k = \mathring{a}_i a_{ik} \times g_i, \quad (3)$$

Where  $u_k$  – measure of the health hazard associated with the violation of sanitary legislation and legis-

lation in the field of consumer protection by specific economic activity;

$a_{ik}$  – an indicator of the change in the frequency of morbidity and mortality with increasing frequency by one violation of the legislation on the  $k$ -th article;

$g_i$ – severity of the  $i$ -th health damage, measured in the range from 0 to 1.

Value  $a_{ik}$  is determined based on a regression analysis according to the state statistical reporting forms (Form №12, "Information on the number of diseases revealed in patients residing in the service area of the medical organizations", the form №1 "Information on infectious and parasitic diseases", form C51 "Distribution of deaths by sex, age groups and causes of death", Form № 29-09 "Information on outbreaks of infectious diseases ") by the subjects of the Russian Federation for 3 years and expert evaluation of the hazards of each economic activity and related health problems.

The regression equation in the standard form looks as follows (4):

$$y_i = a_{i0} + \sum_k a_{ik} p_k, \quad (4)$$

where  $y_i$ – dependent variable;

$i$ -ый – health indicator (certain types of the morbidity and death rates);

$p_k$ – independent variable– frequency of violation of the  $k$ -th article of the legislation.

Determination of the coefficients  $a$  was performed with the help of the step-by-step regression analysis using special certified software for statistical data processing.

Health disorders were differentiated by severity. The severity of a disease was evaluated in the range from 0 to 1, where 0 - full health, 1 - death. Such approaches are generally accepted, quantitative characteristics of the severity are consistent with the values adopted in the documents of the World Health Organization. The severity of health problems by classes of diseases was calculated based on the severity of the individual nosology and structure of each class of diseases in the Russian Federation over the past three years.

Examples of the revealed causal relationships between the violation of articles of legislation and health disorders (in terms of specific diseases and disease classes) described with the help of reliable models, and parameters  $a_{ik}$  of these models are given in Table 1. In practical calculations, it is possible to use the values of this parameter that are common for the Russian Federation.

Table 1

Examples of  $a$  coefficient (Violations of Article 19 "Sanitary and epidemiological requirements to the quality of drinking water, drinking and potable water supply" FZ 30.03.1999 N 52-FZ "On Sanitary and epidemiological well-being of the population" by the economic entities)

Types of health disorders	$a$ coefficient
Diseases of the skin and subcutaneous tissue (the child population)	0,0888
Diseases of the skin and subcutaneous tissue (adults)	0,0376
Diseases of the blood-forming organs and certain disorders involving the immune mechanism (children)	0,0165
Diseases of the blood-forming organs and certain disorders involving the immune mechanism (adults)	0,0027
Diseases of the digestive system (children)	0,0827

Diseases of the digestive system (adults)	0,0248
Diseases of the digestive system (population at large)	0,0364
Liver conditions (adults)	0,0005
Liver conditions (population at large)	0,0006
Diseases of the pancreas (population at large)	0,0012
Diseases of the gallbladder, biliary tract (adults)	0,0028
Gastritis and duodenitis (population at large)	0,0054
Endocrine, nutritional and metabolic diseases (children)	0,0171
Endocrine, nutritional and metabolic diseases (adults)	0,0094
Endocrine, nutritional and metabolic diseases (population at large)	0,0114
Thyroid diseases (children)	0,0049
Thyroid diseases (adults)	0,0033
Diseases of the genitourinary system (population at large)	0,0505
Kidney stone disease (children)	0,0001
Kidney stone disease adults)	0,0018
Kidney stone disease (population at large)	0,0015
Diseases of the eye and adnexa (adults)	0,0311
Diseases of the nervous system (adults)	0,0104
New growths (adults)	0,0124
Congenital abnormalities of the blood circulatory system (children)	0,0041
Congenital abnormalities of the blood circulatory system (population at large)	0,0008
Congenital abnormalities (developmental defects), deformations and chromosomal abnormalities (children)	0,0126
Congenital abnormalities (developmental defects), deformations and chromosomal abnormalities (population at large)	0,0024

The indicator that describes the scale of impact of the economic entities (scale coefficient) takes into account the amount of people that can suffer as a result of a sanitary violation or violation of the consumer rights legislation, and the contact time with the hazard typical of the entity.

