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## **SANITARY-EPIDEMIOLOGICAL AUDIT IN RUSSIA AND ABROAD: CHALLENGES AND GROWTH PROSPECTS (ANALYTICAL REVIEW)**

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*The shaping the system of control and surveillance activities in the Russian Federation, which affects the bodies of the sanitary-epidemiological surveillance, requires the development of new forms of cooperation between authorities and legal entities, individual entrepreneurs and population. Such a form may be represented by the sanitary and epidemiological audit as an independent objective assessment of reputable third parties. The audit is intended to check the compliance with the mandatory requirements of the economic entities, performing economic or other activities. The sanitary-epidemiological audit may be associated with a system of certification for compliance with sanitary requirements and may assume the documented confirmation of the compliance issued by the authorized persons.*

*The sanitary-epidemiological audit and the compliance certification to mandatory sanitary requirements can make an alternative to the planned supervision activities on facilities attributed to the category of low and moderate risk of harm to human health. The Russian sanitary legislation does not recognize the sanitary-epidemiological audit as a form of conformity assessment. The analysis of the international experience shows that it is necessary to consolidate the general rules and regulations of the sanitary-epidemiological audit at the legislative level and to develop a set of sublegislative documents in order to implement these norms. The crucial is a creation of the national system capable to regulate the registration and functioning of the organization having a right to conduct the audit activities in the field of hygienic safety. It is reasonable to develop the regulation on the list-register of auditors and to create a special training system for the auditors, who possess the methodology for health risk assessment. The key aspect of the successful introduction of the audit is a granting of presences to the economic entities having compliance certificates as a result of voluntary sanitary-epidemiological audit. The authorities for the accreditation and monitoring of the audit firms in the field of sanitary and epidemiological safety can be given to a federal executive body competent in this field.*

**Key words:** *sanitary and epidemiological audit, state system for control, risk-based supervision, sanitary safety.*

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The vector set by the highest state authorities to cut-down unnecessary administrative barriers to business, to introduce risk-oriented model of control and surveillance presupposes an overall reduction in scheduled inspections by supervisory authorities of legal

entities and individual entrepreneurs, including those whose activities are subject to regulation by sanitary legislation [13,15]. At the same time, tasks of improving habitat safety and preserving national health are still top-relevant [2, 10]. In addition, civilian popula-

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tion and public organizations activities in protection of citizens' rights to safe environment and health have advanced significantly over the recent years. The requirements of foreign economic partners to prove safety of activities, goods and services and law abidance of domestic economic entities are constantly rising.

The Russian Federation entry into the World Trade Organization requires from state authorities an adoption of legislative and other regulatory legal acts aimed at implementing Agreements on the World Trade Organization (WTO), as well as at ensuring training of the Russian entrepreneurs for operating in WTO environment. Special challenges are in improving quality and safety of consumer products made in Russia and imported from abroad [4].

All of this requires new forms of interaction between supervisory bodies, legal entities, individual entrepreneurs, and population as consumers of goods, products, services. Among such forms, sanitary and epidemiological audit can and should act as an independent objective third authorities assessment of legal entities and individual entrepreneurs' compliance with the requirements of sanitary rules and other normative documents in the field of sanitary and epidemiological well-being in implementing their economic or other activities [1, 7]. Sanitary and epidemiological audit can be associated with a certification system for compliance with sanitary requirements and assume documentary confirmation of such compliance by authorized persons. Within the framework of a risk-oriented model of control and surveillance activities, sanitary and epidemiological audit and certification of compliance with mandatory hygienic requirements could make an alternative to scheduled surveillance measures

on sites classified as of low and moderate risk of harm to human health and values under protection [11,12].

To date, in Russia, sanitary-epidemiological audit and voluntary confirmation of operations, works and services compliance with hygienic requirements do not have a reliable legal support. The notion of "audit" and "voluntary certification for compliance with mandatory sanitary requirements" is not given in the federal law of 12.03.1999, No. 52-FZ "On Sanitary and Epidemiological Well-Being". At the same time, for instance, the law of the Republic of Belarus dated January 7, 2012, No. 340-3, "On Sanitary and Epidemiological Well-being of the Population" defines sanitary and epidemiological audit, and establishes that the audit is conducted voluntarily, at the expense of the organizations' own funds and in the order set forth by the Council of Ministers of the Republic of Belarus. The Decree of the Ministry of Health of Belarus on 16.07.2012 No. 99 approved The Regulations on the procedure for sanitary and epidemiological audit. This document establishes that the main objective of an audit is *"... to identify ways and means of reducing the risk of adverse effects of economic or other activities on population life and health through an independent compliance assessment by organizations .... as required by legislation in the field of sanitary and epidemiological welfare of the population and providing recommendations on improving their activities ..."*

