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Research article

ON ISSUES RELATED TO NATIONAL RISK-BASED SYSTEM FOR CONTROL OVER FOOD PRODUCTS DISTRIBUTED ON THE MARKET

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This research is vital given great significance of food safety for population and bearing in mind that food products are an independent object of sanitary-epidemiologic control as it is stipulated by the legislation.

We suggest approaches to creating a risk-based model for control over food products distributed on the market. These approaches involve categorizing food products as per potential health risks for consumers; building up risk profiles of food products; optimizing laboratory support provided for control and surveillance activities taking into account food products safety management.

When categorizing food products, risk is assessed as a combination of probable violation of obligatory requirements to safety and severity of consequences these violations might have. Food products that are assigned into extremely high, high and considerable risk categories are subject to systemic control once a year, every two years or every three years accordingly. In case a surveillance object seems "law-abiding', its category and intensity of control procedures may be changed. Programs for laboratory control over food products are suggested to be based on risk profiles, spotting out priority indicators that make major contributions into risks. Also the approach involves using-mathematical models that describe a relation between a number of observations and an expected answer (as a reduction in quantities of deviating samples at the next stage in the control cycle). This model determines how many samples of priority indicators should be tested in order to achieve a target risk level. It also allows predict an expected number of violations and health risk rates at the next stage in the control cycle given the present number of observations.

85 regional registers of food products were created and categories were determined as per health risks for all groups of food products under surveillance. It was shown that in some cases it was necessary to increase a number of observations over priority ("risky") indicators in order to detect hazardous products and withdraw them from the market. Certain examinations seem redundant as they don't play any role in making control procedures more efficient.

The suggested approaches are universal and dynamic. Basic trends in the model development may include more targeted selection of products for control; risk profiles creations and systemic actualization; further development of laboratory support for control (surveillance) given that the food products market is changing dynamically in the country.

Key words: *food products distributed on the market, risk-oriented control, laboratory control, product safety management.*

Control over safety and quality of products (goods), especially food products that are distributed on the consumer market is among the most important tasks to be solved by authorities in any country and the Russian Federation is no exception[1] [1–5]. On one hand, this is vital due to population being less satisfied with food products when they are not safe and / or do not conform to quality standards [6, 7]; on the other hand, unsafe or low quality food products may cause various diseases, even grave ones in some cases, and this results

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[1] Ob utverzhdenii Doktriny prodovol'stvennoi bezopasnosti Rossiiskoi Federatsii: Ukaz Prezidenta RF ot 21 yanvarya 2020 g. № 20 [On Approval of the Doctrine on the food safety in the Russian Federation: The Order by the RF President dated January 21, 2020 No. 20]. *Garant: the information and legal portal*. Available at: https://www.garant.ru/products/ipo/prime/doc/73338425/ (October 04, 2021) (in Russian).

in poorer medical and demographical indicators [8–11]. Thus, Dubois-Brisonnert [8] showed in their research that approximately 1.5 million cases of food poisoning were annually registered in France only and they caused about 250 deaths. Food-borne diseases include various allergic reactions, communicable diseases with new properties or with more severe clinical course [8, 9], resistance to antibiotics, gastrointestinal disorders, diseases of the nervous system, etc. [10, 11].

According to the documents issued by the World Health Organization, "food safety" is "*assurance that food will not cause adverse health effects to the consumer when it is prepared and/or eaten according to its intended use*". This safety is provided by "*preventing and eliminating hazards caused by contaminants, admixtures, natural toxins or any other substances, whether chronic or acute, that may make food injurious to the health of the consumer or reducing them to acceptable and safe levels*" [2].

Without doubt, application of HACCP (Hazard Analysis and Critical Control Point) principles in food manufacturing is the primary and key component in providing its quality and safety [12]. HACCP system is the internationally tested and accepted efficient tool for managing production processes in order to minimize microbiological, biological, physical, chemical and other risks that products might get contaminated when being manufactured. Its primary advantage is its capability to not only reveal technical, technological, behavioral and any other mistakes at each stage in food production but also prevent them [13]. The system is oriented at maximum assured provision of food safety and quality and this is the primary task that has to be tackled by food industry in its overall operations [14, 15].

We do not intend to lessen the importance of the preventive role played by the system for analyzing risks and critical points and management quality in food manufacturing; still, we should note that the state sanitary control over products (goods) that are already distributed on the market is among the most significant components in the system aimed at protecting health (and sometimes even lives) of food consumers [16, 17]. Control over goods on shelves in retail outlets, in workshops and kitchens of catering facilities etc. is the last and the most direct barrier between potentially unsafe food and people who consume it.

Many countries use risk-based model of food control and surveillance activities [18–21]. The same model started to be developed and implemented by Rospotrebnadzor at the very beginning of the administrative reforms in the Russian Federation. In 2017 the RF Chief Sanitary Inspector approved the methodical recommendations on assigning economic entities into specific categories as per potential health risks[3]. This document ensures spotting out objects under surveillance that create the greatest risks of damage to protected social values.

The Federal Law "On the state control (surveillance) and municipal control in the Russian Federation" that came into force on June 01, 2021[4] stipulates that products (goods) are an

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[2] Codex Alimentarius. General Principles of Food Hygiene CXC 1-1969. *FAO, WHO*. Available at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/fr/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B1-1969%252FCXC_001e.pdf (December 04, 2021).

[3] MR 5.1.0116-17. Risk-orientirovannaya model' kontrol'no-nadzornoi deyatel'nosti v sfere obespecheniya sanitarno-epidemiologicheskogo blagopoluchiya. Klassifikatsiya khozyaistvuyushchikh sub"ektov, vidov deyatel'nosti i ob"ektov nadzora po potentsial'nomu risku prichineniya vreda zdorov'yu cheloveka dlya organizatsii planovykh kontrol'no-nadzornykh meropriyatii: utv. Federal'noi sluzhboi po nadzoru v sfere zashchity prav potrebitelei i blagopoluchiya cheloveka 11 avgusta 2017 g. [MR 5.1.0116-17. The risk-based model of control and surveillance activities in the sphere of providing sanitary-epidemiologic welfare. Classification of economic entities, types of activity and objects under surveillance as per potential human health risks for organization of scheduled control and surveillance activities: methodical guidelines (approved by the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing on August 11, 2017)]. *The Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing*. Available at: https://www.rospotrebnadzor.ru/documents/details.php?ELEMENT_ID=9037 (December 07, 2021) (in Russian).

