

PREVENTIVE HEALTHCARE: TOPICAL ISSUES OF HEALTH RISK ANALYSIS

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ON METHODOLOGICAL SUPPORT FOR RISK-ORIENTED SURVEILLANCE OVER CONSUMER PRODUCTS SAFETY ON THE UNIFIED ECONOMIC TERRITORY OF THE EURASIAN ECONOMIC UNION

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Risk-oriented surveillance is a tool for state regulation over consumer products safety; it is fixed in the legislation of all the states belonging to the Eurasian Economic Union (EAEU). This approach involves concentrations of efforts by all controlling authorities on objects that cause high health risks for population with simultaneous easing off administrative barriers for those objects that cause insignificant risks. It is necessary to work out uniform and easy-to-replicate methodical approaches to organizing risk-oriented surveillance over products in the EAEU and it makes our research truly vital. It would allow to preserve independent national surveillance systems and simultaneously obtain comparable results that would be recognized in all the member states thus ensuring high confidence in any obtained data.

Our research goal was to work out an algorithm and a system of procedures for risk-oriented surveillance over safety of consumer products distributed on the unified EAEU market.

We analyzed regulatory, legal, and methodical documents on issues related to assessing population health risks occurring when consumer products are distributed; forms of statistical reports and algorithms applied for planning control and surveillance activities in the EAEU member states, other countries and unions. We took data collected in Russia and Belarus to analyze results obtained during control and surveillance activities performed in the sphere including results of more than 3 million various laboratory examinations of consumer products conducted over 2014–2017.

We suggest an algorithm for risk-oriented surveillance over consumer products safety that includes three basic stages: 1) ranking of activities performed by juridical persons or private entrepreneurs in the sphere of consumer products distribution as per potential population health risks. The basic goal at this stage is to spot out objects that are subject to the most frequent and profound inspections performed by authorized governmental authorities entitled to check consumer products safety and protect population health; 2) products classification as per population health risks for drawing up surveillance activities schedules. The basic goal at this stage is to make up a list of the most "risky" groups of products for a documentary and laboratory inspection performed at a specific economic entity; 3) determining priority parameters for laboratory support of surveillance activities based on "risk profiles" creation. The goal at this stage is to optimize laboratory support provided for surveillance and to make it more "targeted" via substantiating those parameters of products that are related to the most frequently registered violation of standards and the greatest population health risks.

Procedures and software are developed for each stage in the suggested algorithm.

Key words: consumer products, risk-oriented surveillance, methodical support.

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The Treaty on the Eurasian Economic Union signed on May 29 2014 declares in its Clause No. 56 that the member states are to pursue a coordinated policy in the sphere of sanitary measures application in order to provide sanitary-epidemiologic welfare of the population. Sanitary measures are to be applied basing on the principles that are scientifically substantiated and to an extent necessary for saving lives and improving people's health. Products safety management is a most essential component in implementation of this coordinated policy. At the moment attention is being focused on safety of consumer products distributed on the unified EAEU market as achieving this safety is more than vital. It is related to intense technological development (including nanotechnologies), and these new technologies are often not studied enough in terms of their hygienic parameters [1, 2]; creation of new chemicals [3–5] and biological agents [5, 6] which are directly included into products or contact them; persisting threats of secondary and tertiary products contamination [7–9] etc.

The member states provide criterion grounds for products safety that are based on a comprehensive and wide set of sanitary-epidemiologic requirements and standards fixed in unified sanitary and technical regulations. This system of standards and regulations is being constantly developed basing on new scientific data and research [10]. Simultaneously new activities are being worked out that are aimed at lowering state interference into business and reducing administrative barriers for production and trade. A balance between consumer safety and state regulation over business can be reached, among over things, via wide implementation of risk-oriented surveillance. The main purpose of such surveillance is to concentrate efforts made by

state surveillance authorities on products that cause high risks for consumers' health and to minimize surveillance over products causing law risks [11–13].

Risk-oriented state control (surveillance) is fixed in legal documents issued in many countries and by many international organizations and is efficiently applied in different management spheres. For example, the EU Regulation 2017/625¹ fixes that competent surveillance authorities should focus on objects causing high risks taking into account inspection reports and applying qualitative informative and methodical base when they perform control and surveillance activities. These bases are prepared by such organizations as European Food Safety Authority or EFSA, Food and Veterinary Office or FVO, and others. For example, EFSA provides a methodological base for assessing products risks by systematic publishing of relevant Guidances for Risk Assessment which can be used by all parties who are interested in assessing products safety, such as manufacturers, distributors, authorities responsible for assessing conformity, and control and surveillance authorities [14–16]. It is fixed in legislation that all concerned parties are to be obligatory informed about hazardous products². Risk-oriented surveillance is also fixed in the legislation in the USA, Canada, etc. [17–20].

