PREVENTIVE MEDICINE: URGENT ASPECTS OF RISK ANALYSIS

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RISK ANALYSIS AS A STRATEGIC SPHERE IN PROVIDING FOOD PRODUCTS SAFETY

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The paper dwells on basic issues related to providing food products safety with methodology of population health risk assessment and management under exposure to biological substances, chemicals, or hazardous physical factors of consumer goods. It is shown that Russia, just like many countries all over the world, is facing some global challenges now, in the beginning of the 21st century. These challenges are to be understood and estimated, and efficient measures are to be taken to overcome them. Among such challenges we can mention invention of new materials with poorly examined hygienic properties, increasing variety of technologies in food production, open borders for food products transferring etc.

Population in the Russian Federation is practically completely provided with access to sufficient quantities of food. However, there are still risks related to imbalanced nutrition and unsafe food products. Sanitary-epidemiologic surveillance is provided with a powerful and well-structured organization and functional system which allows to eliminate risks efficiently. Over 7000 sanitary-epidemiologic parameters of food products are subject to control and surveillance in the RF. More than 3000 standards are harmonized within the Eurasian Economic Union regulations. A lot of work is done on developing laboratory control over food products quality. Risk-oriented control over quality and safety of food products is implemented. New approaches to assessing risks related to food products are being developed. New techniques fully incorporate conventional principles of risk assessment and relevant toxicological and epidemiological data and allow to substantiate viewpoints that the Russian Federation has on issues related to hygienic standardization for some biological and chemical agents in food products. Procedures for analysis of new technologies are being developed actively.

There are some strategic areas in development of risk analysis methodology; they are creation of public information databases on food products quality and risks related to them; development of risk prediction procedures including genetic analysis techniques, mathematical modeling, medical and biological research; improved procedures for prediction of individual health risks with development of personified programs for prophylaxis of diseases; development of procedures for obtaining evidence of damage done due to health risk realization; creation of risk-oriented models for managing food products quality and creation of global information field for risk communications.

Key words: *hazard factor, food products, sanitary-epidemiologic surveillance, health risk assessment, development strategy.*

To prevent diseases caused by malnutrition and unsafe food is one of the most important tasks to be solved by the RF state authorities in general and sanitary-epidemiologic surveillance bodies in particular.

Just as many other countries in the world, Russia faced certain global challenges in the beginning of the 21st century; these challenges are to be recognized, assessed and dealt with in the most efficient way. The challenges are variable; they are caused by globalization, borders open for goods and services, an increased variety of technologies and raw materials applied in food products manufacturing, much greater volumes of uncontrollable or poorly controllable trade, first of all, electronic one, state surveillance becoming more democratized etc. (Figure 1).

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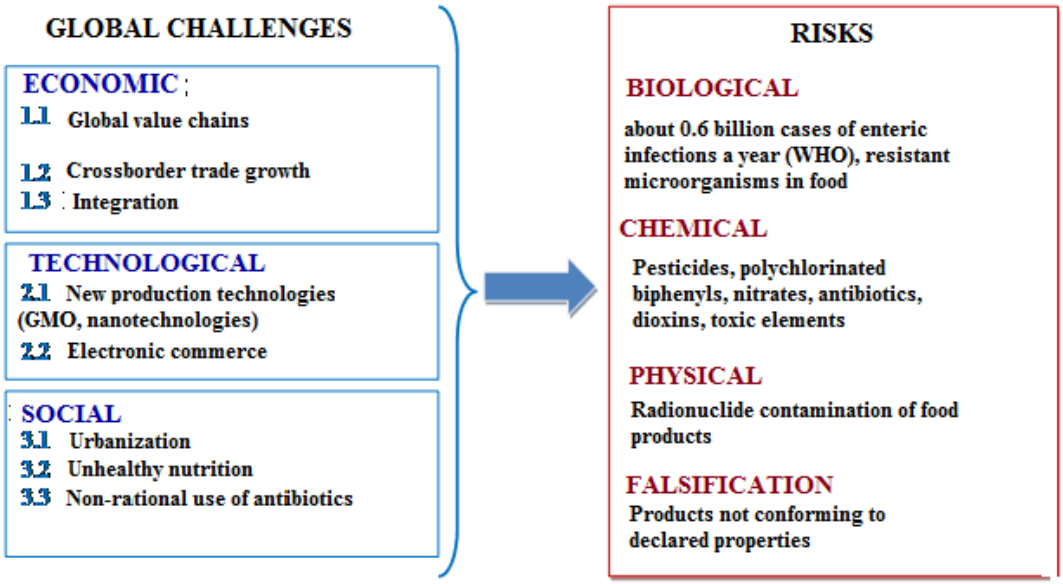