[4] O gosudarstvennom kontrole (nadzore) i munitsipal'nom kontrole v Rossiiskoi Federatsii: Federal'nyi zakon ot 31.07.2020 № 248-FZ [On the state control (surveillance) and municipal control in the Russian Federation: The Federal Law issued on July 31, 2020 No 248-FZ]. *KonsultantPlus: the reference system for legal documentation*. Available at: http://www.consultant.ru/document/cons_doc_LAW_358750/ (September 30, 2021) (in Russian).

independent object under control (Clause 16). Before that products were controlled only as a component of economic entities activities.

Accordingly, just as any other objects that are subject to control, products are to be assigned into specific categories as per potential health risks and intensity of surveillance activities should be relevant to these risks. Passage of this law required developing science-based approaches to planning control and surveillance activities in regard to products (goods). And since it is chemical and biological contamination of food that is the primary hazard factor, laboratory control is seen to be the most significant component in any surveillance activity.

Control over products distributed on the market aims to detect, remove and completely eliminate (withdraw) unsafe products from distribution. Simultaneously there should be signal to all participants on the market that surveillance will reliably provide this elimination.

Bearing all this in mind, we can see two primary tasks in planning control procedures:

– to determine types of food that are subject to the most intense control (but still, all food products distributed on the market should be under control);

– to substantiate optimal volumes of laboratory analyses of specific products taking their risk category into account.

Solution to the first task (spotting out priority food products) can be found in the methodical document approved by the RF Chief Sanitary Inspector in 2016[5]. The document stipulates how to assess a specific food product as per risk criteria. Health risk is examined in full conformity with its definition as a combination of a probable undesirable event (violated requirement to product safety) and severity of consequences.

The document also allows assigning food products into specific categories as per health risks taking into account frequency of violations of mandatory requirements to safety and severity of probable health disorders among consumers given the current consumption of a specific food product, both values being statistically established at a given moment (period) of time. The document is widely used in practice by Rospotrebnadzor regional offices [22, 23].

At present this methodical document is to be brought into line with the provisions stipulated by the 248-FZ since it should provide a solution to the second task, namely minimal sufficient or optimal numbers of laboratory analyses performed on products with different health risk levels.

A classic solution to the task how to determine a sufficient number of instrumental measurements can be derived with a formula used to calculate an error of mean for a binary random variable. The aim is to determine a number of measurements that provide detection of deviations from a standard (criterion) with preset precision and level of significance). To do that, Koichubekov [24], for example, suggested performing sampling studies of products during a year with a sampling volume calculated as per the following ratio:

$$n = \frac{Z^2 p(1-p)}{\Delta^2}, \qquad (1)$$

where n is a number of sampling studies (a sampling volume); p is estimated frequency of violations of hygienic standards; Δ is permissible error in frequency of violations of hygienic standards; Z is a quantile of standard normal distribution of the order 0.975.

A volume of sampling studies determined as per the ratio (1) allows quite certain determination how frequently violations are detected. Any increase in a sampling volume will result in a smaller error but, accordingly, a decrease in it will lead to a greater one. Such ap-

[5] Klassifikatsiya pishchevoi produktsii, obrashchaemoi na rynke, po risku prichineniya vreda zdorov'yu i imushchestvennykh poter' potrebitelei dlya organizatsii planovykh kontrol'no-nadzornykh meropriyatii: Metodicheskie rekomendatsii (utv. Prikazom Rospotrebnadzora ot 18.01.2016 g. № 16) [Classification of food products distributed on the market as per potential health risks and property losses by consumers for organizing scheduled control and surveillance activities: Methodical guidelines (approved by the Order by Rospotrebnadzor issued on January 18, 2016 No. 16)]. Moscow, The Federal Center for Hygiene and Epidemiology of Rospotrebnadzor, 2016, 38 p.

proach to organizing control and surveillance activities involves greater numbers of measurements for products with low frequency of violations than for those with high frequency. This situation contradicts to principles of the risk-based approach that involves stricter control over objects with more frequent violations of sanitary requirements and lower burden on objects that comply with them.

An issue related to substantiating a relevant sampling volume when surveillance over products is organized within the risk-based approach requires taking into account cause-effects relations between frequency of detected violations and a number of accomplished studies.

If we accept a hypothesis that a reduction in frequency of violations results from an increase in intensity of surveillance, then we face another task which is how to determine a volume of sampling and accomplished studies that provide achieving the preset level of detected violations or risk.

Therefore, instead of solving a task how to assess product quality with preset reliability, it seems advisable to set a management task a solution to which can provide results with greater significance for sanitary services and food consumers. That is, we have to answer a question: how many samples and of what product should be taken and examined during control and surveillance activities to ensure reduction in a number of deviating samples to a certain (preset or target) level bearing in mind that resources are limited.

It is very important to answer this question since efficiency of instrumental research differs as per product groups, specific indicators, and regions [25–27].

Since the research results give grounds for making decisions on elimination of discrepancies, administrative measures, etc., it is essential to develop unified and science-based approaches to the content and volumes of analyses performed in control over food distributed on the market.

Our research aim was to develop approaches to optimizing the risk-based sanitary-epidemiological control (surveillance), including laboratory support, as a tool for managing food safety.

We should bear in mind that the research focuses only on food safety. Aspects related to risk-based assessments whether product marking or quality conform to mandatory requirements, including falsification, require separate investigation.

Materials and methods. Products (goods) for which violations of mandatory sanitary requirements were detected were considered unsafe food.

Potential health risk was determined as a combination of probable violation of requirements to a specific product, severity of health disorders caused by this violation, and an exposure scope taken as a number of people consuming unsafe food.

Health risks for consumers were assessed as per the algorithm stated in the approved methodical recommendations[5] taking into account that generally products distributed on the consumer market were characterized with violations of mandatory requirements with frequency established by control and surveillance activities.

A probability that obligatory requirements would be violated was described by the frequency of detected violation in all regions in the Russian Federation. Bearing the precautionary principle in mind, we took 95 % percentile in the distribution of a regional relative indicator (a number of violations per 1 inspection) over the last three years as frequency of violations.

Severity of consequences for consumers' health caused by unsafe food was taken as a combination of severity of health disorders for a specific consumer caused by unsafe food (values close to zero meant that health disorders were mild and values close to 0.95 meant they were severe) and a scope of these disorders. The scopes were determined by estimating volumes of food consumption, regional peculiarities taken into account[6].

[6] Potreblenie osnovnykh produktov pitaniya naseleniem Rossiiskoi Federatsii [Consumption of basic food products by population in the Russian Federation]. *The Federal State Statistic Service*. Available at: https://rosstat.gov.ru/compendium/document/13278?print=1 (September 27, 2021) (in Russian).

Food products were categorized as per potential health risk according to the criteria stipulated in the Provisions on the Federal State Sanitary Surveillance[7]).