The EAEU member states also adhere to risk-oriented surveillance [21, 22]. Thus, Clause No. 8.1 of the RF Federal Law No.294-FZ³ fixes a risk-oriented approach to state control in order to achieve optimal use of labor, material, and financial resources required for accomplishing state control (surveillance), to lower expenses borne by juridical persons and private entrepreneurs, and to make activities performed by state

¹ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on Official Controls and Other Official Activities Performed to Ensure the Application of Food and Feed Law, Rules on Animal Health and Welfare, Plant Health and Plant Protection Products. – URL: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0625&from=EN> (date of visit February 07, 2019).

² Commission Regulation (EU) No 16/2011 of 10 January 2011: Laying down implementing measures for the Rapid alert system for food and feed [web-source] // Official Journal of the European Communities. – 2011. – URL: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2011:006:FULL&from=EN> (date of visit February 06, 2019).

³ The Federal Law "On protecting rights of juridical persons and private entrepreneurs when accomplishing state control (surveillance) and municipal control" issued on December 26, 2008 No. 294-FZ (the last edition). URL: http://www.consultant.ru/document/cons_doc_LAW_83079/ (date of visit February 01, 2019).

control (surveillance) authorities more efficient. In Belarus, "The Regulations on the order of inspections organization and procedure" approved by the Order signed by the Belarus President on October 16, 2009 No. 510⁴ approve the criteria for assigning economic entities that are subject to surveillance into a specific risk group for drawing up inspections schedules.

The Code issued in Kazakhstan on October 29, 2015 No. 375-V and entitled "The Business Code of the Kazakhstan Republic"⁵ (Chapter 13, Clause 141) specifies that state control and surveillance are performed taking into account distribution of economic entities that are subject to surveillance into four groups basing on risk assessment. Risk is considered as a possible damage done to people's lives or health, the environment, legal interests of physical and juridical persons, or valuable interests of a state due to activities performed by an economic entity under surveillance; a degree of a such damage should also be taken into account.

Risk-based systems for drawing up inspections schedules are fixed in the Law issued in Armenia "On organization and accomplishment of inspections in the Republic of Armenia"⁶ and also in the Law issued in Kirgizstan on May 25 2007 No. 72 "On a procedure for accomplishing inspections at economic entities"⁷.

But at the same time it is vital to develop uniform and easy-to-replicate methodical approaches to organizing risk-oriented surveillance over products. If experts had an access to a united criterion base for determining products safety and common approaches to differentiation (classification or ranking) of surveillance objects as per risk levels, it would allow to preserve independent systems for national state surveillance and simultaneously obtain comparable results

recognized in all the member states thus ensuring high confidence in all the obtained data.

All the above mentioned gave grounds for attempts made by the Eurasian Economic Commission (EAEC) to develop common principles for creating and functioning of a typical risk-oriented model for control and surveillance activities as regards providing products safety on the territory of the Eurasian Economic Union. In 2017–2018 Russian and Belorussian experts who worked together within a project supported by the EAEC⁸, substantiated certain approaches that could be applied within national systems for control over products safety as a unified methodical base. The present paper dwells on these approaches.

Our research goal was to work out an algorithm and a system of procedures for risk-oriented model of surveillance over safety of consumer products distributed on the common EAEU market.

Research objects and methods. The algorithm and the system of procedures were developed taking into account regulatory, legal, and methodical documents existing in the sphere of population health risks assessment, providing products (goods) safety, and accomplishing control (surveillance) over products distributed on the market (there are approximately 200 regulatory and methodical documents issued in the EAEU member states – Belarus, Kazakhstan, Kirgizstan, Armenia, and the Russian Federation); we also examined and took into account documents issued by international organizations (including the World Trade Organization, Codex Alimentarius Commission, the World Health Organization, the UN Food and Agriculture Organization, The Organization for Economic Cooperation and Development, The

⁴ The Order signed by the Belarus President on October 16, 2009 No. 510 " On development of control (surveillance) activities in Belarus. URL: www.bgs.by/files/files/10.doc (date of visit February 01, 2019).

⁵ The Code of Kazakhstan Republic "The Business Code of the Kazakhstan Republic" (with amendments and latest supplements on January 21, 2019) URL: https://online.zakon.kz/Document/?doc_id=38259854 (date of visit February 01, 2019).

⁶ The Law of the Republic Armenia issued on July 12, 2000 No. ZR-60 "On organization and accomplishment of inspections in the Republic of Armenia". URL: http://base.spinform.ru/show_doc.fwx?rgn=3039 (date of visit February 01, 2019).