Sanitary and epidemiological audit is foreseen also by an Article 62-1 of the Code of the Republic of Kazakhstan *"On People Health and Healthcare System"*<sup>1</sup>. The document stipulates that *"the results of sanitary and epidemiological audit influence the determination of risk profile for epidemically significant objects under state*

<sup>1</sup> On People Health and Healthcare System: The Code of the Republic of Kazakhstan No. 193-IV of September, 18, 2009 (as amended on 21.04.2016 г.) Available at: <http://www.wipo.int/wipolex/ru/details.jsp?id=16058> (18.08.2016)

<sup>2</sup> Rules for sanitary-epidemiological audit. Approved by the Order of the Minister of National Economy of the Republic of Kazakhstan No. 216 of 17.03. 2015. Available at: [https://tengrinews.kz/zakon/pravitelstvo\\_respubliki\\_kazahstan\\_premier\\_ministr\\_rk/zdravoohranenie/id-V1500010846/](https://tengrinews.kz/zakon/pravitelstvo_respubliki_kazahstan_premier_ministr_rk/zdravoohranenie/id-V1500010846/) (18.08.2016)

<sup>3</sup>Data as of October, 1, 2016.

*sanitary and epidemiological surveillance ... and positive results of sanitary and epidemiological audit are the basis for epidemically significant objects' exemption from inspections done under a special procedure".* The rules for conducting sanitary and epidemiological audit have been approved<sup>2</sup>. Thus, the auditors entitled to work in Kazakhstan are included in the state-register and are to submit annually the reports on sanitary and epidemiological audit to the body authorized in sanitary and epidemiological wellbeing. The form of such a report is unified and approved. However, the law provides for a number of restrictions aimed at eliminating any affiliation of the auditors to the object of audit and improving credibility of the obtained results. A list of legal entities, passed the audit procedure and got a report on compliance with mandatory requirements, is posted on the government website <http://kzpp.gov.ru>. Among 1067 legal entities and individual entrepreneurs audited<sup>3</sup> are preschool institutions, public catering facilities (cafes, canteens), swimming pools, SPA-salons, dental offices and other objects, the audit reports thereon can be used to form plans for control and surveillance activities. This list reviewed by consumers gives an opportunity to choose the most reliable services providers. In this case, the register publishes data on each auditor who signs an audit report for a specific object. This, of course, increases the auditor's responsibility, on the one hand, and is a quality guarantee of the audit performed in favor of goods and services consumers.

In accordance with the Republic legislation, audit firms and auditors personally are liable for the breach of auditing rules, and the re-

sults of sanitary and epidemiological audit can be recognized as invalid in cases, if the established audit procedure was violated or the results thereof were falsified in the audit report preparation. Disputes arising as a result of sanitary and epidemiological audit are resolved through legal proceedings. It should be noted that the audit report conclusion may be the basis for exemption from special procedure for inspections in the Republic of Kazakhstan<sup>4</sup>.

A sound legal basis for auditing has been established in the US and EU countries [3, 8]. At the same time, audit covers a wide range of areas of economy – from accounting to medical and preventive activities. The forms of the audit organization have been elaborated in detail, the methodological materials system for auditing has been developed, published and is constantly updated. It should be noted that abroad the credibility of voluntary audit and compliance certification is quite high. In developed countries, there are tens of thousands of audit firms (only in the United States there are more than 45,000 of them. While audit firms in the United States and Great Britain are highly independent in preparation, qualification of results, in the control over how honest auditors perform their duties, in Europe countries, auditing activities are much more strictly controlled by state through a system of normative legal acts [8].

It should be noted that abroad credibility of voluntary audit and compliance certification is quite high [17]. Many large, internationally recognized firms (such as Food Safety Sanitation, SGS, Food Safety and Inspection Service, etc.) carry out auditing and implement voluntary assessment procedures for compliance with national, European and international re-

<sup>4</sup>Procedure for risk assessment system' formation by the state agencies (with the exception of the National Bank of the Republic of Kazakhstan). Approved by the Order of the Vice-Minister of National Economy of the Republic of Kazakhstan No.343 of April, 17, 2015

<sup>5</sup>Audit *Konsaltingovi tseñtr «SIVEKS»*. Available at: <http://rospotreb.com/audit/> (20.09.2016)

<sup>6</sup> Audit sanitarnogo sostoyaniya pomozhet podgotovit'sya k vneplanovym proverkam Rospotrebнадзора. *SERKONS*. Available at: [http://www.serconsrus.ru/press\\_centr/intervyu\\_s\\_klientami/audit\\_sanitarnogo\\_sostoyaniya\\_pomozhet\\_podgotovitsya\\_k\\_vneplanovym\\_proverkam\\_rospotrebнадзора/](http://www.serconsrus.ru/press_centr/intervyu_s_klientami/audit_sanitarnogo_sostoyaniya_pomozhet_podgotovitsya_k_vneplanovym_proverkam_rospotrebнадзора/) (22.09.2016)

