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Research article



# **DEVELOPING THE RISK-BASED MODEL OF SCHEDULED** SANITARY-EPIDEMIOLOGIC CONTROL OF PREPARED FOOD PROVIDERS

## I.V. May, N.V. Nikiforova, E.V. Sedusova, N.V. Zaitseva

Federal Scientific Center for Medical and Preventive Health Risk Management Technologies, 82 Monastyrskaya St., Perm, 614045, Russian Federation

The relevance of the study is determined by a substantial change in the structure of services offered by prepared food providers and a growth in outbreaks of communicable diseases due to violations of the mandatory sanitary-epidemiological requirements by prepared food providers and nutrition units in establishments. The aim of this study was to develop the methodical support for the risk-based model of the sanitary-epidemiological control over economic entities operating as prepared food providers. The study was accomplished following the enquiry of the RF Chief Sanitary Inspector.

The general principles of risk calculation and identification of risk categories of an economic activity and production facilities remaining intact, a suggestion is to take a value of a temporary exposure criterion for prepared food providers as equal to 1.0 when determining numbers of exposed population. This is justified since a time of a contact with a potential infectious agent in food is of no significance. In addition to that, the model development entails mandatory consideration of population with risks of negative exposures due to consuming food offered by takeaways.

The study results indicate that consideration of takeaway food and correct consideration of people's contacts with a potentially hazardous infectious agent lead to a substantial increase in levels of health risks. Accordingly, there is a growth in the share of economic entities, which, according to potential risks of health harm for consumers, can be assigned into the categories of 'extremely high risk' and / or 'high risk' (from 1.3 to 8.2 % and from 1.7 to 32 % accordingly in the Perm oblast and Moscow oblast as two pilot regions). The resulting structure of risk categories economic entities are assigned into is more adequate to the current sanitary-epidemiological situation in the country and provides reliable protection for consumers' health.

The prospects of the model development involve accumulation and science-intense analysis of digital branch and interdepartmental data on the branch functioning, results of control and surveillance activities, and health impairments in population associated with risk factors typical for activities performed by prepared food providers.

Keywords: sanitary-epidemiological control (surveillance), risk-based model, prepared food provision, risk category of economic activity and production facilities, risk of health harm, consumers' health, conscientiousness, planning.

been and remain the focus of special attention paid to them by sanitary-epidemiological control (surveillance) $^{1}$  [1, 2]. The main reason for it is that a considerable part of the country population can be potentially affected by quality and safety of prepared food since al-

Prepared food providers have always most two thirds of urban Russians (62 %) consume it. Another important thing is that these consumers are basically working age people  $(73-88 \%)^2$ . Catering services are provided practically for all pre-school children facilities, schools, healthcare organizations, social aid institutions, etc.

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Irina V. May - Doctor of Biological Sciences, Professor, Deputy Director for Research (e-mail: may@fcrisk.ru; tel.: +7 (342) 237-25-47; ORCID: https://orcid.org/0000-0003-0976-7016).

Nadezhda V. Nikiforova - Candidate of Medical Sciences, Head of the Laboratory for Procedures of Sanitary-Hygienic Monitoring (e-mail: kriulina@fcrisk.ru; tel.: +7 (342) 237-18-04; ORCID: https://orcid.org/0000-0001-8060-109X).

Ella V. Sedusova - Researcher of the Sanitary and Hygienic Analysis and Expert Examinations Laboratory (e-mail: ella@fcrisk.ru; tel.: +7 (342) 237-18-04; ORCID: https://orcid.org/0000-0003-4599-083X).

Nina V. Zaitseva - Academician of the Russian Academy of Sciences, Doctor of Medical Sciences, Professor, Scientific Director (e-mail: znv@fcrisk.ru; tel.: +7 (342) 237-25-34; ORCID: http://orcid.org/0000-0003-2356-1145).

<sup>&</sup>lt;sup>1</sup> Tarmaeva I.Yu., Belykh A.I. Sanitarno-epidemiologicheskii nadzor za predpriyatiyami obshchestvennogo pitaniya [Sanitary-epidemiological surveillance over prepared food providers]: manual. Irkutsk, the Irkutsk State Medical University, 2013, 79 p. (in Russian).

<sup>&</sup>lt;sup>2</sup> Obshchepit dlya vsekh: sovremennaya auditoriya restorannogo i kulinarnogo biznesov v Rossii [Food service for everybody: modern consumers of restaurant and culinary business in Russia]. VCIOM: News of the Russian Public Opinion Research Center, 2013. Available at: https://wciom.ru/analytical-reviews/analiticheskii-obzor/obshhepit-dlya-vsekh-sovremennayaauditoriya-restorannogo-i-kulinarnogo-biznesov-v-rossii (September 11, 2023) (in Russian).

As of the beginning of 2023, more than 190 thousand prepared food providers are registered in the country according to official state statistical data. They are diners, cafeterias, restaurants, cafes, bars, and other similar facilities<sup>3</sup>. The total square of dining areas is almost 20.5 million m<sup>2</sup> or 600 thousand seats. The annual turnover of prepared food providers in Russia was estimated to equal almost 2 billion rubles in 2022 [3].