⁷ The Law of the Kirgizstan Republic issued on May 25, 2007 No. 72 "On a procedure for accomplishing inspections at economic entities". URL: <http://cbd.minjust.gov.kg/act/view/ru-ru/202105> (date of visit February 01, 2019).

⁸ The scientific research entitled "Risk-oriented surveillance model in the sphere of providing safety of products for people's health". Cipher N-17/197.

International Organization for Standardization, The European Committee for Standardization, etc.). We examined statistical reports, algorithms for planning control and surveillance activities including those ones accomplished under compliance with requirements fixed in the WTO agreements on sanitary and phytosanitary measures, standards developed by the Codex Alimentarius Commission etc.; it allowed us to choose data sources that were the most suitable for creating a risk-oriented surveillance model in the EAEU member states. When modeling cause-and-effect relations between frequency of cases in which obligatory requirements to products safety were violated and detected damages done to consumers' health, we applied data taken from the state statistics collected in Russia and Belarus including analysis of cases in which damage was done to consumers' health. Certain conclusions and suggestions were based on results of more than 3 million laboratory research on products collected over 3 years (2015–2017).

When setting a task to create a risk-oriented model for surveillance over products, we assumed that a) products themselves were not a subject in legal relationships; b) goods can appear on the consumer market only due to activities performed by juridical persons or private entrepreneurs⁹; c) products (goods) safety can be managed only via managing activities performed by juridical persons or private entrepreneurs.

We took into account the following propositions:

- scheduled surveillance over products is accomplished through control and surveillance over juridical persons and private entrepreneurs. Consequently, the most immediate task here is to identify juridical persons and private entrepreneurs that cause high risks for consumers' health;

- when a control and surveillance inspection is being accomplished directly at an economic entity, it is impossible to examine all the goods or products. Therefore, it is very important to have a priori knowledge what products (goods) can be the most hazardous or "risky";

- compliance of goods to safety criteria is, as a rule, determined with instrumental research and volumes of such research are often limited. Therefore, it is vital to primarily control those parameters of products non-compliance of which to hygienic standards can most certainly result in the highest consumer health risks.

Basic results. We suggest an overall algorithm for a risk-oriented model for surveillance over products safety which includes three main stages:

- 1) ranking (classifying) activities performed by juridical persons or private entrepreneurs and related to consumer products distribution as per potential risks of damage to population health. The main goal at the stage is to spot out economic entities which should be subject to the most frequent and profound inspections accomplished by state bodies authorized to monitor products safety and to protect consumers' health;

- 2) classifying products as per possible risks of damage to health in order to draw up inspections schedules. The main goal at this stage is to make up a list of the most "risky" product groups in order to perform a documentary and laboratory inspection at a specific economic entity (juridical person or private entrepreneur);

- 3) determining priority parameters for laboratory support provided for surveillance activities on the basis of created "risk profiles". The main goal at the stage is to optimize laboratory support provided for surveillance, and to make it more "targeted" via substantiating those product parameters which are most frequently non-compliant with requirements fixed in standards and violation of which causes the highest consumer health risks.

Implementation of the suggested model is aimed at determining exactly unsafe products that cause the highest consumer health risks during surveillance activities and to do it in the most convincing way applying all the available tools.

The algorithm is given in greater detail on Figure 1.

⁹ Products made by citizens for their private purposes and for consumption at their households were not considered in the research.