<sup>7</sup>SES AUDIT. *Rosproizvoditel': spravochno-informatsionnaya sistema*. Available at: <http://rosproizvoditel.ru/company/4943-ses-audit> (22.09.2016)

<sup>8</sup>Sanitarnyi audit. *SANPIN-HELP.RU*. Available at: <https://sanpin-help.ru/sanitarnyj-audit/> (22.09.2016)

<sup>9</sup> Sanitarnyi audit i konsalting Available at: <http://sanering.ru/company/> (25.09.2016)

quirements, including such demanding, as ISO 22000:2005 standards "Food Security Management Systems. Requirements for any organization in the food chain", ISO 22006:2009 "Quality Management Systems. Guidelines for the Application of ISO 9001:2008 to Crop Production, FAO Food and Nutrition Paper 63 "Street Foods", etc. [16, 20, 21]. For all auditors in the West, compliance with GAAS standards (audit standards) is mandatory. Interstate audits are in place with mandatory data publication [18, 19]. Compliance with auditing rules (standards) is verified through such analytical procedure, as reviewing internal and external audit documentation. It is namely the preparation of auditor's working papers, with the details of audit planning, its progress, accounting and control system analysis, findings obtained from specific sections of an audit, indicates that the audit was in fact performed and the data – not falsified [14].

Nowadays, food safety audit is the most demanded in assessing the objects under surveillance for compliance with sanitary and epidemiological requirements [16, 20, 23]. Such types of audit, as audit-inspection (one-time audit before entering a new project or partnership), audit in monitoring mode (as a means of systematic self-control), or a targeted problem-oriented audit (when there is a problem and there is a need to identify the causes and sources of the given problem) [22].

In the Russian Federation a number of organizations offer and provide services on sanitary and epidemiological audit (for instance, SIVEX Consulting Center in Moscow<sup>5</sup>, "Sercons" LLC<sup>6</sup>, registered in Moscow and having branches in Yekaterinburg, Samara, Kazan and other cities, CSC "SAS-Audit", Moscow<sup>7</sup>, "SANPIN-HELP", Moscow<sup>8</sup>, "Sanering" LLC, Moscow<sup>9</sup> and etc.). As there is no accreditation system for sanitary audit in Russia, auditors register is absent, no proce-

dures and forms of audit data reporting in place, it does not seem possible to assess service quality, or adequacy of its cost. As a rule, today's sanitation audit is performed immediately before the planned measures of state control. The main objective is to avoid administrative penalties in the form of fines, orders to suspend operations and other sanctions. Undoubtedly, audit results eliminate the revealed inconsistencies with sanitary requirements. However, in a number of cases, such inconsistencies are being masked or competently circumvented during an inspection period. The main purpose of an audit is a real reduction in risks of causing harm to population health, improving safety of environment, formation of social responsibility of an economic entity pale into insignificance.

At the same time, it is obvious that audit, as a procedure for self-monitoring, professional assessment, "onlooking", is in demand by business entities. However, the main obstacle to the fully-realized and efficient use of sanitary audit is the lack of regulatory framework and incentives established in legislation<sup>10</sup> to conduct sanitary audit for enterprises, organizations, individual entrepreneurs.

However, the practice for legislative consolidation of audit as an instrument of public administration in Russia is available. Thus, Federal Law No. 307-FZ dated 30.12.2008 "On Auditing" and Resolution of the Russian Federation Government No. 696 of September 23, 2002 "On Approval of Federal Auditing Rules (Standards)" regulate financial (accounting) audit. Audit activities are carried out by audit firms and individual auditors who are members of one of the self-regulatory organizations of auditors. Self-regulating organizations conduct certification of auditors, monitor quality of audit firms operation, individual auditors work with respect to their members, and maintain a register of audit firms and auditors. The authorized federal body (the

<sup>10</sup>Federal Law ddt. August, 8, 200. No. 126-FZ "On licensing of certain types of activities" Available at: <http://www.consultant.ru/cons/cgi/online.cgi?req=doc; base=LAW;n=191768#0> (25.09.2016).

RF Ministry of Finance) introduces data on self-regulating auditor organizations into the state register of SROs and effects government control (surveillance).