Prepared food providers are an essential part of a comfortable environment for the country population but they are simultaneously a source of health hazards for their consumers [4, 5]. First of all, they pose a serious threat of food poisonings and infections (foodborne diseases)<sup>4</sup>. The issue is not typical only for Russia; it is rather a global one [6, 7]. The World Health Organization states that, despite all the advances in strict regulation, implementation of up-to-date systems for food safety and state control, millions of people still fall sick with foodborne diseases and thousands die from them every year<sup>5</sup>. Microbial diseases account for one third of the global burden of foodborne diseases [8, 9].

An extremely difficult sanitary-epidemiological and economic situation during the COVID-19 pandemic and after it (2019–2022) has brought about substantial changes in prepared food services both in Russia and worldwide. The most important change is a rapid development of take-out food services during a period when visits to restaurants, cafes, or diners became much less frequent. Food consumption was observed to shift from stationary dining areas of prepared food providers to apartments, offices, cars or other spaces just after restrictions had been introduced at the beginning of the pandemic. In Russia, approximately 35 % of orders were consumed beyond a restaurant in January – October 2021; the share grew up to 53 % over the same period in 2021. The volume of delivered orders grew by 125 % over the first 10 months of 2021 in comparison with the same period in 2019<sup>6</sup>. Chain stores started to sell pre-packed restaurant food or create joint projects, for example, combining a coffee shop with a flower shop or placing grills to make hotdogs in non-food chains.

The number of food providers who deliver their products through aggregators has grown by 27.5 % and the number of food providers who deliver either themselves or use delivery service providers has grown by 5.6 times. This service involves delivery to an end customer, which is hardly controllable as regards its epidemiological and hygienic safety. In addition to that, it is difficult to estimate the exact number of people who consume take-out food and this does not allow any operative control of population exposed to a risk associated with low quality products (as opposed to estimating the number of people who visit stationary dining areas of prepared food providers).

A drastic decline in economic activity of prepared food providers during the COVID-19 pandemic restrictions had another negative consequence. A lot of experienced and highly qualified professionals left the branch and this led to human resources being in deficiency in the post-COVID period; as a result, food providers had to hire workers with much lower qualifications [10, 11]. The latter creates risks of incomplete conformity with the mandatory hygienic safety requirements at food preparing facilities since new workers do not have sufficient experience and knowledge in the sphere.

Pandemic and post-pandemic changes overlapped with changes in the overall economic situation in the country. In the last two years, growing costs of prepared food for consumers have led to faster development of the most affordable segments in the branch such

<sup>&</sup>lt;sup>3</sup> Roznichnaya torgovlya i obshchestvennoe pitanie. Ob"ekty roznichnoi torgovli i obshchestvennogo pitaniya [Retail trade and food service. Retail outlets and prepared food providers]. *Rosstat*. Available at: https://rosstat.gov.ru/statistics/roznichnayatorgovlya (October 01, 2023) (in Russian).

<sup>&</sup>lt;sup>4</sup> Todd E.C.D. Overview of Biological Hazards and Foodborne Diseases. In book: Encyclopedia of Food Safety, 2<sup>nd</sup> ed., 2014, pp. 221–242.

<sup>&</sup>lt;sup>5</sup> The global burden of disease: generating evidence, guiding policy. Seattle, USA, Institute for Health Metrics and Evaluation, 2013. Available at: https://www.healthdata.org/sites/default/files/files/policy\_report/2013/GBD\_GeneratingEvidence/IHME\_GBD\_GeneratingEvidence\_FullReport.pdf (October 03, 2023).

<sup>&</sup>lt;sup>6</sup> Komrakov A. Obshchepit rastet iz-za peremen v modelyakh povedeniya rossiyan [Prepared food market grows due to changes in Russians' behavioral models]. *Nezavisimaya gazeta*. Available at: https://www.ng.ru/economics/2023-08-24/4\_8809\_food.html (October 03, 2023) (in Russian).

as fast food, Grab&Go and fast casual. Consumers mind their expenses very carefully. In recent years, the highest sale surge (in actual units) has been identified in fast food segments of prepared food service. According to VCIOM surveys', 38 % of the country population goes to fast food outlets regularly. The figure is twice as high as 12 years ago. Data provided by the Platforma OFD (the largest country fiscal data operator) indicate that demand for shawarma has grown considerably in Russia in 2023<sup>8</sup>. Sales of this dish have grown by 2-3 times on such sites and in such retail chains as Yandex Food, Ozon fresh, Azbuka vkusa, Perekrestok, and Donner24 (Dodo pizza). For example, 590,000 thousand shawarmas were sold during the five months in 2023 within the Open Kitchen project in the Perekrestok retail chain and this is by 2.5 times higher than in the previous year. Shawarma sales have grown by 265 % in the Donner24 (Dodo pizzas) chain etc. Still, fast food is considered hazardous for health by hygienists and epidemiologists in very many countries [12-15]. Some foreign experts state that an average annual risk of Staphylococcus spp., Salmonella spp., and E. Coli infection is very high for consumers of street fast food and can reach 100 % in some cases [12, 13].