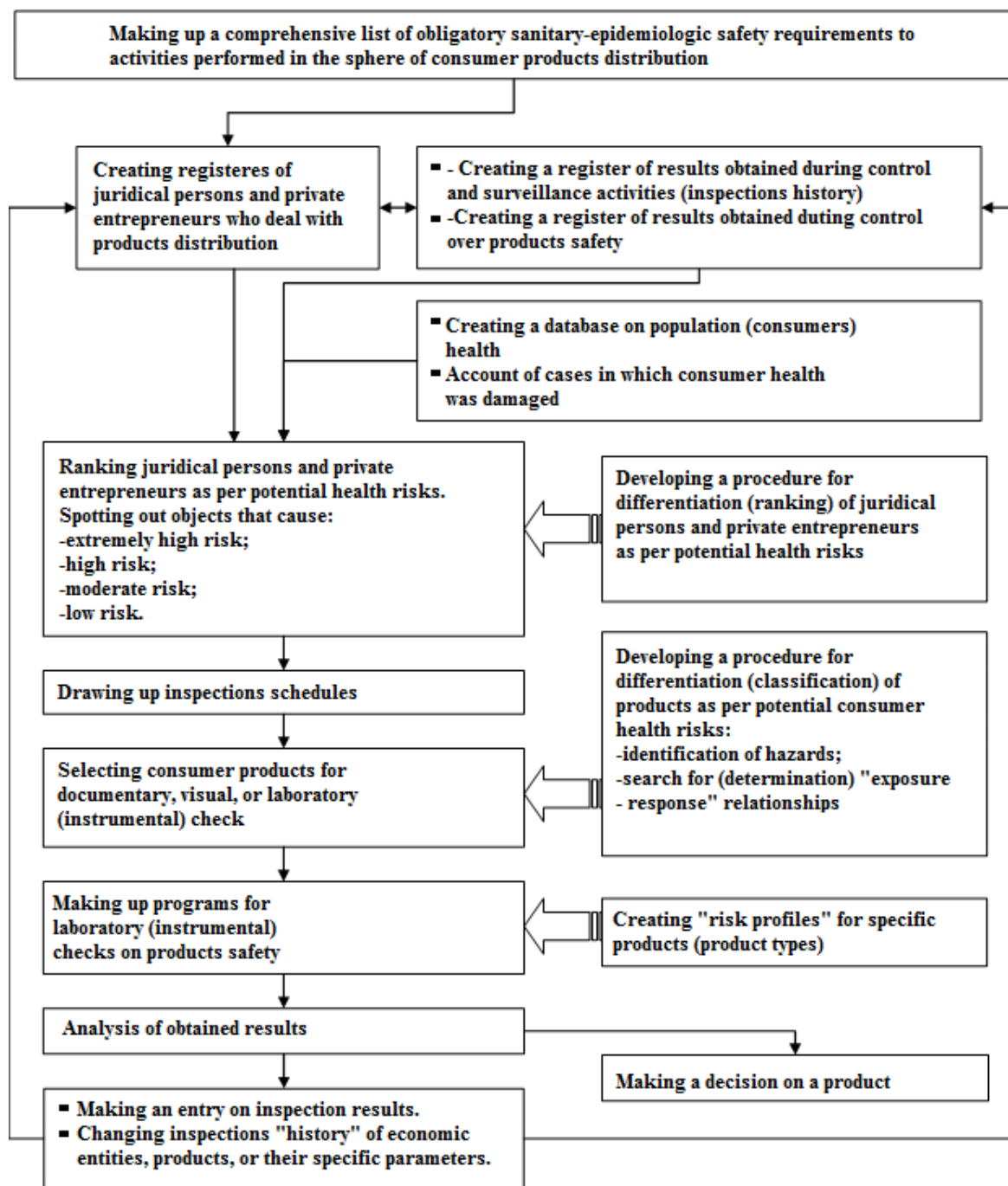


Figure 1. An overall algorithm for organizing control and surveillance activities taking into account classification of products as per potential health risks

The first stage is ranking (classifying) activities performed by juridical persons or private entrepreneurs in the sphere of consumer products distribution as per potential population health risks; it involves having the complete data on economic entities under surveillance which are systemized in registers, inventories, databases, etc. Such registers or databases should contain data on activities performed by a ju-

ridical person or a private entrepreneur, where they take place and how long a production process is, as well as volumes of manufactured (distributed) goods or rendered services. Besides, it is extremely important to accumulate and systematize results of control and surveillance activities including results of documentary, visual, and laboratory examinations of products as well as registers of cases in which

damage was done to population health (or if such registers have not been created yet, there can be registers of population health parameters). The registers are considered to be an information database for calculating and predicting probable frequency of obligatory requirements violation by economic entities performing various activities in the sphere of consumer products distribution and probable negative responses to such violations (in case when obligatory sanitary requirements are violated, it can be probability of deaths or diseases among potential consumers, breach of sanitary-epidemiologic welfare etc.)

A scope of potential negative impacts (that is, health damage cases) is determined by scales of activities performed by a juridical person or a private entrepreneur. We suggest to assess a gravity of damage that was done according to the WHO recommendations applying a scale from 0 to 1, where 1 means death; any figures close to 1 are considered grave health disorders, and those close to 0 are mild disorders, symptoms, syndromes, etc. [23].

Methodical approaches to classification can vary significantly; however, just like any other risk assessment techniques, they should take into account both probability of a hazardous event (violation of standard levels fixed for hazardous factors) and a gravity of consequences caused by this event. In order to exclude or minimize subjective experts estimations, we suggest to develop a risk assessment procedure on the basis of actual statistical data collected during control and surveillance activities, data on hazards related to activities performed by juridical persons or private entrepreneurs and products distributed on the market, statistics on health damage cases or any other data on health disorders, and mathematic modeling techniques.