The indicator is calculated using the average values typical of the economic entity (for example, number of employees, number of hospital beds, number of students at preschools and secondary schools, shopping space, production volumes at food industry enterprises, volume of extracted and

treated water for the drinking water supply, etc.) and distribution coefficients that help convert the statistical indicators into the number of people under exposure (for example: length of hospital stay, specific consumption of food products, specific water consumption, etc.) using the following formula (5):

$$M = V \times K(V), \quad (5)$$

where  $M$  – an indicator that describes the number of people under exposure to a certain economic activity;

$V$  – an indicator that quantizes an economic entity and determines the number of people under exposure;

$K(V)$  – a coefficient of nondimensionalized  $V_k$ .

For convenience of the practical calculation of the scale of exposure, reduction coefficients by different type of economic activity are enclosed in Appendix 8.

The indicator is flat for all types of economic entities; at the same time, it is aimed at using available statistical data that describes various economic entities and their activities.

The indicator, along with others used in risk evaluation, has a period of one year; respectively, the scale coefficient also describes the scale of exposure during a year.

In order to classify the economic entities and their activities by the level of health risk related to the sanitary violations and violations of the consumer rights legislation, we used a scale that breaks down the risks of health damage into four classes:

1) an extremely high level of potential hazard (I class of hazard);

2) a high level of potential hazard (II class of hazard);

3) an average level of potential hazard (III class of hazard);

4) a low level of potential hazard (IV class of hazard).

Classification of the economic entities in terms of risk of health damage (level of potential hazard) is presented in Table 2.

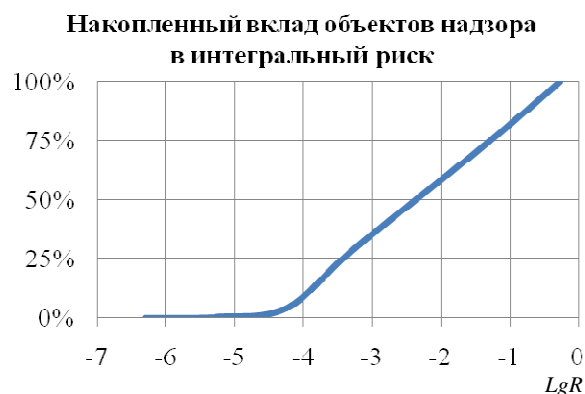
Table 2.

Classification of the economic entities by the level of risk of health damages

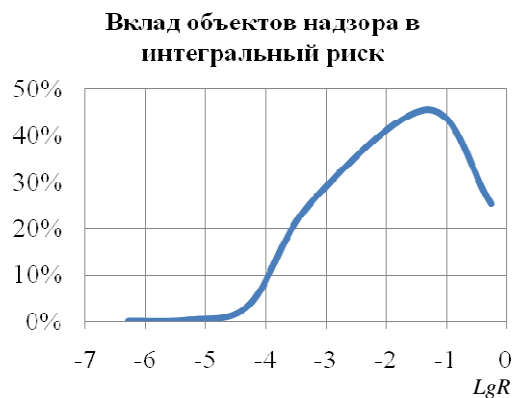
Class of potential hazard of an economic entity and type of activity (unit of supervision)	Characteristics of the potential risk of health hazard	Risk of health hazard
I class of hazard	Extremely high	More than $10^{-1}$
II class of hazard	High	$10^{-1} - 10^{-3}$
III class of hazard	Average	$10^{-3} - 10^{-5}$
IV class of hazard	Low	Less than $10^{-5}$

The classification scale was obtained on the basis of distribution analysis of the values of health damage risk for all the RF units of supervision (at large) included in the state industrial statistics. It was determined that the distribution falls under the Poisson's law. The values of the risk of

health damage corresponding to the limits of the classification scale range were obtained as values of the distribution quartile (first quartile – 25<sup>th</sup> percentile, second quartile – median (50<sup>th</sup> percentile), third quartile – 75<sup>th</sup> percentile). The density and health damage risk spread function are presented in the Figure below



**Accumulation contribution of the economic entities into the total risk**



**Contribution of the economic entities into the total risk**

Figure. Density (a) and function (b) of health damage risk distribution\* Density (a) – share of the economic entities with a certain value of health damage risk \*\*Distribution function (b) – share of the economic entities with a certain range of health damage risk

According to the scale, the first class of hazard has a very insignificant amount of economic entities. Most economic entities fall under the third and fourth classes of hazard.