In general, basic challenges for the branch include the following: trying to control prices of

prepared dishes given the ongoing growth of food prices, rents and labor costs; keeping hired employees and hiring new ones given tough competition on the labor market and declining prestige of basic branch occupations; the necessity to maintain consumer loyalty [14, 15].

These challenges the branch has to face at the moment have coincided with a period when the state scheduled control has become less strict<sup>9</sup>. The state took certain measures to ease the administrative burden in order to support business activities. At the same time, some studies report that less strict surveillance can lead to economic entities becoming less committed to conform to safety requirements and more prone to render low quality works or services to the population, to sell products that do not conform to technical regulations or sanitary rules etc. The reason is that businesses try to make the maximum possible profits in a situation when risks of administrative or any other liability are rather low [16].

The foregoing is partially confirmed by branch statistical data provided by the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing. Thus, according to the Report Form 'Data on Infection Outbreaks' issued in 2020–2022, incidence of foodborne diseases (outbreaks) has tended to grow at prepared food facilities over the last three years (Table 1).

Table 1

Year	Food manufacturers		Prepared food providers and food stores		Canteens	
	Outbreaks, total	Diseased, people	Outbreaks,	Diseased, people	Outbreaks total	Diseased, people
		total / children	total	total / children	Outoreaks, total	total / children
2020	1	9/3	13	267 / 63	40	1223 / 1026
2021	1	63 / 54	14	320 / 104	45	1503 / 1346
2022	0	0	26	592 / 161	74	2220 / 1502

Incidence of foodborne diseases (outbreaks) in the Russian Federation (2020–2022)

<sup>7</sup> Mal'gavko S. VTsIOM: pochti 40 % rossiyan regulyarno poseshchayut zavedeniya bystrogo pitaniya [VCIOM: almost 40 % Russians visit fast food outlets regularly]. *TASS*, 2022. Available at: https://tass.ru/obschestvo/15318415 (October 07, 2023) (in Russian).

<sup>&</sup>lt;sup>8</sup> Mingazov S. Spros na shaurmu vyros v dva-tri raza na fone podorozhaniya drugogo fastfuda [Demand for shawarma has grown twice or thrice against growing prices of other fast food]. *Forbes*, 2023. Available at: https://www.forbes.ru/biznes/491390-spros-na-saurmu-vyros-v-dva-tri-raza-na-fone-podorozania-drugogo-fastfuda (October 07, 2023) (in Russian).

<sup>&</sup>lt;sup>9</sup> Ob osobennostyakh organizatsii i osushchestvleniya gosudarstvennogo kontrolya (nadzora), munitsipal'nogo kontrolya: Postanovlenie Pravitel'stva RF ot 10.03.2022 № 336 (red. ot 10.10.2023) [On peculiarities of organizing and accomplishing state control (surveillance), municipal control: the RF Government Order issued on March 10, 2022 No. 336 (last edited on October 10, 2023)]. *GARANT: information and legal support*. Available at: https://base.garant.ru/403681894/ (October 12, 2023) (in Russian).

These data provide clear evidence that both the number of infection outbreaks and the number of people who got infected at prepared food facilities was two times higher in 2022 than in 2020. An average number of disease cases tended to be higher in foci of foodborne diseases than in foci of waterborne ones or contact infections. Thus, for example, this figure was 59.7 % for outbreaks of foodborne diseases in the Perm kraj [17]. Therefore, a potential risk of foodborne disease outbreaks requires control and prevention. The latter is especially important since there is a rather alerting growth in a number of infected children. It is worth noting that not one outbreak of a foodborne disease was registered at food production enterprises in 2022.

Bearing in mind considerable hazards associated with foodborne diseases [18–20], research organizations provide methodical support for state regulation all over the world. Reports are published regularly to inform about detected violations of food safety and quality; recommendations are issued to present the best sampling and sample analysis practices and research techniques [21–23]; relevant Internetresources are created and maintained<sup>10</sup>.

The risk-based control model remains fundamental in surveillance activities performed by regulatory authorities practically in all developed countries [24–26].

The Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing was among the first to start theoretical development of the risk-based control model [27]. Methodical approaches to identifying categories of activities performed by objects under surveillance were developed and implemented in 2015–2017<sup>11</sup>; in 2021, they were fixed in the country legislation by the Order on the State Sanitary-Epidemiological Control (Surveillance)<sup>12</sup>. Still, changes in a structure of rendered services and a specific sanitary-epidemiological situation in the country require further development of the methodical basis for control, first of all, as regards prepared food providers.

This study was accomplished following the enquiry of A.Yu. Popova, the RF Chief Sanitary Inspector, to provide the country population with better protection from risks associated with harmful effects on consumers' life and health due to services rendered by prepared food providers.

The aim of this study was to develop the methodical support for the risk-based model of the sanitary-epidemiological control over economic entities operating as prepared food providers.