The relevant laws of the Russian Federation include fire safety audit, tax and environmental audit [5, 6, 7]. So, for example, the legal basis for environmental auditing is formed by Federal Law No. 7-FZ of January 10, 2002 "On Environmental Protection", which provides for an "environmental audit" as an independent, comprehensive documented assessment of an entity's economic and other activities compliance with the requirements, including of standards and normative documents ... requirements of international standards and preparation of recommendations for improving such activities ". In the development of federal approaches to environmental auditing, the Law of St. Petersburg of December 26, 2005 No.712-109 "On Urban Environmental Control in St. Petersburg and Administrative Responsibility for Violations in Environmental Protection", determines objects of urban environmental control not subject to scheduled inspection:

- that have implemented and supported environmental control system (environmental management system) at the enterprise and submitted relevant documents to the executive body of state power in St. Petersburg that implements urban environmental control;

- once in two years submitting a positive conclusion of environmental audit in the executive body of state power in St. Petersburg, which implements urban environmental control.

Similar approaches can be used also at arranging sanitary and epidemiological audit. So, for example, audits conclusions can be taken into account by Rospotrebnadzor when performing control and surveillance functions. Authorized bodies of state power may not conduct scheduled inspections of those objects of economic and other activities that will submit the conclusions of sanitary audit that the requirements of sanitary legislation,

regulatory documents are fully complied with, and hygienic standards are observed at these objects. At the same time, state inspectors will be able to selectively check the objects under control. If violations in contradiction with the sanitary audit conclusion are revealed, then the established order of selective state sanitary surveillance is being canceled, and application is introduced to annul certification of the auditors who performed sanitary audit at the given facility.

In general, introducing the procedure for sanitary audit and voluntary compliance assessment can reduce the number and frequency of inspections on sites that, being socially responsible, bear the burden of voluntary audit, are open and transparent to civil society and supervising authorities and ensure that their products and services are in conformity with the established requirements and standards. According to a number of researchers, a competent, modern, and having unique information resources audit institution is able to perform both regulatory and constructive functions, ensuring the selection of promising directions for the development of the country.

At the same time, it is obvious that state participation in ensuring proper quality of auditing is mandatory. According to the Russian legislation in licensing, this procedure is subjected to the types of activities, the implementation of which may entail damaging rights, legitimate interests, health of citizens, etc. It seems that low professional or deliberately biased auditing in ensuring sanitary and epidemiological welfare of the population can create prerequisites for damage to protected values, including health of citizens, since an appropriate management decisions are taken (or not taken) based on audit findings. In this regard, it seems rational to legislatively consolidate the licensing procedure for auditing organizations or individual auditors. This statement is also expressed by specialists in other areas of audit [7, 12].

At the same time, sanitary and epidemiological audit does not violate property rights and promotes market economy development,

decreases administrative pressure on business by reducing surveillance activities in the field of sanitary and epidemiological well-being. Moreover, developing and implementing risk-oriented model of control and surveillance at the national level is also most responsive to audit objectives on identifying and eliminating the most problematic "bottlenecks" in the managed sphere [22].

It should be noted that qualified auditors are in demand always and everywhere, and the demand for this profession increases every year. And the main task of audit services currently is not only to monitor compliance with legislation that regulates various aspects of enterprises operations, but also to systematically eliminate and prevent downsides in this activity.

In general, to introduce sanitary-epidemiological audit in habitat and population health quality management system in the Russian Federation, it is necessary to:

- establish sanitary and epidemiological audit as a form of assessing the compliance of activities and assets used with the legislation requirements at a statutory level;

- create national system that regulates emergence and registration of organizations with the right to auditing in the field of hygiene security. Authorities for accreditation of audit organizations in hygiene security may be given to a federal executive body competent in this activity;

- establish the procedure for accreditation (registration, recording) of audit services in the field of ensuring sanitary and epidemiological welfare of the population with definition of qualification requirements for auditors and technical experts; to establish a body for certification in hygienic safety.

- develop rules for conducting sanitary and epidemiological audit and forms of data presentation thereof;

- develop Regulations on auditors' registers in the field of sanitary and epidemiological welfare of the population and conducted audits of legal entities and individual entrepreneurs;

- create a system for the special training of auditors who, in particular, have the methodology for assessing the risks of harm to health and other socially significant values protected by Rospotrebnadzor;

- determine place, role of sanitary and epidemiological audit in public administration system for population sanitary and epidemiological welfare and its relation to the risk-oriented control and surveillance activities of Rospotrebnadzor;

- establish at statutory level preferences for economic entities that have certificates of compliance based on voluntary audit results;

- arrange for monitoring and annual analysis of auditing results.

The system of sanitary and epidemiological audit in the country can be developed as one of the activities in the market of sanitary-epidemiological operations and services subject to licensing (accreditation).

A separate direction of audit as an instrument of the population sanitary-epidemiological welfare may be a sanitary-epidemiological audit of a territory, city, municipalities (county, district).

In general, introducing sanitary audits into practice, as well as using its results for inspections, will be an important step towards improving the quality of services and works performed, upgrading efficiency of control and surveillance activities and safety of the Russian Federation citizens

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