The suggested methodology helps develop a federal classifier of economic entities by the level of potential risk to public health. Placing an economic entity into a specific class of hazard serves as a basis for scheduling planned supervisory activities. In such a way, the economic entities in the first class of hazard (extremely high level of potential risk to public health) can be recommended continuous supervision (once a quarter); the entities in the second class of hazard (high risk) – once a year at most, with a possibility of increasing the frequency; the entities in the third class of hazard (average risk) – once every three years at most; the entities in the fourth class of hazard – once every five years, or exemption from inspections, with a possibility of regular inspections of once every five years or exemption.

The frequency of planned inspections at the economic entities in the first and second classes of hazard can be changed in the following way:

- if the site inspections for the last three year show that the relative frequency of the sanitary violations and violations of the consumer rights legislation is lower as compared to the average Russian level for the same period, then the period between the planned inspections increases by one year in regards to the current frequency;

- if the site inspections for the last three year show that the relative frequency of the sanitary

violations and violations of the consumer rights legislation is lower as compared to the average Russian level for the same period, then the period between the inspections decreases to the standard period;

- the period between the planned inspections can be increased only twice meaning that the maximum period may differ from the standard period by 2 years at most.

The economic entities in the fourth class of hazard may be exempt from the planned inspections subject to the following terms:

- no violations of the sanitary legislation revealed during the last inspection;
- no validated complaints about the activities of the economic entity from the public, other legal entities, governmental agencies, and local authorities;

The following factors will be taken into account when planning inspection activities: the level of law-obedience which is characterized by the ratio of the number of violations of the sanitary legislation and the consumer rights legislation and the number of conducted inspections; completeness and timely performance of the orders and instructions; the share of non-standard samples collected in the course of laboratory studies.

The economic entities with the worst indicators within one class of hazard will be subject to priority supervision.

The frequency of planned inspections can be lowered for the entities for which the probability of

violations is lower than the country's average for that type of economic entities.

The classification of the type of activities within one economic entity serves as a ground for the development of the content and volume of the supervisory activities in the course of comprehensive inspections of compliance with the sanitary legislation (Table 3).

The maximum allowable frequency of planned supervisory activities is determined by the RF laws and regulations. The content of supervisory activities for the entities in various classes of hazard and health risk is determined by the Administrative regulations and other normative documents adopted by the authority in the sphere of compliance with the sanitary and epidemiological legislation.

Table 3.

Organization of the federal state sanitary and epidemiological supervision (control) depending on the class of hazard of an economic entity in terms of public health risk

Class of potential hazard of the economic entity	Type of activity	Laboratory support of control (supervisory) activities
I class of hazard (extremely high risk)	Planned site inspections	Conducting a full range of laboratory and instrumental examinations in the course of supervisory activities (control)
II class of hazard (high risk)	Planned site inspections	Conducting a full range of laboratory and instrumental examinations in the course of supervisory activities (control)
III class of hazard (average risk)	Planned site inspections and document audits	Conducting a minimum of laboratory and instrumental examinations in the course of supervisory activities (control)
IV class of hazard (low risk)	Document audits, control of production control	Ensuring control of production control at the economic entity

The testing of the approaches in Perm Krai showed that among all the facilities involved in wastewater disposal (discharge of sewage waters) into the natural aquifers, only one economic entity was referred to the first class of hazard – the largest water treatment facilities in the region that discharge the sewage water from the city of one million people into the river upstream in regards to other towns using the same draining system. 20% of the entities involved in the same economic activity were referred to the group of high risk entities; 51% - to the group of average risk entities; 48% - to the group of low risk entities.

Among the studied entities involved in food trade, no entity was referred to the class of

extremely high and high hazard risk; 25% of the entities were referred to the group of moderate (average) risk – mainly, large retail store chains that serve a large population group; 75% of the retail units were referred to the group of low hazard risk.

Reconnaissance assessment of the potential hazard risk of 6400 entities of sanitary and epidemiological supervision in Perm Krai showed that almost 70% of the economic entities do not present high or average risk to public health. The level of supervision of such entities can be weakened, and the focus of the control efforts can be transferred to the entities of extremely high and high risk.

Surprise inspections based on complaints from the public and other legal entities, detected violations of the hygienic requirements and standards, etc. are still relevant and must be performed along with planned inspections and other supervisory activities regardless the class of hazard of an economic entity.

Overall, the suggested approaches are aimed at stimulating the economic entities to comply with the current legislation for the purposes of improving the economic climate in the country due to reduction of the administrative barriers improving the environmental quality, and supporting a healthy nation.



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