**Materials and methods.** The study relied on using principles, criteria and methodical approaches to risk-based control stipulated by the Federal Law No. 248<sup>13</sup> and the Order on the State Sanitary-Epidemiological Control (Surveillance).

Frequency and contents of scheduled control activities at prepared food providers are determined according to a category identified for a specific economic entity as per potential risks of damage to protected values, namely, life and health of service consumers. A level

<sup>&</sup>lt;sup>10</sup> Food safety. Best Practice. Available at: https://foodsafety.ru/best-practices (October 12, 2023) (in Russian).

<sup>&</sup>lt;sup>11</sup> The Methodical Guidelines 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. i vved. v deistvie Rukovoditelem Federal'noi sluzhby po nadzoru v sfere zashchity prav potrebitelei i blagopoluchiya cheloveka, Glavnym gosudarstvennym sanitarnym vrachom Rossiiskoi Federatsii A.Yu. Popovoi 11 avgusta 2017 g. [Risk-based model for control and surveillance activities in the sphere of providing sanitary-epidemiologic well-being. Ranking economic entities, types of activities, and objects under surveillance as per potential risks of damage to health for organizing scheduled control and surveillance activities, approved and enacted by A.Yu. Popova, the Head of the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing, the RF Chief Sanitary Inspector on August 11, 2017]. *KODEKS: electronic fund for legal and reference documentation*. Available at: https://docs.cntd.ru/document/555601296 (October 02, 2023) (in Russian).

<sup>&</sup>lt;sup>12</sup> O federal'nom gosudarstvennom sanitarno-epidemiologicheskom kontrole (nadzore): Postanovlenie Pravitel'stva RF ot 30.06.2021 № 1100 (s izm. i dop.) [On the Federal State Sanitary-Epidemiological Control (Surveillance): The RF Government Order issued on June 30, 2021 No. 1100 (with alterations and supplements)]. *GARANT: information and legal support*. Available at: https://base.garant.ru/401431882/ (October 02, 2023) (in Russian).

<sup>&</sup>lt;sup>13</sup> O gosudarstvennom kontrole (nadzore) i munitsipal'nom kontrole v Rossiiskoi Federatsii: Federal'nyi zakon ot 31 iyulya 2020 g. № 248-FZ (s izm. i dop.) [On state control (surveillance) and municipal control in the Russian Federation: The Federal Law issued on July 31, 2020 No. 248-FZ (with alterations and supplements)]. *GARANT: information and legal support*. Available at: https://base.garant.ru/74449814/ (October 02, 2023) (in Russian).

of risk is a calculated value and is based on actual long-term results of control and surveillance activities (history of inspections), theoretical data on influence exerted by foodborne factors on human health and data on actual volumes of services rendered to the population provided by economic entities.

The basic formula for risk calculation (Formula 1) considers likelihood of a negative event that can cause harm (damage) to people's life and health (p) and severity of this harm (g). A negative event is detected violation of mandatory safety requirements relevant for an analyzed activity:

$$R_i(l) = p(l) \cdot g(l), \tag{1}$$

where p(l) is likelihood that the *i*-th economic entity that performs the *l*-th economic activity (*l* is prepared food provision) will violate the mandatory safety requirements stipulated by the sanitary legislation; likelihood is estimated relying on frequency of detected violations of the mandatory requirements per one inspection;

g(l) is the indicator that describes severity of health harm due to violation of the mandatory safety requirements stipulated in the legislation by an economic entity that performs the *l*-th economic activity.

Severity of health harm (damage) is estimated considering data on severity of actual health harm (disease) for a specific person and potential prevalence of likely negative health outcomes (Formula 2):

$$g(l) = u(l) \cdot M(l), \qquad (2)$$

where u(l) is the indicator that describes severity of negative health outcomes due to violation of the mandatory safety requirements by an economic entity that performs the *l*-th economic activity; M(l) is the indicator that describes how many people are exposed to activities performed by this economic entity (scale of exposure), million people.

Likelihood that sanitary legislation would be violated is described relying on frequency of violations detected during control and surveillance activities at a surveillance object that performs the analyzed economic activity (p(l)). The value of p(l) is determined as 95%percentile of distribution of the regional relative frequency of violations detected during one inspection at objects under surveillance that perform the *l*-th economic activity (prepared food provision) over not less than three last years.

Development of the existing approaches to identifying a category of an economic activity performed by an economic entity and calculation how many people use services of prepared food providers<sup>14</sup> stipulates using data on the number of services rendered during one year directly in stationary dining areas (inside diners, canteens, cafes, bars, restaurants, etc.) and volumes of prepared food consumed beyond them. It seems optimal to verify such data using checks and / or actual statistical records of guests and provided take-out food.