Figure 1. Global challenges that cause consumer health risks

Control and surveillance activities performed by state authorities and scientific research accomplished in many countries allowed to detect biological agents and toxic chemical elements in food raw materials and/or food products; these hazardous substances occurred there in concentrations higher than those fixed in safety standards [1–6]. Biological, chemical, and radiation risk factors can occur in various sections in food chains. As a rule, biological contamination of food results from violated requirements to a technological process or workers' personal hygiene [7–9]. Hazardous chemicals such as toxic metals, dioxins, or polychlorinated biphenyls (PCBs) can accidently occur in food products due to environmental pollution when air, water, and soils are contaminated. Chemicals that are contained in technological equipment can be released from materials this equipment is made of and which contact food etc. [4–6, 10, 11]. Radiation contamination most frequently occurs due to application of unsafe raw materials or environmental contamination [12, 13]. Microorganisms in food products that are resistant to antibiotics are another serious problem [14–16].

Food products contamination causes elevated risks for health of consumers from various age and social groups. Chemical factors (pesticides, polychlorinated biphenyls, nitrates, antibiotics, dioxins, heavy metals, etc.) causes risks of digestive pathologies, as well as pathologies in the nervous and immune systems, blood pathologies etc. Biological risks can lead to infectious as well as some somatic diseases. As per data taken from the World Health Organization (WHO) report on global burden of foodborne diseases, low quality or unhealthy food annually causes almost 600 million enteric infections cases[1]. As it is outlined in the report, about 30% of all the death cases caused by foodborne diseases are registered among children under 5, in spite of this age group accounting for only 9% of the total world population. The WHO experts note that in Europe more than 23 million people annually fall ill due to unsafe food consumption and it leads to 5,000 death cases.

[1] WHO estimates of the global burden of foodborne diseases: foodborne disease burden epidemiology reference group 2007–2015 [web-source] // World Health Organization. – URL: http://www.who.int/foodsafety/publications/foodborne_disease/fergreport/en/ (date of visit June 01, 2018).

The Russian Federation faces similar problems related to unsafe food as developed countries do. As for providing population with sufficient quantity of food, we can state that this issue has practically been solved. But there are still risks associated with nutrition being balanced and food products being safe. Food products are often falsified, and it is a critical problem existing in the Russian Federation. Trade in food stuffs and volumes of imported food products have grown significantly over recent years; imports often include goods that don't conform to national hygienic standards and it makes issues related to food trade globalization and growing volumes of imports more and more vital. In 2017 The Federal Service for Surveillance over Consumer Rights Protection and Human Well-being examined more than 290 thousand food samples within monitoring over food products safety; samples were examined to check their conformity with hygienic standards as per chemical contaminants concentrations. A share of samples not conforming to the standards amounted to 0.44%. 1,192,000 samples were examined to check their microbiological safety; 4.03% out of them didn't conform to hygienic standards.

The country still faces serious challenges related to healthy nutrition as more than 90% people living in the RF have excessive quantity of simple carbohydrates in their daily ration. As a result, more than half Russians who are older than 30 suffer from overweight and obesity and it can lead to cardiovascular diseases, malignant neoplasms, and pancreatic diabetes. In 2016 primary morbidity with obesity among adults older than 18 amounted to 285.85 per 100,000 adult people (it was 284.85 in 2015; 188.05 in 2014; 161.84 in 2013; 123.56 in 2012)[2]. Vitamins and microelements are not consumed in sufficient quantities in many Russian regions.

Hygienic and social problems related to providing population with healthy and safe nutrition have been recognized and discussed at various levels, including parliamentary one[3]; these discussions led to approval on some strategic documents such as "The RF Food Security Doctrine"[4], "Fundamentals of the state policy related to healthy nutrition of population for the period up to 2020"[5], "The concept for developing internal food aid in the Russian Federation"[6], "The Strategy for improving food products quality in the Russian Federation for the period up to 2030"[7]. All these documents state that the state policy related to healthy nutrition has the following key targets: to preserve and to improve population health, and to prevent diseases associated with unsafe products, insufficient and unbalanced nutrition.