In full conformity with international approaches, we suggest to assess a risk as a combination of probability, gravity, and a scope of negative exposure as per the following formula (1):

$$R^I = \sum_i (p_i u_i) M \quad (1)$$

where p_i is a probability that i -th requirement (standard) in sanitary legislation is violated at

industrial objects where I -type activity is performed;

u_i is a parameter that characterizes damage done to population health when i -th requirement (standard) in sanitary legislation is violated at industrial objects where a specific activity is performed; it is calculated as

$$u_k = \sum_i \alpha_{ik} g_i,$$

where α_i is a parameter that reflects changes in mortality or morbidity frequency when frequency of violation as per k – th clause in the legislation increases by 1; g_i is a parameter that reflects gravity of i -th health disorder varying within a range from 0 to 1.

M is a parameter that characterizes number of population exposed to activities performed by an industrial enterprise.

Probability of a case in which requirements are violated is determined basing on inspections histories of juridical persons and private entrepreneurs and, taking into account "precaution" principles, can be taken as a 95% percentile of violations frequency over several years. It means that a risk as per "violation probability" criterion can be underestimated for not more than 5% of object under surveillance. (For example, we analyzed results of control and surveillance activities performed by Rospotrebnadzor in 2014–2017 at more than 1,000 retail outlets and revealed that non-compliance with sanitary-epidemiologic requirements to food products and materials and products that contacted them was registered with an average frequency equal to 0.58 per 1 inspection. Maximum frequency amounted to 1.37; 95%-percentile was equal to 0.85 per 1 inspection). Violations frequency and 95%-percentile which is taken into account when economic entities or products are classified should be revised at least once a year.

Probability and gravity of a response (damage done to a consumer health) is the second component in a risk caused by an economic entity and its activities. An obligatory action at this stage is to identify a hazard, to describe hazardous factors and negative consequences caused by exposure to such factors as comprehensively as it's only possible. Relative damage

to health caused by violation of obligatory safety requirements (u_k^l) is calculated on the basis of systemic, including expert one, analysis of cause-and-effect relations between frequency of legislation violations and prevalence of health disorders (mortality and primary morbidity) among population taking into account their gravity. This task is complicated and science-intensive, and it requires access to databases on violations frequencies and population health.

Obtained mathematical models which are biologically substantiated are subject to obligatory statistical significance check. Only authentic correlation models can be applied to assess risks. Table 1 contains several models obtained in the research and applied to assess health risks caused by products. The models can be applied many times, they can be supplemented and revised by scientific organizations from time to time.

Table 1

An example of models that describe cause-and-effect relations between frequency of cases in which obligatory requirements to activities related to consumer food products distribution are violated and population health disorders (a is a number of cases per 1 violation) with assessing potential damage caused by these violations (a copy taken from a system of models obtained basing on the analysis of data collected in 84 RF regions over 2014–2017)

Category	A clause in 52-FL which was violated	Nosology	Contingent	Model parameters		Gravity of a disorder (g)	A parameter that characterizes damage to health caused by violation of legal requirements (u)
				a	F		
Food products manufacturing, catering and retail trade in food products, overall	Clause 15	Gastritis and duodenitis	Adults	0.00150	22.08	0.140	0.00021
	Clause 15	Gastritis and duodenitis	Total population	0.00160	23.33	0.112	0.00018
	Clause 17	Digestive organs diseases	Adults	0.00930	8.12	0.161	0.00150
	Clause 19	Pancreas diseases	Children	0.00910	7.65	0.441	0.00400
	Clause 20	Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	Adults	0.03310	20.31	0.273	0.00902
Food products manufacturing, including drinks; tobacco products manufacturing	Clause 17	Enteric infections	Adults	0.01950	18.44	0.016	0.00031
	Clause 19	Stomach and duodenum ulcer	Children	0.00060	6.21	0.181	0.00012
			Total population	0.00011	6.85	0.196	0.00002
Catering	Clause 19	Non-infectious enteritis and colitis	Children	0.01690	13.13	0.372	0.00630
	Clause 25	Gastritis and duodenitis	Adults	0.00487	15.26	0.139	0.00068
		Gastritis and duodenitis	Total population	0.00444	13.37	0.126	0.00056
Retail trade in food products, including drinks, and tobacco products	Clause 15	Gastritis and duodenitis	Adults	0.00154	8.96	0.139	0.00022
		Gastritis and duodenitis	Total population	0.00165	8.15	0.126	0.00018
	Clause 17	Digestive organs diseases	Adults	0.00930	14.87	0.161	0.00150
	Clause 19	Certain infectious and parasitic diseases	Adults	0.03450	20.12	0.288	0.00993