The value u(l) describes severity of health outcomes that can occur due to violations of the mandatory safety requirements to activities performed by prepared food providers. It is within the range between 0 (no negative effects) and 1 (death). The value is identified following the WHO recommendations and data taken from relevant literature sources (thus, severity for listeriosis is 0.141; toxoplasmosis, 0.005; acute paratyphoid infections, 0.006; diarrhea, 0.074, etc.)<sup>15</sup>. To identify a category of a prepared food provider, severities of health outcomes were weighed in accordance with frequency of their likelihood

<sup>&</sup>lt;sup>14</sup> Prilozhenie. Raschet pokazatelei, kharakterizuyushchikh chislennost' naseleniya pod vozdeistviem faktorov potentsial'nogo riska prichineniya vreda zdorov'yu cheloveka ob"ektami sanitarno-epidemiologicheskogo nadzora: Metodicheskie rekomendatsii, utv. prikazom Rospotrebnadzora ot 07.10.2015 N $_{0}$  1025 [Appendix. Calculation of indicators that describe how many people are exposed to risk factors of potential health harm due to activities of objects under sanitary-epidemiological surveillance: Methodical guidelines, approved by the Order of Rospotrebnadzor issued on October 07, 2015 No. 1025]. *GA-RANT: information and legal support*. Available at: https://base.garant.ru/71334864/53f89421bbdaf741eb2d1ecc4ddb4c33/ (October 08, 2023) (in Russian).

<sup>&</sup>lt;sup>15</sup> WHO methods and data sources for global burden of disease estimates 2000–2019. Geneva, WHO, 2020, 47 p. Available at: https://cdn.who.int/media/docs/default-source/gho-documents/global-health-estimates/ghe2019\_daly-methods.pdf (October 11, 2023).

in case the mandatory safety requirements were violated by prepared food providers,

Scales of negative effects are suggested to be calculated as per the following formula (3):

$$M_i^j = N_i^j \cdot T_i^j, \tag{3}$$

where  $N_i^j$  is the number of people in the *j*-th population group exposed to activities performed by the *i*-th object per one day, million people;

 $T_i^{j}$  is the sizeless coefficient that considers average annual duration of contacts between the *j*-th population group and the *i*-th object under surveillance per one day.

The  $T_i^j$  coefficient is calculated as per the following formula (4):

$$T_i^{\ j} = \frac{t_j^1}{24} \cdot \frac{t_j^2}{365},\tag{4}$$

where  $t_j^1$  is the value for prepared food providers; the value  $t_j^{1/24}$  is recommended to be taken as equal to 1.0 since duration of a contact with a potential infectious agent in food is of no significance;

 $t_j^2$  is the number of days per year during which a potential contact occurs between the *j*-th population group and an object under surveillance (represented by the number of workdays per year for a prepared food provider), days.

It is suggested to use the following formula for prepared food providers who render their services only in stationary dining areas (5):

$$N_i^s = V_{seats} \cdot \frac{t_1}{t_2}, \qquad (5)$$

where  $N_i^s$  is the number of consumers who use buy prepared food from the *i*-th object under surveillance and consume it in stationary dining areas, people/day;

*V<sub>seats</sub>* is the number of seats provided for consumers on average per year;

 $t_1$  is the duration of a work shift, hours/day;

 $t_2$  is the average time necessary to render one service, hours.

The following formula should be used for objects that offer only take-out food (6):

$$N_i^d = \frac{V_{year}}{t_2}, \tag{6}$$

where  $N_i^d$  is the number of consumers who buy take-out food from prepared food providers, people;

 $V_{year}$  is the number of consumers who are provided with prepared food by an object under surveillance, people/year;

 $t_2$  is the number of workdays in a year.

To develop the earlier suggested approaches, the parameter  $V_{year}$  can be calculated as:

- ratio of the total mass of prepared takeout food (kg) to the average mass of the basic product (kg);

- ratio of the annual turnover of prepared take-out food (rubles) to the average value of the basic product (rubles).

Both categories of consumers should be considered when analyzing prepared food providers who sell food in both ways, as take-out and to be consumed in a stationary dining area; that is  $N_i^j = N_i^s + N_i^d$ .

It is noteworthy that no changes have been made in the approach, which assumes it is necessary to summate a risk created by activities performed by a prepared food provider  $(R^l)$  at different food providing facilities  $(R_i(l))$ (Formula 7):

$$R^{l} = \sum_{i} R_{i} \left( l \right) \tag{7}$$

A risk category for an economic activity performed by an economic entity is established exactly by the levels of this summated risk, which in general determines frequency of scheduled control and surveillance inspections as regards activities of an object under surveillance.

**Basic results.** We have analyzed how frequently prepared food providers tend to violate the mandatory safety requirements. The analysis relied on branch statistical data provided by Rospotrebnadzor. The results indicate that economic entities operating in the brunch are generally not as 'law-obedient' as economic entities operating in other branches. On average in the country, almost two thirds of prepared food providers faced claims made by Rospotrebnadzor following the results of control inspections. In 2022, more than 33.1 thousand violations of the mandatory safety requirements were recorded as per results of scheduled and off-scheduled control and surveillance activities at prepared food providers (5096 inspections overall); this means more than 6.5 violations per one inspection.

The parameter established by the Order on Sanitary-Epidemiological Surveillance, p = 6.88, was taken as a unified national frequency of violations. Weighted average severity of health outcomes was taken as 0.0059 in accordance with the same document.