To provide nutrition safety in the RF, the following priority tasks are to be solved:

– providing food security in the country and making safe and qualitative food products available for all social layers of the population;

– creating a strategic system for providing population with food products in conformity

[2] On sanitary-epidemiologic welfare of the population in the Russian Federation in 2017: The State report. – M.: The Federal Service for Surveillance over Consumer Rights Protection and Human Well-being, 2018. – 268 p.

[3] On legal measures and techniques for preventing distribution of counterfeit, falsified, and low quality products in the Russian Federation: Recommendations given on the Parliamentary hearings on February 14, 2006 [web-source] // The RF State Duma Committee for economic policy and entrepreneurship: Official web-site. – URL: http://www.duma.gov.ru/econpolicy/parlam/140206/index.shtml (date of visit June 01, 2018).

[4] On Approval of the RF Food Security Doctrine: The RF President Order issued on January 30, 2010 No. 120 [web-source] // The CIS states legislation. – URL: http://base.spinform.ru/show_doc.fwx?rgn=30398 (date of visit June 01, 2018).

[5] On Approval of the Fundamentals of the RF state policy related to healthy nutrition of population for the period up to 2020: the RF Government Order issued on October 25, 2010 No.1873-p [web-source] // GARANT: information and legal portal. – URL: http://www.garant.ru/products/ipo/prime/doc/12079847/ (date of visit June 01, 2018).

[6] On Approval of the Concept for developing internal food aid in the Russian Federation: the RF Governmental Order issued on July 03, 2014 No.1215-p [web-source] // KonsultantPlus. – URL: http://www.consultant.ru/document/cons_doc_LAW_165323/ (date of visit June 01, 2018).

[7] On Approval of the Strategy for improving food products quality for the period up to 2030: the RF Government Order issued on June 29, 2016 No.1364-p [web-source] // The RF Government official web-site. – URL: http://government.ru/docs/23604/ (date of visit June 01, 2018).

with scientifically grounded physiological nutrition standards;

– minimizing threats associated with intolerable risks caused by chemical and microbiological factors of food products;

– stimulating development of manufacturing and market distribution of qualitative food products;

– stimulating activities aimed at making people inclined to pursue healthy life style, including healthy nutrition;

– protecting vulnerable population cohorts including pre-school and school children;

– preventing and decreasing diseases associated with insufficient and unsafe nutrition including a 30% decrease in prevalence of obesity and primary hypertension.

If all the Eastern European and Central Asian countries join their efforts fighting basic critical problems related to food products safety and quality, it will allow to reduce hazards of alimentary and infectious diseases among population and will become an essential component in achieving strategic goals fixed in the UN program 'United Nation Decade of Action on Nutrition"[8].

Rospotrebnadzor, acting within its authority, is responsible for products safety; the organization applies such tools for managing health risks as administrative and criminal liability for violation of sanitary legislation; withdrawal of products from the market; setting limits to spheres of application; relevant marking of products; informing consumers about health risks; assigning products into risky deliveries category[9]. Today, The State Sanitary and Epidemiologic Surveillance is equipped with a powerful and well-structured organizational and functional system. More than 7 thousand sanitary-epidemiologic parameters are controlled in the RF and the Customs Union member states in the sphere of food raw materials and food products safety and more than 3 thousand out of them were harmonized when a unified legislative base for the Customs Union Agreement was created[10].

In 2017 the RF Government approved on an action program for implementing the Strategy for improving food products quality in the country for the period up to 2030[11]. This action program included some draft regulatory documents aimed at harmonizing national legislation with the Eurasian Economic Union acts as regards determination of food products quality, principles of healthy nutrition, making improvements into product marking and control over it. Information resources that provide population with data concerning consumer rights protection, quality and safety of goods have been developed further, and people are constantly informed about food products safety and quality and principles of healthy nutrition.

Experts are working out identification criteria (markers) for food products that can help to detect falsification and that can be used in analytical techniques for detecting falsified food products; laboratory control over food products quality is being improved, especially regarding food manufactured with biotechnologies and state registration of food products [17, 18]; a risk-oriented approach to state control (surveillance) has been implemented in the sphere of providing food products safety and quality [19].

Methodology of health risk analysis is considered to be a priority scientific instru-

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[8] United Nation decade of Action on Nutrition, work program for 2016–2025 [web-source] // The World Health Organization. – URL: http://www.who.int/nutrition/decade-of-action/workprogramme-2016to2025/ru/ (date of visit June 01, 2018).