Objects were assigned into the following risk categories: extremely high risk, high risk, considerable risk, average risk, moderate risk, and low risk.

We analyzed the following data to determine necessary scope of laboratory support for control and surveillance activities (a number of analyses and food samples):

– data on a number of taken samples as per specific food products in a given region and in all the RF regions over the last few years (the Statistical Report Form "Data on the results of the federal state surveillance accomplished by Rospotrebnadzor regional offices" issued in 2010–2020);

– data on a number of detected violations as per specific indicators for the same food products on a regional and country level;

– data on probable adverse effects on consumers' health that may be caused by violated requirements to a specific indictors and severity of these effects;

– volumes in which specific foodstuffs are consumed in a given region (according to statistical reports provided by Rosstat and sampling studies of household spending);

– population in a given regions including its age structure (children and adults).

We assumed there was the following functional link:

$$n \sim puM\,, \qquad (2)$$

where n is a number of analyses; p is frequency of detected violations of a hygienic standard; u is specific severity of health disorders; M is an exposure scope (practical calculations involved using a number of consumers or population related to 100,000 as a scale factor); the sign "~" means there is a certain functional link.

The formula (2) is general in it essence and reflects the basic hypothesis that covers all safety indicators and all food products; therefore, indices that identify specific food products and safety indicators are omitted.

When a specific safety indicator is considered for a given food product, specific severity of health disorders is the constant; therefore, we can derive the equation (3) with its precision up to the constant:

$$\frac{n}{M} = v \sim p\,, \qquad (3)$$

where v is a specific volume of analyses regarding a standardized indicator (hygienic standard) for a specific food product.

A specific volume of analyses v was taken as a number of food product analyses per 100,000 people in a RF region that were accomplished or planned to be accomplished during control and surveillance activities over a calendar year.

Within system analysis a specific volume of analyses is a vector that describes a number of analyses for a system of safety indicators $V^T = \{v_i\}, i = 1...I$, where I is a number of standardized indicators for an examined food product. The whole system of indicators or its part can be determined from just one food sample.

The functional link between a number of accomplished analyses aiming to determine whether food conforms to hygienic standards and frequency of detected violations (3) is the basis for management tasks.

Food safety in a region is an object to be managed. This safety is determined by a system of indicators reflecting how often hygienic standards are violated and creating a space with different states of an object to be managed given by the phase vector:

$$P^T = \{p_i\}, i = 1...I. \qquad (4)$$

[7] O federal'nom gosudarstvennom sanitarno-epidemiologicheskom kontrole (nadzore) (vmeste s «Polozheniem o federal'nom gosudarstvennom sanitarno-epidemiologicheskom kontrole (nadzore)»): Postanovlenie Pravitel'stva RF ot 30.06.2021 N 1100 [On the federal state sanitary-epidemiologic control (surveillance) (together with "The Provisions on federal state sanitary-epidemiologic control (surveillance)"): The RF Governmental Order issued on June 30, 2021 No. 1100]. *KonsultantPlus: the reference system for legal documentation*. Available at: http://www.consultant.ru/document/cons_doc_LAW_389344/c3ec9aec7f786991ebd558c3002ea5caa6a22c1a/ (September 27, 2021) (in Russian).

Given that health is influenced by a whole set of all standardized safety indicators, we can establish that management aims to control the functional that describes health risk and can be given as the following equation:

$$Risk = \left(\sum_i p_i u_i \right) M = \\ = \left(\sum_i p_i \sum_j \alpha_{ij} g_j \right) M \to \min, \quad (5)$$

where α_{ij} is a coefficient describing a *j*-th health disorder caused by violated *i*-th safety indicator; g_j is a severity of consequences when the *j*-th health disorder is detected.

Finding a solution to the task (5) requires identifying hazard for each indicator of specific food products. Probable negative health responses caused by violated hygienic food standards were established based on literature data. Coefficients describing severity of health disorders were taken in accordance with the recommendations issued by the WHO[8] and data of the meta-analysis provided by Minsu Osk with colleagues [28].

Bearing probable responses to violations in mind, we believe that the system should involve creating "risk profiles" for food products, that is, determining indicators that make the greatest contribution to overall risks caused by food and are subject to the priority and strictest control.

And the task here was to determine a desirable frequency of control over priority (risk) factors so that frequency of detected violations could reach a desirable (target) level in the next control cycle. Therefore, contents and scopes of laboratory analyses become an instrument for managing food safety.

A functional link between actual frequency of detected violations (a state of food as an object to be managed) and management vector is determined through statistical modeling of relationships based on departmental statistic data. Attention is paid to intensity of laboratory control over food safety and frequency of detected violations.

We assumed that frequency of control and surveillance activities and analyses influenced frequency of violations of mandatory requirements in the next year.

A type of this functional relation was determined by an exponential model corresponding to the argument that it was possible to make food fully conforming to safety criteria by a significant increase in intensity of control and that total absence of control results in food safety going down to its critical values.

All the aforementioned hypotheses borne in mind, we searched for relationships between management indicators and a state of food in accordance with the following regression model:

$$p_i^{t+1} = a1_i \left(v_i^t \right)^{a2_i}, \quad (6)$$

where p_i^{t+1} is a frequency of violation of *i*-th standardized food indicator detected in the year t+1; m_i^t is a number of accomplished analyses regarding the *i*-th indicator in the year *t*; M^t is a number of consumers; $a1_i$, $a2_i$ are parameters of the regression model and the parameter *b* is conditioned with $a2_i < 0$.

There are certain limitations imposed on management indicators and food indicators in the management task (5)–(6):

– limitations on achievement of target values (target safety) by indicators describing food safety:

$$p \le p^* \text{ or } p_i \le p_i^{Цел}, i = 1...I. \quad (7)$$

We should note that it is advisable to take into account provision of surveillance authorities with necessary resources ($\sum_i n_i \le W$) when solving the task. But it requires a separate study bearing in mind other criteria related to optimization of control systems. It is also vital to determine target food safety, that is, to

[8] Global burden of disease 2004 update: disability weights for diseases and conditions. *WHO*. Available at: https://www.who.int/healthinfo/global_burden_disease/GBD2004_DisabilityWeights.pdf (September 01, 2021).

determine acceptable risk level and, accordingly, acceptable frequency of detected violations of specific indicators. We should remember that detecting all probable violations of mandatory requirements involves total control over food which seems too expensive and rather inefficient. The issue is a task to be solved within strategic planning and requires participation by experts and decision-makers. In the present research a target safety level p_i^* was given by average country frequencies of detected violations as of the end of 2020 or by a specifically preset parameter being 1 % of samples with detected violations.