Data on volumes of take-out food sold by prepared food providers were collected in three pilot regions (Tatarstan, Perm krai and Moscow oblast) together with obtaining more precise data on potential numbers of customers who were served in stationary dining areas.

The obtained results indicate that generally objective and correct consideration of data on take-out food consumption can lead to substantial changes in the actual number of people exposed to the analyzed conomic activity (prepared food provision). Thus, 43 % of prepared food providers sell take-out food in Perm; of them, 31 economic entities (1.9 %) do it round the clock. For example, Burger King provides on average 4000 food deliveries per month or 129,600 kg of prepared food per year. If we take an average helping of 450 grams per person, than daily, apart from visitors served in a stationary dining area, 789 people are provided with take-out food. Vkusno I Tochka delivers approximately 69,120 kg of take-out food per year or 2400 deliveries per month etc.

Consideration of such a parameter as 'people who consume take-out food' and modified exposure time considering a specific infectious agent in prepared food resulted in 20–50 % growth in levels of potential health risks created by some economic entities. Thus, for example, after all the parameters were considered correctly, the level of risk grew from 8.89E-05 (considerable risk) to 1.19E-04 (high risk) for one of prepared food providers in Perm. The same or similar changes were established for other prepared food providers as well.

These new results of risk assessment made it possible to revise risk categories for all prepared food providers. Tables 2 and 3 provide tentative identifications of risk categories obtained for prepared food providers in the Perm krai and Moscow oblast considering the new reality in this branch.

The results obtained by testing these new approaches indicate that the actual number of economic entities belonging to 'extremely high risk' and / or 'high risk' categories as per potential health harm for consumers is considerably higher than the number of such entities calculated relying on older approaches, which were developed in 2017. In the Perm krai, the share of objects with extremely high and high risks grew from 1.3 to 8.2 %; in the Moscow oblast, from 1.7 to 32 %. Even in a situation when certain limitations are imposed on the number of scheduled control and surveillance activities, this provides stricter sanitary-epidemiological surveillance over activities performed by prepared food providers and, accordingly, better protections of consumers' health.

Table 2

Risk category	Without considering take-out food		According to the new model that considers take-out food (deliveries) for 701 objects	
	JP/PE	Facilities	JP/PE	Facilities
Extremely high risk (R > 1E-03)	0	0	0	0
High risk (1E-04 < $R \le 1E-03$ )	27	259	154	534
Considerable risk (1E-05 $\leq$ R $\leq$ 1E-04)	990	1519	1512	1962
Medium risk (1E-06 $\leq$ R $\leq$ 1E-05)	814	894	209	221
Moderate risk (1E-07 $\leq$ R $\leq$ 1E-06)	15	15	4	4
Low risk ( $R \le 1E-07$ )	33	34	0	0
TOTAL	1879	2721	1879	2721

Risk categories as per potential health harm identified for juridical persons and private entrepreneurs who operate as prepared food providers and their food providing facilities. Perm krai\*

N o t e : \* providers of prepared food for children are not included.

#### Table 3

Risk category	Without considering take-out food		According to the new model that considers take-out food (deliveries)	
	JP/PE	Facilities	JP/PE	Facilities
Extremely high risk ( $R > 1E-03$ )	5	169	241	589
High risk (1E-04 $\leq$ R $\leq$ 1E-03)	55	141	862	1169
Considerable risk $(1E-05 < R \le 1E-04)$	949	1330	1741	1951
Medium risk (1E-06 $\leq$ R $\leq$ 1E-05)	1432	1663	315	327
Moderate risk (1E-07 $\leq$ R $\leq$ 1E-06)	599	643	35	36
Low risk (R $\leq$ 1E-07)	412	439	258	313
TOTAL	3452	4385	3452	4385

Risk categories as per potential health harm identified for juridical persons and private entrepreneurs who operate as prepared food providers and their food providing facilities. Moscow oblast

**Discussion.** The risk-based model for control and surveillance activities is dynamic in its essence and able to react relevantly to changes occurring on the product and service market as well as to changes in the society as the major carrier of protected values. These are its most important properties [26, 28].

A growing number of foci of acute intestinal infections associated with prepared food providers and a considerable growth in volumes of take-out food deliveries have made it necessary to objectively revise risk categories of economic entities operating in this sphere. Well-grounded increase in the number of prepared food providers who can be and should be subject to more frequent scheduled surveillance is aimed at only one thing, that is, better protection provided for the country population.

At the same time, the approach that protects rights and interests of socially responsible and conscientious economic entities remains unchanged. According to the valid regulatory documents, juridical persons or private entrepreneurs under control, who are assigned into categories of high, considerable, medium and moderate risks, can be assigned into a lower risk category in case no orders have been made for them to eliminate violations of the mandatory safety requirements following the latest control (surveillance) activity<sup>16</sup>. Accordingly, both frequency and procedures of scheduled surveillance activities are changed for 'lawobedient' economic entities.

In general, the risk-based control model applied by the Federal Service for Surveillance over Consumer Rights Protection and Human Wellbeing has proven to be highly effective and able to produce good results over the years it has been in use [29, 30].