Table 2

A scale for classifying activities performed by juridical persons or private entrepreneurs as per potential health risk

Hazard category	Health risk category	Health risk value	Recommended frequency of scheduled inspections
1 hazard category	Extremely high	More than $1 \cdot 10^{-3}$	The highest (in conformity with the EAEU member- states legislations), for example, at least once a year
2 hazard category	High	$10^{-4} < R \leq 1 \cdot 10^{-3}$	From 1 time in 2 years to 1 in 5–7 years
3 hazard category	Considerable	$10^{-5} < R \leq 1 \cdot 10^{-4}$	
4 hazard category	Average	$10^{-6} < R \leq 1 \cdot 10^{-5}$	
5 hazard category	Moderate	$10^{-7} < R \leq 1 \cdot 10^{-6}$	
6 hazard category	Low	$R < 10^{-7}$	Are released from scheduled inspections

Number of population exposed to activities performed by an industrial object is determined as a function of production capacity at an economic entity under surveillance or rendered services.

When all the components are known (frequency of registered violations, a scope of health damage as per 1 violation, number of exposed population), activities performed by an economic entity under surveillance can be characterized with a certain risk value.

We suggest a risk scale that can be applied to classify surveillance objects; it allows to assign activities performed by a certain object to this or that risk category taking into account scopes of such activities (Table 2).

Objects ranking gives grounds for differentiation of scheduled inspections frequency and their procedures. We suggest to fix maximum frequency of inspections for objects that cause extremely high and high risks and minimal frequency for those that cause low risks (or to completely release them from any scheduled inspections). Scheduled inspections at objects that cause extremely high, high, and, partially, considerable risks should be field ones and there should be laboratory support provided for them.

The approaches were tested on economic entities in Russia that were subject to surveillance. Totally, almost 400 thousand juridical persons and private entrepreneurs that dealt with catering were under state surveillance; the tests revealed that about 2.5% of them could be ranked as objects causing extremely high risk, and 5.5%, high risk. And it is these economic entities that are subject to the most frequent and

systemic control. Approximately 17.3% economic entities cause significant risks, and 38.55%, average risk. Scheduled inspections at such objects should be performed with lower frequency. And almost 10% of economic entities are ranked as objects with low risk and they can be released from any scheduled inspections thus allowing to redirect resources of a surveillance authority and to concentrate its efforts on objects that cause high risks. A share of objects that cause extremely high and high risks in the sphere of wholesale and retail trade (predominantly in food products) amounted to 2.1 and 4.87% respectively; objects that caused low risks accounted for almost 20%. The obtained data are well in line with data taken from scientific literature; according to literature sources, a share of objects that create high risks and are subject to the most frequent control by surveillance authorities doesn't exceed 8-10% of the overall number of objects under state surveillance. But as for unscheduled inspections performed according to the rules fixed in the legislation of the EAEU member states, they are not excluded and can take place at any time. Besides, a risk-oriented model can (and should) include some measures that can assign an object either into a stricter category (when considerable violations of obligatory requirements are detected during an inspection) or into a less strict one (when there are no violations of obligatory requirements and all the recommendations given by surveillance authorities or any other conditions fixed for the process have been adhered to).

Risk-oriented surveillance over activities performed by juridical persons and private en-

trepreneurs is supplemented with a similar approach to surveillance over products and it allows control and surveillance authorities to choose the most hazardous products for documentary and laboratory examinations.

Methodical approaches allow to quantitatively estimate risks as a combination of potential frequency with which obligatory requirements to products can be violated and relative damage done to consumers' health in a case when specific requirements are violated. The formula for calculating risks caused by food products is given below (2).

$$R'_{\text{total}} = \sum_i (p_i^l u_i^l) W, \quad (2)$$

where p_i^l is a probability that obligatory safety requirements to food products are violated as per i-th hazard factor during a single inspection. A hazard factor can be a chemical, a microbe or a parasitic agent, a radiological parameter, a genetically modified organism, or any other factor that is examined when control and surveillance activities take place;

u_i^l is relative damage to health caused by violations of sanitary-epidemiologic requirements to an i-th hazard factor related to food products;

W is a coefficient that characterizes consumption of food products by people.

Frequency (probability) of cases in which obligatory safety requirements to products can be violated as per i-th hazard factor during a single inspection is determined as per statistical data provided by a surveillance authority; it is calculated as a ratio of examination results with detected violations of requirements and standards to the overall number of examinations.