Finding solutions to the management task (5)–(7) in regard to a specific food product determines a number of analyses corresponding to preset target safety levels.

$$v_i^* = \left(\frac{p_i^*}{a1_i} \right)^{1/a2_i}. \qquad (8)$$

A number of analyses accomplished in a specific region is determined by a specific number of analyses multiplied by a number of consumers (population): $n_i^* = v_i^* M$. The necessary number of analyses is determined as a maximum component of the vector $N^T = \{n_i\}, i = 1...I$.

Essentially a solution to the task (5)–(7) regarding a system of indicators and specific food products helps determine a certain common federal standard of laboratory support for control and surveillance activities; this standard will allow developing an analysis program for a given region. And if we want to satisfy the boundary condition (8), we should set and solve the optimization task (5) with the target function.

When this optimization task is set for a given region, it results in occurring contradictions associated with the established model (6) not being consistent with actual ratio between a number of analyses and frequencies of detected violations. It means that a different number of analyses is required in different regions to provide the same frequency of detected violations.

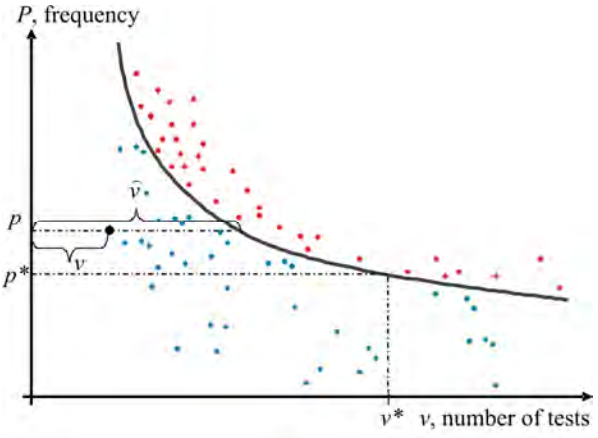

Figure 1. General view of "a number of analyses – detected frequency of violations" relationship for estimating efficiency of laboratory analyses given the preset target level

This assumption indicates that accomplished laboratory tests regarding food safety may have different efficiency.

Actually the model (6) divides the dispersion diagram into some areas where the given curve divides all the analyses into two groups (Figure 1).

Points describing a situation when scopes of accomplished tests do not provide achievement of a target level at the next step in management are located above the curve; that is, control activities do not result in withdrawing all the unsafe food from the market in the current situation in a given region and their preventive effect is not sufficient. A lot of violations are likely to be detected again during the next control cycle.

Points describing a situation when scopes of laboratory analyses provide achieving a target level are located below the curve. And if a target level is well-grounded, in some cases scopes of laboratory analyses can be estimated as redundant and it is possible to reduce them in order to save resources and redistribute expenses to provide control over other indicators.

Management in a specific region is described with an actual ratio between frequency of violations of standardized indicators (p_i) and intensity of laboratory analyses (v_i); its aim is to change a scope of analyses ($v_i + \Delta v_i$) in such a way so that a target frequency of detected violations ($p_i \to p_i^*$) is achieved. A change in a specific scope of analyses is determined as per the ratio (9):

$$\frac{v_i}{\hat{v}_i} = \frac{v_i + \Delta v_i}{v_i^*}. \quad (9)$$

An absolute change in a scope of analyses is determined in accordance with the scale factor (10):

$$\Delta n_i = \Delta v_i M. \quad (10)$$

If we use the equations (9), (10), we can calculate scopes of analyses necessary for a specific region regarding specific indicators and food products and their changes against the last reporting year. These calculations allow planning relevant laboratory support for control and surveillance over food safety.

Basic results. Priority food product groups that were subject to the most frequent surveillance activities were determined at the first stage in developing plans for control over food. Overall, we created the federal register and 85 regional ones containing data on various food products. Table 1 provides a part of a regional register with determined risk categories.

We determined that from 8 to 15 large product groups (various food products) could be assigned into categories of extremely high, high, and considerable risk depending on frequency of detected violations and regional consumption peculiarities. Meat and meat products, milk products, poultry, eggs and products made of them, fish, other seafood, etc. were assigned into these three categories practically in every region.

Since food that is assigned into these three categories (extremely high, high, and considerable risk) is subject to systemic control, necessary volumes of schedules control and surveillance activities seem to be rather considerable.

Table 1

A part of a regional food products register (with risk categories determined for larger product groups)

Food (product group)	*P**	*U***	Risk rate and category***		*N*****	Contribution to total risk, %	A share of a total number of samples, %
Meat and meat products	0.039	5.477	2.16E-01	1	9,121	6.31	12.75
Poultry, eggs, and products made of them	0.107	4.172	4.45E-01	1	3,223	13.01	4.51
Milk and milk products	0.036	28.168	1.01E+00	1	10,241	29.52	14.31
Butter and fat-based products	0.025	6.154	1.52E-01	1	1,995	4.44	2.79
Fish, shellfish, and products made of them	0.16	1.178	3.67E-01	1	2,932	10.73	4.10
Culinary	0.032	1.772	6.59E-02	2	16,675	1.93	23.31
Flour and cereals	0.011	0.420	2.67E-03	3	3,225	0.08	4.51
Bakery	0.01	0.259	1.89E-03	3	2,962	0.06	4.14
Sugar	0.09	0.970	4.46E-02	2	92	1.30	0.13
Confectionary	0.02	2.293	2.66E-02	2	7,754	0.78	10.84
Fruits and vegetables	0.015	15.321	1.71E-01	1	5,320	5.00	7.44
Mushrooms	0.029	0.687	1.38E-02	2	100	0.40	0.14
Non-alcoholic drinks	0.023	2.396	4.23E-02	2	1,008	1.24	1.41
Juices and nectars	0.022	0.725	1.43E-02	2	830	0.42	1.16
Alcoholic drinks	0.018	1.348	1.84E-02	2	2,075	0.54	2.90
Honey and beekeeping products	0.144	0.038	9.50E-03	3	22	0.28	0.03
Food products for children	0.02	6.166	4.59E-01	1	589	13.42	0.82
Canned food	0.062	1.261	4.86E-02	2	1,040	1.42	1.45
Grain (seeds)	0.019	0.075	2.48E-03	3	344	0.07	0.48
Mineral water	0.024	2.909	5.20E-02	2	498	1.52	0.70
Bottled water	0.03	0.562	2.97E-02	2	425	0.87	0.59
Salt	0.028	0.091	1.30E-03	3	559	0.04	0.78
Total	–	–	3.19E+00	–	–	100.00	100.00

N o t e : * p is frequency of detected violations, 95-th percentile over 2010–2020 (taking into account control and surveillance activities and industrial control);