At the same time, there are wide prospects of its further development, primarily, as regards providing more solid grounds for control and making it more targeted, including control of economic activities performed by prepared food providers.

This development should be based on accumulation of digital data on an actual sanitary-epidemiological situation in the country, results of control and surveillance activities performed in all regions in the country both in the branch in general and as per specific objects operating in it (ordinary restaurants, fast foods, cafes, coffee shops, etc.). History of inspections that considers data differentiated as per object types will provide more precise and well-grounded determination of specific frequency of cases when the mandatory requirements are violated at each type of the analyzed objects. It also helps estimate and describe specified features of such violations and severity of likely health outcomes. In general, digitalization and science-intense analysis of big

<sup>&</sup>lt;sup>16</sup> O federal'nom gosudarstvennom sanitarno-epidemiologicheskom kontrole (nadzore): Postanovlenie Pravitel'stva RF ot 30.06.2021 № 1100 (s izm. i dop.) [On the Federal State Sanitary-Epidemiological Control (Surveillance): The RF Government Order issued on June 30, 2021 No. 1100 (with alterations and supplements)]. *GARANT: information and legal support*. Available at: https://base.garant.ru/401431882/ (October 02, 2023) (in Russian).

data arrays gives an opportunity to provide the most solid grounds for identification of risk objects. On the one hand, this will ensure that regulatory efforts are concentrated on objects that pose the highest threats for consumers. On the other hand, this makes it possible to eliminate excessive administrative barriers for conscientious economic entities who are assigned into categories with minimal risks.

More intensive interdepartmental cooperation should become the most important trend in the development of risk-based control (surveillance). The present study has revealed that data on volume of consumed take-out food are collected by Rospotrebnadzor experts practically 'by hand', by communicating directly with economic entities during scheduled inspections or other activities. It is very difficult to verify these data. Still, analysis of the statistical reports issued in the branch indicates that several relevant data sources are available including:

- statistical report form No. MP (micro) Data on Key Performance Indicators of a Micro-Business in \_\_\_\_\_, which contains an indicator called 'Prepared Food Turnover (Section 4, line 21)'<sup>17</sup>;

- statistical report form No. MP Data on Key Performance Indicators of a Small Business in \_\_\_\_\_, which contains an indicator called 'Total Volume of Prepared Food Sold to Consumers (Section 3, line 12)';<sup>18</sup> - statistical report form No. P-1 Data on Volumes of Produced and Shipped Goods and Services in 20\_\_\_, which contains an indicator called 'Prepared food turnover (Section 3, line 27)'<sup>19</sup>. This form is to be filled and submitted by juridical persons, including those with separate divisions, that produce and sell goods and / or render services;

- federal statistical report form No. 1-TORG (MO) Data on Retail Outlets and Prepared Food Providers Submitted by Local Authorities<sup>20</sup>.

Organized information exchange between different departments would help Rospotrebnadzor verify the register of economic entities which at present is being filled with initial data for calculating a risk category. It will also provide more solid grounds for calculating risk levels for an economic activity and each specific production facility.

Consideration of a specific regional sanitary-epidemiological situation in the branch can become another promising trend in the development of the risk-based control model. Outcomes caused by violations of the mandatory safety requirements to prepared food provision are not unique and resulting diseases in consumers are the same in all regions but frequency of detected violations is rather specific and differs greatly from region to region. Thus, 237 inspections (73 scheduled and 164 offscheduled) were accomplished in the Sverd-

<sup>&</sup>lt;sup>17</sup> Ob utverzhdenii Ukazanii po zapolneniyu formy federal'nogo statisticheskogo nablyudeniya N MP (mikro) «Svedeniya ob osnovnykh pokazatelyakh deyatel'nosti mikropredpriyatiya»: Prikaz Rosstata ot 01.11.2022 № 794 [On Approval of the Instructions how to fill the Federal Statistical Observation Form No. MP (micro) Data on Key Performance Indicators of a Micro-Business: the Order by the Rosstat issued on November 01, 2022 No. 794]. *Normativ Kontur*. Available at: https://normativ.kontur.ru/document?moduleId=1&documentId=435209 (October 14, 2023) (in Russian).

<sup>&</sup>lt;sup>18</sup> Ob utverzhdenii Ukazanii po zapolneniyu formy federal'nogo statisticheskogo nablyudeniya N PM «Svedeniya ob osnovnykh pokazatelyakh deyatel'nosti malogo predpriyatiya»: Prikaz Rosstata ot 24.03.2023 № 130 [On Approval of the Instructions how to fill the Federal Statistical Observation Form No. MP Data on Key Performance Indicators of a Small Business: the Order by the Rosstat issued on March 24, 2023 No. 130]. *Normativ Kontur*. Available at: https://normativ.kontur.ru/document? moduleId=1&documentId=445367 (October 14, 2023) (in Russian).