Damage to health is assessed either as per results of cause-and-effect relations modeling or as per data taken from relevant scientific literature. Table 3 contains examples of mathematical models that show "violation of obligatory requirements to food products safety" – "consumers' health disorders" relations (they are taken out of more than 800 authentic models that were obtained during the present research).

Table 3

Examples of parameters included into mathematical models that show "violations of sanitary standards for products safety – consumers' health disorders" relations

Products (group of products)	A parameter with detected violation of sanitary standards	Population contingent	Health disorders	Model parameter	
				a^*	F
Confectionary	Microbiological parameters	Total population	Enteric infections	12.99	16.22
Canned food	Microbiological parameters	Total population	Certain infectious and parasitic diseases	50.00	25.12
Dairy canned products	Microbiological parameters	Children	Enteric infections	19.81	17.17
Cream products	Microbiological parameters	Children	Enteric infections	10.47	12.43
Cream products	Microbiological parameters	Older than employable population	Enteric infections	0.28	6.88
Cream products	Microbiological parameters	Employable population	Enteric infections	8.96	8.98
Cooked products in retail outlets	Pathogenic microorganisms	Total population	Certain infectious and parasitic diseases	500.50	19.63
Meat and meat products	Antibiotics	Children	Non-infectious enteritis and colitis	12.21	17.11
Butter and fat products	Pesticides	Older than employable population	Diseases of the liver	87.04	12.56
Vegetables	Nitrates	Total population	Diseases of the blood and blood-forming organs	56.93	18.45

* A growth in morbidity (cases / 100 thousand people) when frequency of violations grows by 1%.

Risk assessment methodology is quite versatile and it makes all the sequential steps in the algorithm interrelated and consistent. But at the same time, data that are applied in calculations can be completely different in the EAEU member states in spite of the unified methodological base. Violations of obligatory requirements are detected with significantly different frequency in different regions due to peculiarities of products manufacturing, storage, and transportation to an end customer.

Thus, alcohol and non-alcohol drinks, honey, tropical and subtropical fruit and some other goods in Armenia are ranked as "low-risk products" while in the RF a probability that requirements to safety of these products are violated is rather high. This discrepancy by no means is to be considered an inconsistency. It is quite possible that certain product groups differ significantly in the EAEU member states. But still, priorities that exist in different EAEU countries can be interesting and important for surveillance authorities of a state that imports products manufactured in another state on its customs territory. We should note that, nevertheless, if unified methodical approaches to selecting priorities were applied, it would allow to assess objectivity of estimations made in each EAEU member state.

The third stage in the algorithm for risk-oriented surveillance implementation involves creating risk profiles for a specific product in order to optimize laboratory control. A risk profile is a set of standardized safety parameters that is typical for a specific product; the set should include parameters regulated by such hygienic requirements that are violated most frequently and gravity of these violations should also be taken into account.

Creation of a risk profile for a product involves profound analysis of long-term laboratory research on products quality and safety. The basic tasks here are to spot out products groups (types) which are characterized with the highest probability that sanitary-hygienic standards and requirements to them are violated and these violations can be detected with instrumental research; to identify parameters obligatory requirements to which are violated

with the highest frequency; to assess potential consumers' health risk when products with detected violations are distributed on the market.

For example, we analyzed how frequently safety requirements were violated and assessed health risks when examining migration of chemical admixtures from construction and finishing materials (approximately 3 thousand samples of products belonging to 30 groups in the Commodity Nomenclature for Foreign Economic Activities (CN FEA) on the RF territory). We detected the following factors that caused risks for consumers' health: formaldehyde, phenol, hydrogen chloride and ammonia; these factors formed risk profiles for products from the CN FEA groups 4410, 4411, 4412 (flakeboards, wood-fiber boards, pressed plywood, etc.); other standardized admixtures (approximately 16 parameters) were practically never registered in quantities higher than standards and didn't cause any health risks.

We revealed that acrylonitrile was a risk factor for materials from the group 4814 (acrylic wallpapers etc.); other migrating standardized admixtures didn't cause any significant risks.

There were several products groups (CN FEA 3922 - bathtubs and sinks; CN FEA 4601 - wicker products and materials for wickerwork, mats, screens, etc; CN FEA 4823 - paper, cardboard, cellulose cotton, etc.; CN FEA 5602 - felt; CN FEA 5703-5705 - textile carpets, carpets made of felt or taffeta; CN FEA 5905 - textile wallpapers) for which data collected over long-term period were analyzed and the analysis revealed it was not necessary to provide scheduled systemic laboratory support for them as frequency of detected violations in terms of chemicals migration amounted to less than 0.01%, and hygienic standards in all the detected cases were exceeded only slightly, by 1.1-2.0. Therefore, laboratory support provided for a surveillance activity should be oriented at estimating priority risk factors including an increase in number of examined samples. Other admixtures can be included into inspections programs on the residual principle.