** U is potential health risk for consumers; covers both severity and scale of consequences;

*** Risk categories: 1 means extremely high risk; 2, high; 3, considerable;

**** N is an average number of samples taken in 2010–2020.

Table 2

Changes in frequency of detected violations of hygienic requirements to food taken in dynamics (per 1 inspection)

Food (product group)	2013	2014	2015	2016	2017	2018	2019	2020	Relative change 2020/2013
Total	0.019	0.020	0.020	0.020	0.018	0.017	0.017	0.016	–15.8
Meat and meat products	0.017	0.017	0.018	0.017	0.018	0.017	0.017	0.017	0.0
Milk and milk products	0.022	0.024	0.025	0.028	0.024	0.024	0.022	0.019	–13.6
Poultry, eggs, and products made of them	0.028	0.030	0.029	0.029	0.026	0.027	0.024	0.023	–17.9
Fish, shellfish and products made of them	0.026	0.044	0.035	0.034	0.028	0.022	0.020	0.021	–19.2
Culinary	0.028	0.025	0.025	0.023	0.022	0.022	0.022	0.021	–25.0
Alcoholic drinks, beer	0.003	0.009	0.009	0.007	0.005	0.004	0.004	0.004	+33.3
Non-alcoholic drinks	0.014	0.018	0.018	0.020	0.018	0.014	0.013	0.013	+7.1
Potato	0.008	0.006	0.005	0.004	0.003	0.002	0.003	0.004	–50.0
Melons and water melons	0.023	0.011	0.013	0.017	0.012	0.014	0.021	0.018	–21.7
Fruits and berries	–	0.004	0.006	0.005	0.005	0.004	0.003	0.003	–
Canned food	0.008	0.019	0.018	0.019	0.020	0.018	0.020	0.016	+100.0
Biologically active additives to food	0.007	0.008	0.009	0.008	0.008	0.007	0.007	0.007	0.0
Mushrooms	0.057	0.045	0.041	0.035	0.040	0.027	0.026	0.021	–63.2
Grain and grain products	0.002	0.002	0.002	0.002	0.001	0.003	0.002	0.002	0.0
Honey and beekeeping products	–	0.017	0.015	0.012	0.008	0.012	0.014	0.017	+1600.0
Mineral water	0.011	0.014	0.016	0.014	0.017	0.015	0.014	0.013	+18.2
Flour and cereals	0.005	0.010	0.010	0.007	0.006	0.005	0.004	0.007	+40.0
Food products for children	0.004	0.006	0.004	0.005	0.006	0.004	0.005	0.006	+50.0
Food provided by catering facilities	0.024	0.022	0.022	0.023	0.021	0.022	0.022	0.019	–20.8
Butter and fat products	0.009	0.010	0.011	0.011	0.010	0.009	0.006	0.008	–11.1
Juices	0.005	0.006	0.007	0.007	0.005	0.007	0.006	0.007	+40.0

And we should remember that laboratory support provided for control activities should be proportionate to health risks and its aim should be constant improvement of a situation (a decreasing share of samples deviating from safety standards as stated in the present research). We comparatively analyzed risk rates and categories determined for various food products to reveal that overall distribution of laboratory analyses wasn't completely relevant to a contribution made by a specific group into potential health risks (Table 1).

In some cases inconsistence between frequency of laboratory analyses and product risks results in absence of any significant positive improvements of food safety on the consumer market.

Thus, a contribution made by the product group "poultry, eggs and products made of them" to the total health risk amounted to 13 % in the analyzed region but a share of product samples amounted to only 4.5 % in the total number of taken samples. But the frequency of detected violations as per microbiological indicators amounted to 9 % for this product group in 2013–2019 in that region and no stable decrease was detected in that period. A share of samples deviating from safety standards as per microbiological indicators amounted to 9.2 % in 2013; 8.13 % in 2015; 9.0 % in 2017; 6.8 % in 2019; and 7.8 % in 2020. Therefore, a target steady growth in safety of this product group and, consequently, food as a whole, is not achieved.

On the contrary, high frequency of analyses performed on culinary products in the region resulted in declining frequency of violations, from 2.5 % in 2013 to 1.03 % in 2019.

We analyzed detected frequencies of violations as per the most common food products in the Russian Federation in dynamics. The analysis revealed that in spite of the overall positive ascending trend in food safety there was no positive dynamics detected for certain product groups or there was even a negative trend (Table 2).

It should be noted that a decrease in a number of samples deviating from hygienic standards was achieved for such food products as "fish, shellfish and products made of them", "butter and fat products", "food provided by catering facilities", "potato", "melons and watermelons" etc. A share of deviating samples tended to grow for such product groups as "juices", "non-alcoholic and alcoholic drinks", "food products for children", "canned food", and some others.

In some cases a growth in a number of deviating samples is due to improved laboratory support provided for control activities and it allows identifying qualitative and quantitative violations that have never been detected before. However, the task to increase safety remains vital even when more developed control systems are now available.

We should note that detected overall frequencies of violations provided in the Table 2 are given taking into account a considerable share of tests that haven't detected any violations or have been detecting them with very low frequency. On one hand, it means that in general food distributed on the consumer market in the country is safe. On the other hand, long-term history of accomplished analyses initially assumes that "detection" is extremely low as per certain indicators and analyses are predicted to yield poor results.

For example, according to data taken from the Statistical Report Form "Data on the results of the federal state surveillance accomplished by Rospotrebnadzor regional offices in 2020" 25 thousand food samples were examined in the country to detect strontium-90 in them. There wasn't any detected sample that deviated from hygienic standard as per this indicator. 120.9 thousand food samples were analyzed to detect arsenic in them and the contaminant was detected only in 17 of them (0.014 %) belonging to 9 product groups (90 product groups were analyzed overall).

But at the same time, a share of samples deviating from hygienic standards as per microbiological indicators amounted to 4.45 % for "poultry, eggs, and products made of them" on average in the country and the total number of analyzed samples amounted to 49.5 thousand for this products group; 5.6 % of 25.18 thousand analyzed samples for "fish and shellfish" product group; 9.7 % of 2.28 thousand analyzed samples for "canned food" products group, etc.

Shares of detected violations are also very different in across regions. Thus, frequency of detected violations as per microbiological indicators amounted to 0.18 % of 556 tests for "poultry, eggs, and products made of them" in Kursk region in 2020 (it was by almost 25 times lower than on average in the country, 4.5 %); but it was 8.69 % of almost the same number of analyzed samples (564) in Vologda region (2 times higher than on average in the country).

This situation requires creating "risk profiles"[9] or such a characteristic of a product that comprises all necessary data on related risks. Table 3 provides an example of a risk profile created for the "milk and milk products" product group in a specific region.