<sup>&</sup>lt;sup>19</sup> Ob utverzhdenii Ukazanii po zapolneniyu form federal'nogo statisticheskogo nablyudeniya N P-1 «Svedeniya o proizvodstve i otgruzke tovarov i uslug», N P-2 «Svedeniya ob investitsiyakh v nefinansovye aktivy», N P-3 «Svedeniya o finansovom sostoyanii organizatsii», N P-4 «Svedeniya o chislennosti i zarabotnoi plate rabotnikov», N P-5(M) «Osnovnye svedeniya o deyatel'nosti organizatsii»: Prikaz Rosstata ot 30.11.2022 № 872 [On Approval of the Instructions how to fill the Federal Statistical Observation Form No. P-1 Data on Volumes of Produced and Shipped Goods and Services, N P-2 Data on Investments into Non-Financial Assets, N P-3 Data on the Financial Position of an Organization, N P-4 Data on Staff Number and Wages, N P-5(M) Basic Data on Activities of an Organization: the Order by the Rosstat issued on November 30, 2022 No. 872]. *Normativ Kontur*. Available at: https://normativ.kontur.ru/document?moduleId=1&documentId=437548 (October 14, 2023) (in Russian).

<sup>&</sup>lt;sup>20</sup> Ob utverzhdenii formy federal'nogo statisticheskogo nablyudeniya N 1-TORG (MO) «Svedeniya ob ob"ektakh roznichnoi torgovli i obshchestvennogo pitaniya»: Prikaz Rosstata ot  $30.08.2021 \text{ N} \pm 527$  (v red. Prikaza Rosstata ot  $17.12.2021 \text{ N} \pm 925$ ) [On Approval of the federal statistical report form No. 1-TORG(MO) Data on Retail Outlets and Prepared Food Providers: the Order by the Rosstat issued on August 30, 2021 No. 527 (as part of the Order by the Rosstat issued on December 17, 2021 No. 925)]. *Normativ Kontur*. Available at: https://normativ.kontur.ru/document?moduleId=1&documentId=415386 (October 14, 2023) (in Russian).

lovsk oblast at prepared food providers in 2022; as a result, 6397 violations of the mandatory safety requirements were identified, that is, 27 violations per one inspection. Frequency of violations was 20.6 per one inspection in Saint Petersburg and 12.6 in Moscow. Frequency of detected violations is below 5.0 per one inspection in such regions as Buryatia, Belgorod oblast, Lipetsk oblast, Novosibirsk oblast, Kaluga oblast, Vladimir oblast, Perm krai, etc. Consideration of region-specific frequency of violations would allow performing stricter control in regions where the situation with prepared food providers is unfavorable and redirect regulatory efforts onto other objects in regions with low frequency of violations detected at prepared food providers. Still, considered frequency of violations is to be revised in dynamics following the results of the most recent control and surveillance activities and this task remains highly relevant. Therefore, the system reacts most operatively to changing risk profiles and shows that safety control measures are risk-based, transparent and do not aim to infringe upon interests of economic entities operating in the branch.

International experience gives evidence of one more promising trend in the development of the risk-based control model as regards safety of prepared food provision. This is implementation of a hybrid form of regulation in which public and private actors warrant data sharing and information exchange between them [31]. Civil society is able to join the risk communication system via social networks; this is extremely important for stimulating voluntary conformity with the mandatory safety requirements as well as effective distribution of limited regulatory resources.

## **Conclusions:**

♦ In 2020–2022, there was a growth in incidence of infectious diseases associated with prepared food providers; also, over the same period, there were considerable changes in the structure of services rendered by such economic entities. This gave grounds for modifying the existing methodical approaches to calculating potential risks of health harm and establishing risk categories for this economic activity and food preparing facilities as basic criteria for planning control and surveillance inspections; • Development of the methodical support provided for the risk-based model preserves the fundamental principles for risk calculation and identification of a risk category; still, when calculating indicators that describe numbers of exposed population, a suggestion is to take a temporary exposure criterion as equal to 1.0 since a time of a contact with a potential infectious agent in food is of no significance. The calculation also includes mandatory consideration of people who face risks of negative health outcomes due to consuming take-out food;

◆ The results obtained by testing these new approaches indicate that consideration of take-out food and correct consideration of contacts visitors can have with a potentially hazardous infectious agent lead to a substantial growth in the share of economic entities that can be assigned into 'extremely high risk' and / or 'high risk' categories as per potential health harm for consumers (from 1.3 to 8.2 % in the Perm krai; from 1.7 to 32 % in the Moscow oblast). This structure of prepared food providers as per risk categories is undoubtedly more adequate given the current sanitaryepidemiological situation in the country and provide better health protection for consumers;

♦ In general, the risk-based control model has relevant instruments to protect interests and rights of socially responsible and conscientious economic entities since it allows assigning an economic entity into a lower risk category provided that they do not have any orders given by the Rospotrebnadzor to eliminate violations of the mandatory safety requirements detected during surveillance activates;

◆ The prospects of the model development involve accumulation and scienceintense analysis of digital branch and interdepartmental data on the branch functioning, results of control and surveillance activities, and health impairments in population associated with risk factors typical for activities performed by prepared food providers.

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