Stricter and more frequent control over risky products and orientation at priority parameters in inspection programs with simultaneous decrease in frequency of measuring parameters

that are less informative should eventually provide growth in consumer market safety without any increase in overall expenses on instrumental support provided for inspections.

Undoubtedly, it is necessary to perform laboratory control as per a wide range of parameters. Methodical approaches indicate that this control should either be performed in a screening mode when profound examinations are accomplished on a great quantity of similar products and are aimed at creating a risk profile for them, or it should be random and performed on random samplings in order to assess average compliance with hygienic standards fixed for products safety. A share of such examinations can be equal to about 20% according to recommendations given by world practice [34].

Results of each inspection performed within the frameworks of the suggested model are to supplement and to expand the database which was an initial one for priorities determination. We should note that only this exact structure of the system provides consistent efficiency of control activities and gradual growth in overall quality of distributed goods. And as priority juridical persons and private entrepreneurs as well as the most unsafe goods are under constant and systemic control, including laboratory one, such goods should gradually be "washed out" from distribution and it will lead to a growth in overall consumers safety.

Conclusion. Profound analysis of the legislation and surveillance practices in the sphere of consumer products distribution in the EAEU revealed that the EAEU member states were in general committed to providing consumer products safety and to minimizing risks for people lives and health. The legislation in practically each member state envisages both product risks assessment and risk-oriented surveillance. The situation can be considered a good ground for developing a system of coordinated and mutually beneficial activities related to risk-oriented surveillance over products. Such a system would allow to make interstate relationships more confident and objective and create efficient barriers for products that are hazardous for population health but at the same time it would minimize administrative barriers for

products that don't cause any grave (significant, high, and alike) risks for consumers health in the unified EAEU economic space.

Basing on principles of risk assessment as a combination including probable violation of obligatory sanitary requirements to products as well as probability and gravity of consequences such violation would lead to, we suggest a model for risk-oriented surveillance that can be applied in all EAEU member states as a methodical base for creating national models for surveillance over products.

The suggested model includes three inter-related modules:

1) Ranking activities performed by economic entities that deal with consumer products distribution as per potential risks of damage to health. Methodical support offered by the module allows to spot out such juridical persons or private entrepreneurs whose activities performed in the sphere of products manufacturing, trade, or catering don't meet sanitary requirements and cause the highest risks for consumers health; it also allows to fix periodicity of scheduled inspections which is relevant to risks.

2) Classification of products as per consumer health risks.

Methodical support offered by this module, basing on actual frequency with which sanitary requirements to products are violated and on consequences of such violations, allows to spot out such consumer products which are the most "risky" for consumers. It allows to select priority, or, in other words, the most hazardous products for examinations during scheduled inspections.

3) Creation of risk-oriented and differentiated laboratory support for scheduled control and surveillance activities.

Modules are provided with methodical support and specialized software.

The procedure was tested in the RF and Belarus; its practical feasibility has been proven. But still, unified approaches to products classification as well as risk-oriented surveillance model can function efficiently in the EAEU only if all their structural components are present. They are:

–information base for surveillance that includes formalized, verified, and structured data

on parameters of inspected products; on cases in which obligatory requirements to products were violated; on consequences of such violations; on evidence proving that health disorders were caused exactly by hazardous factors related to products;

- methodical and mathematical tools and software that allow to process data arrays, to obtain simple and easy-to-understand statistics on results of control and surveillance activities (calculation of violation frequencies on product types in general, as per specific factors, manufacturers, etc.), as well as to perform more science-intense operations: to detect relationships within "products - damage to health" system or "risk management activities - products risk characteristics" system; to assess average and maximum expected gravity of health disorders; etc.;

- organizational structure that is provided with qualified personnel; this structure should collect, process, and analyze data, and inform all the concerned parties about obtained results.

- well-organized channels for information exchange; some participants use then to feed ini-

tial data into the system (control results including laboratory tests reports, data on injuries, intoxication, diseases, complaints about products etc.), and other participants give a feedback when they "communicate" results of assessing hazards or risks related to this or that product. And informing about risks is supposed to transform into more complicated and sophisticated data exchange form, namely, risk communication.

Overall, the system of risk-oriented surveillance over products is developing quite intensely. Mutual disclosure of results obtained during control and surveillance activities, data exchange, and multi-sided informing about cases in which damage to health occurred give grounds for further development of the system and creation of barriers preventing unsafe products from entering the common EAEU market.

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