Risk profiles give grounds for determining priority indicators that are provided with the optimal number of laboratory analyses at the next stage in the control cycle. Risk profiles for the same food can be different in different regions; but still, there are common regularities that can be used as a reference in case there are no data available for a specific region.

Table 4 provides priority indicators for some food products. These are indicators that are the most frequently violated in most regions in the Russian Federation and make the greatest contributions to total health risks.

We can see that frequencies of violations making the most considerable contributions to health risks are extremely uneven. Thus, control over safety of milk and milk products most frequently detects violations as per microbiological indicators and benz(a)pyrene and less frequently as per antibiotics and radiation factor, Lead, arsenic, pesticides, pathogenic

[9] Tamozhennyi kodeks Evraziiskogo ekonomicheskogo soyuza. Stat'ya 376 [The Customs Code of the Eurasian Economic Union. Clause 376]. *KonsultantPlus: the reference system for legal documentation*. Available at: http://www.consultant.ru/document/cons_doc_LAW_215315/95bff3c3e7d43c52b5a973884657f2796374a3fe/ (September 14, 2021) (in Russian).

Table 3

Creating a risk profile for a chain "product hazard" – "probable adverse effect on health" – "severity of consequences"

Standardized indicator	Probable health response	Severity of health disorder*	Frequency of violations	Risk created by a factor*	Rank in risk profile
Listeria monocytogenes	Enteric infections	0.27	0.02	0.0054	6
Pseudomonas aeruginosa	Enteric infections Acute enteric infections with pseudomonas etiology	0.27	0.06	0.016	3
Aflatoxin M1	Damage to the liver Immunity suppression Cancer	0.75	0.00	0.00	–
Yeast and mold, total	Pancreatitis	0.498	0.15	0.075	1
Chloramphenicol	Allergic eczema Anaphylactic reactions* Dysbacteriosis	0.235	0.02	0.005	7
Radionuclides	Cancer	0.65	0.00	0.000	–
Melamine	Damage to the kidneys	0.36	0.00	0.000	–
Benz(a)pyrene	Cancer	0.75	0.02	0.015	4
Lead	Immunity disorders Cancer	0.65	0.02	0.013	5
Arsenic	Damage to the nervous system Cancer	0.75	0.01	0.065	2
Cadmium	Damage to the kidneys Damage to the endocrine system Cancer	0.65	0.00	0.00	–

Note: * means that the precautionary principles taken into account, risk calculation involved focusing on the most severe health disorders.

Table 4

Frequency of detected violations of mandatory requirements in the Russian Federation

Indicator	Registered frequency of violations, 2013–2020, %	
	95 % percentile*	Average
Milk and milk products (R = 8.01E-01. Extremely high risk)		
Microbiological indicators	5.97	4.82
Benz(a)pyrene	3.37	1.84
Sanitary-chemical indicators	3.33	0.87
Antibiotics	0.99	0.53
Cesium-137	0.58	0.28
Pathogenic microorganisms	0.12	0.05
Lead	0.06	0.02
Arsenic	0.06	0.02
Pesticides	0.02	0.01
Mycotoxins	0.01	0.00
Mercury	0.01	0.00
Cadmium	0.01	0.00
Imported milk and milk products (R = 1.21E-01. Extremely high risk)		
Microbiological indicators	5.81	4.49
Sanitary-chemical indicators	3.76	0.87
Antibiotics	1.44	0.49
Pathogenic microorganisms	0.08	0.02
Cadmium	0.07	0.01

End table 4

Confectionary (R = 2.8E-02. High risk)		
Parasitological indicators	25.00	25.00
Microbiological indicators	4.99	4.42
Cadmium	0.10	0.05
Pathogenic microorganisms	0.09	0.04
Sanitary-chemical indicators	0.09	0.03
Mycotoxins	0.06	0.01
Pesticides	0.04	0.01
Mercury	0.01	0.00
Lead	0.01	0.00
Fruits and vegetables (R = 1.19E-01. Extremely high risk)		
Microbiological indicators	4.70	3.14
Nitrates	2.25	1.50
Sanitary-chemical indicators	2.00	1.26
Cesium-137	0.76	0.44
Pathogenic microorganisms	0.61	0.31

N o t e : * means the table provides data on indicators with their value being 0.01 %.

microorganisms etc. are registered in concentrations and quantities exceeding permissible levels less frequently than in 5 samples of analyzed 1,000; mycotoxins, mercury and cadmium are detected in approximately 1 case of 1,000 analyses; copper, nickel, chromium and melamine are detected even less frequently.

Obviously, it is necessary to determine an optimal structure of laboratory support that would provide not only the most reliable detection of unsafe food but also an opportunity to reduce a number of violations during the next cycle of control and surveillance activities.

Accumulated and formalized data on results obtained due to control over food in all regions in the Russian Federation collected over 10 years gave grounds for establishing and analyzing 2,835 relationships between frequencies of violations of standardized safety indicators and a number of detected violations, Figure 2 provides examples of some models and Table 5 provides a wider list of indicators.

When modeling the relationships, we applied moving average to clear the initial data from random spread.

The Figure 2 shows that if analyses are performed with low intensity, it almost always leads to a high percentage of violations ("overestimated" product hazard); however, growing intensity of analyzing doesn't always result in greater shares of detected violations (redundant instrumental research). And getting a complete picture of a product doesn't require analyzing different product indicators with the same frequency.

The built relationships were used to find a solution to the management task (5)–(7) and it allowed determining target volumes of analysis and adjusting analysis programs for different food products during control and surveillance activities.

Table 5 provides an example of calculations accomplished for a specific region in regard to some food products.

It is obvious that indicators contributing to health risks with mandatory requirements to them being violated the most frequently require a much greater number of analyses than are actually accomplished. Thus, if we want to achieve a target frequency of detected violations as per microbiological indicators for meat which is equal to 0.1 % (and an actual detected per cent of deviating samples is 6.5 %), we can clearly see that accomplished analyses are not enough. Analysis intensity should grow practically by three times and it should result in withdrawing products from the market that are unsafe as per this indicator and in preventing them from being distributed again in the next control cycle. Control over physical and chemical indicators and pathogens should also become more intense.

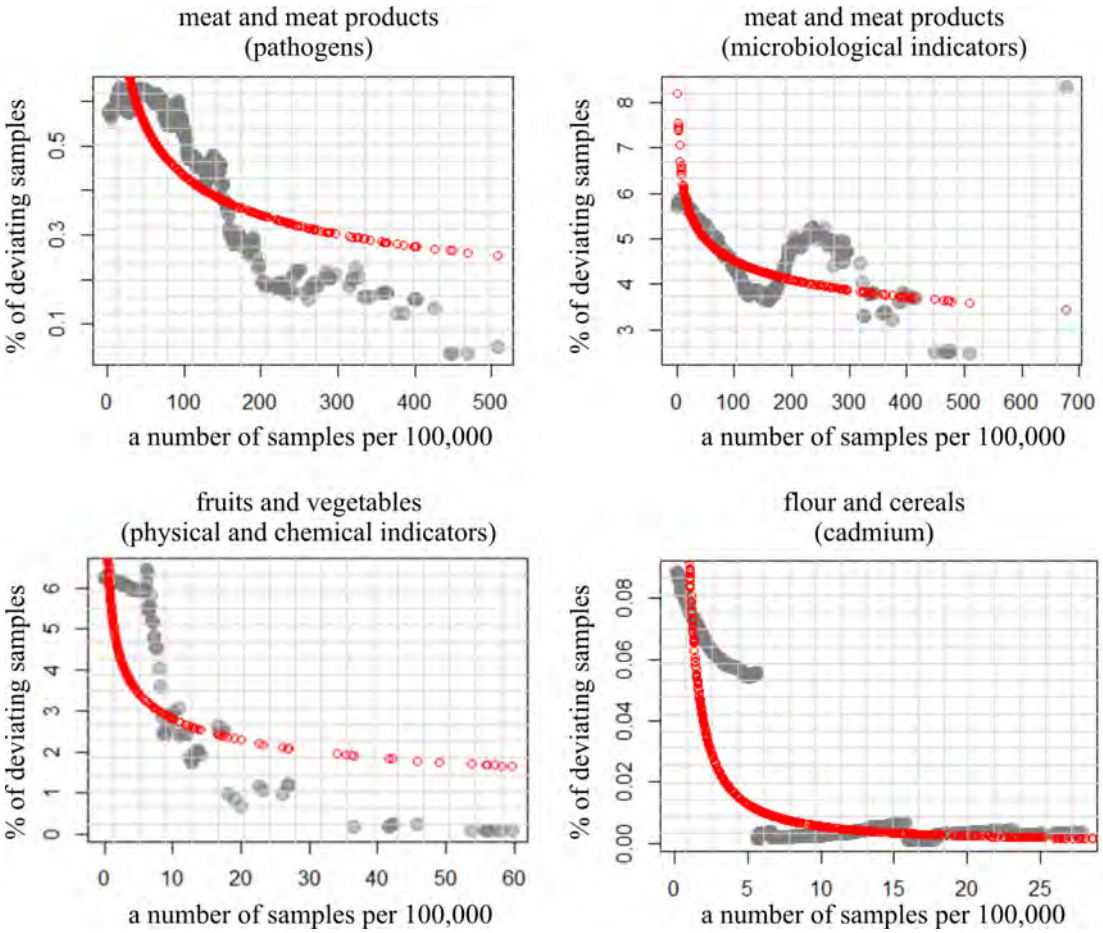

Figure 2. Examples of models that describe relationships between frequencies of violations of standardized product indicators and a number of analyses (analyses/100 thousand people)

More intense and frequent control aims to provide maximum possible detection of unsafe food and to eliminate it from distribution. Another aim is to give a clear signal to economic entities that control over such food will remain frequent and intense.

We should note that if frequency of detected violations as per "risky indicators" goes down to 1 % for meat and meat products, this will lead to reduction in overall risk rates in the country, from 2.16E-01 (extremely high risk) to 3.51E-02 (high risk); that is, this food will be assigned into another risk category as per potential health risk. If, for example, we set a target frequency at 0.1 % as per priority indicators in the next control cycle, then we can expect this food to move into "considerable risk" category, etc. Ultimately, it is exactly these strategic tasks that should be tackled by control and surveillance authorities when they perform their activities regarding food distributed on the market.

In some cases absence of any detected deviating samples might be due to insufficient volumes of analysis in a given region (in our example it concerns parasitological indicators and antibiotics in meat) as it is indicated by relationships obtained for the country as a whole.

But at the same time analyzing aimed at determining antibiotics, arsenic, and lead in milk seems redundant since actual number of analyses doesn't result in declining numbers of detected samples that do not conform to hygienic standards.

Therefore, optimization of laboratory control doesn't necessarily mean an increase in a number of analyses; instead, it involves creating such a structure of laboratory analysis that is relevant to the current sanitary-epidemiologic situations in regard to food distributed on the market.

Table 5

Parameters of models that describe relationships between frequencies of violated safety indicators and a number of analyses for some food products

Safety indicators	*a1*	*a2*	*N*	R^2	*F*	*p*
Meat and meat products						
Microbiological indicators	119.613	-0.108	837	0.372	494.8	1.86E-86
Pathogenic microorganisms	87.239	-0.120	556	0.588	789.8	1.1E-108
Physical and chemical indicators	25.492	-0.153	366	0.443	289.7	3.27E-48
Parasitological indicators	3.367	-0.126	46	0.181	9.71	0.003218
Antibiotics	6.533	-0.135	90	0.362	49.9	3.62E-10
Milk and milk products						
Arsenic	8.431	-0.200	16	0.741	40.08	1.86E-05
Pathogenic microorganisms	125.609	-0.057	135	0.066	9.43	2.60E-03
Lead	9.281	-0.108	20	0.201	4.54	4.73E-02
Physical and chemical indicators	97.323	-0.287	479	0.755	1467.9	1.1E-147
Antibiotics	9.996	-0.064	167	0.123	23.05	3.51E-06
Confectionary						
Microbiological indicators	56.257	-0.077	567	0.204	144.4	8.92E-30
Pathogenic microorganisms	37.080	-0.134	77	0.344	39.40	2.03E-08
Fruits and vegetables						
Cadmium	9.510	-0.238	42	0.519	43.2	7.49E-08
Microbiological indicators	17.666	-0.222	381	0.310	170.3	2.07E-32
Pesticides	19.495	-0.077	23	0.375	12.70	0.001897
Physical and chemical indicators	8.4550	-0.381	153	0.621	247.8	1.18E-33
Parasitological indicators	59.901	-0.054	286	0.152	50.8	8.49E-12
Sanitary-chemical indicators	77.635	-0.015	474	0.016	7.89	0.005176
Canned food						
Microbiological indicators	14.347	-0.119	406	0.341	209.0	1.78E-38
Nitrates	0.849	-0.169	26	0.207	6.26	1.95E-02
Physical and chemical indicators	7.841	-0.179	346	0.504	349.5	2.58E-54

Table 6

An example of calculating volumes of analysis necessary to estimate safety indicators for certain food products in a model region (population is 2,589 thousand people), the target share of deviating samples should not exceed 1 %

Food product / Safety indicator	Actual, 2020			Target values			Δn, analyses
	p	v_{actual}, analyses / 100,000	n_{actual}	*p**	*v**, analyses / 100,000	*n**	
Meat and meat products							
Microbiological indicators	6.15	37.69	976	1.0**	119.61	3,097	+2,118
				5.26* **	**102.3**	**2,649**	**+1,978**
Physical and chemical indicators	4.64	7.49	194	1	25.49	660	+466
				3.1	**9.54**	**441**	**+247**
Pathogenic microorganisms	3.09	37.52	971	1	87.24	2,259	+1,288
Parasitological indicators	0	0.66	17	1	3.37	87	+60
Antibiotics	0	2.82	73	1	6.53	169	+96
Milk and milk products							
Physical and chemical indicators	9.2	81.45	2,109	1	97.32	2,519	+410
				8.9	**94.12**	**2,437**	**+328**
Antibiotics	0.87	17.73	459	1	9.99	259	-200
Arsenic	0	20.89	541	1	8.43	218	-310
Pathogenic microorganisms	0	95.36	2,469	1	105.61	3,252	+30
Lead	0	25.30	655	1	9.28	240	-415

Note: ** recommended (model) frequency of violations of sanitary-epidemiologic requirements;
*** average Russian frequency of violations of sanitary-epidemiologic requirements in 2020.

Target criteria may be set step-by-step in the process and this means that we don't plan a single intense increase in volumes of analysis but consider a step-by-step change in the structure of it. For example, average country value of an indicator might be selected as the first target management criterion.

Thus, if we set 5.26 % as a target management criterion for frequency of detected deviating samples as per microbiological indicators for meat, it will require a lower number of analyses accomplished during a year than for achieving a lower target level of 1.0 % (Table 2, shaded lines). The same goes for a number of analyses accomplished to determine levels of physical and chemical indicators in meat and milk.

Achieving an intermediate target level provides an opportunity to set stricter targets and tasks in the next control cycle.

An indicator that requires the greatest number of analyses (taking into account peculiarities related to sampling for different types of analyses) is a limiting one in determining volumes of product samples necessary to accomplish laboratory research.

Discussion. The suggested approaches that provide implementing the risk-based model for control over food distributed on the market are universal and dynamic in their essence.

Assigning food products into different risk categories as per potential health risks takes into account both how frequently mandatory requirements are violated and severity of consequences these violations might have. Thus, a differentiated approach to selecting types (groups) of food products under control is provided. And food products may be assigned into another risk category only if their safety indicators have changed as it becomes apparent due to a share of detected samples that don't conform to the existing sanitary-epidemiologic standards (severity of consequences is a constant in most cases). And the change can be both for the worse (assigning a product into higher risk category since frequency of detected violations has grown) and for the better (when a product has become safer).

It is important that this approach to assigning food products into different risk categories has a potential for development. Given that the results obtained by control and surveillance activities are integrated taking into account a product type, manufacturer, and supplier, risk assessment may become much more targeted and concrete. Potentially more "problem" products can be spotted in a group of homogenous food and they are subject to first priority and stricter control. The most vital task in this case is to create a unified information space for control and surveillance activities with a possibility to analyze all the collected data on various foods distributed on the market.

Also it seems advisable to create specific "risk profiles" that take into account not only frequency of violations detected by laboratory tests but also severity of negative consequences these violations may have. Scientific substantiation provided for these risk profiles gives an opportunity to estimate the necessity and intensity of control over such most hazardous indicators as radioactivity, occurring carcinogens or mutagenic admixtures, etc. [29].

The suggested approach entails that average country levels of detected deviating samples will decline in each next control cycle (this means annually given the current planning system), that is, food distributed on the consumer market will become safer as per health risks criteria. Programs for instrumental research will be adjusted and optimized according to new available data.

It is also assumed that if due to some reasons a share of deviating samples is growing together with decreasing frequency of analyses thus unavoidably resulting in growing health risks for consumers, then there will be higher frequency of control procedures accomplished in regard to the indicator for which this growth is detected. That is, the higher is a share of detected violations as per a specific indicator and health risks for the consumer, the more targeted a program for laboratory research becomes concentrating on this very indicator.

But at the same time, bearing in mind that food manufacture is developing and there are changes in types and structure of raw materials,

applied production technologies, food storage and transportation, it is suggested to analyze approximately 20 % of all food samples as per all standardized indicators. Frequency of sampling for a specific food product is determined based on a risk category this product is assigned into. Any random detections within this stochastic approach can change an overall risk profile and result in more systemic study on indicators that have not been listed among priority ones before.

We should also note that these approaches are feasible provided that the Unified Information and Analytical System of Rospotrebnadzor is available and functioning since all the results obtained by laboratory research and analyses are to be accumulated in its databases.

Results obtained by control and surveillance activities performed within a year control cycle are to be analyzed properly since it provides necessary grounds for efficient planning of contents and volumes of control and surveillance activities for the next cycle.

Conclusions. Risk-based surveillance over products distributed on the market is stipulated in the federal legislation and requires scientific substantiation and methodical support.

The suggested model gives an opportunity to assign food products into different risk categories as per potential health risks for the consumer. Health risk is determined as a combination of a probability that mandatory requirements to product safety would be violated and severity of consequences such a violation may have. Food that is assigned into categories of extremely high, high, or considerable risk is subject to systemic control annually, every 2 or every 3 years accordingly. The model provides a possibility to change a risk category as per potential health risk for a specific food product and to make control procedures less intense in case a product has become safer. On the contrary, in case violations have started to be detected more frequently, a risk category may change for the worse and control will become stricter.

Programs for laboratory control over food are to be developed according to the principle that entails a number of analyses performed to check a specific indicator being relevant to potential health risk for the consumer. It is advisable to apply mathematical models that describe a relationship between a number of analyses and an expected result being a decrease in a number of deviating samples in the next control cycle.

The model also provides a possibility to determine a number of samples that are to be analyzed to achieve a target level or expected number of violations in the next cycle (in the next year) given the preset number of analyses. Target criteria are fixed taking into account risk indicators and can be determined and achieved step by step taking into account actual resources available to laboratory centers in regions.

The suggested approaches can be tested and implemented based on the Unified Information and Analytical System of Rospotrebnadzor where all results obtained by control and surveillance activities are accumulated including all data obtained by laboratory analyses.

The model has prospects for development and improvement. Priority trends in its development include more targeted selection of products to be controlled; creations and systemic revision of risk profiles, regional peculiarities of goods distributed on the market taken into account; optimization of laboratory support provided for control (surveillance) given a lot of dynamic changes occurring on the food market in the country.

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