[9] The Provisions on the Federal Service for Surveillance over Consumer Rights Protection and Human Well-being: The RF Governmental Order issued on June 30, 2004. No. 322 (last edited as the RF Government Order dated May 21, 2013 No. 428) [web-source] // GARANT: information and legal portal. – URL: http://base.garant.ru/12136005/ (date of visit June 01, 2018).

[10] The Customs Union Agreement on sanitary measures [web-source] // the Eurasian Economic Commission. – URL: http://www.tsouz.ru/MGS/mgs-11-12-09/Pages/mgs25-28-pril1.aspx (date of visit June 01, 2018).

[11] On Approval of the action program for implementing the Strategy for improving food products quality in the country for the period up to 2030 approved by the RF Government Order dated June 29, 2016 No. 1364-p: the RF Government Order dated April 19, 2017 No, 738-p [web-source] // KonsultantPlus. – URL: http://www.consultant.ru/document/cons_doc_LAW_215997/ (date of visit June 01, 2018).

ment that allows to solve issues related to control over raw materials and food products safety at the state level [20]. At present Russia has all the necessary resources to implement the most up-to-date approaches to assessing product risks. 800 test laboratory centers that operate within Rospotrebnadzor system are certified by the state (including 8 centers certified within DAkks system). They perform instrumental research in order to determine actual quality and safety of food products. Over several decades the Federal Information Fund for social and hygienic monitoring (FIF SHM) has been accumulating not only data on products parameters and environmental objects but also medical and demographic data (birth rate, mortality, morbidity with basic nosologies per age groups and regions, results of preventive examinations performed on children and teenagers etc.). This system integrates data obtained during toxicological monitoring performed in every region in Russia. The FIF SHM, together with the results of control and surveillance activity, provides information grounds for risk assessment (hazard identification, determination of "dose – effect" dependence, exposure assessment).

Experts are creating new approaches to assessing product risks including those that incorporate mathematic modeling for risk evolution over time [21]. And these new approaches fully implement conventional risk assessment principles and relevant toxicological and epidemiologic data. Application of these new approaches allows to substantiate opinions expressed by the RF on hygienic regulation of certain biological and chemical agents in food products and to do it solely in order to protect consumers' health (Table). For example, when justifying maximum permissible levels of tetracycline, experts applied a mathematical model that described changes in intestinal microflora balance and assessed risks of related pathologies [22]. When a hygienic standard for ractopamine was developed, experts modeled evolution of risk during an average life span under actual exposure taking into account excretion of ractopamine out of a body [23].

Experts are actively developing techniques that allow to analyze new technologies including genetic engineering, nanomaterials application, use of bacteriophages to prolong shelf-life or to increase food products safety. Such technologies are widely used both in Russian and all over the world, and their potential use for people's health is huge. However, potential hazards related to these technologies make it necessary to objectively assess risks associated with their application [24, 25]. When considering risks associated with new technologies, it is necessary to reach balance between unconditional provision of safety for this generation and cones-

Table

Russian hygienic standards substantiated with risk assessment that differ from international ones

Hazard factor	Food products	Russian standard substantiated as per risk criteria	Codex Alimentarius Commission standard
Ractopamine	Meat products	Total absence	0–0.01 mg/kg
L.Monocytogenes	Meat products, fish, dairy products	Absence in 25 grams of a products	100 CFU/g (for products distributed on market)
Tetracycline	Meat products	10 μg/kg (0.01 μg/kg)	from < 0.1to 1.2 μg/kg
Nitrates	Fruit and vegetables	Salad, fresh onion – up to 4,000 μg/kg Potatoes – 250 μg/kg Tomatoes – up to 300 μg/kg Carrots – up to 400 μg/kg Cucumbers – up to 400 μg/kg Cabbage – 900 μg/kg Beetroot – 1,400 μg/kg	Salad, fresh onion – up to 4,500 μg/kg

Figure 2. Methodology of consumer health risks assessment: basic components

quent ones, on the one hand, and an urgent need to provide progress in manufacturing and distributing products with a lot of useful consumer properties, on the other hand.

Criteria that underlie safety assessment are to be clear and they are to be communicated to people so that the latter could participate in the process at its early stages. It is necessary to openly and clearly communicate risks to all the concerned parties that can be influenced by food-related hazards. Information exchange will help to organize a profound dialogue between all the parties (consumers, manufacturers, and distributors) in risk analysis process and will allow them to equally participate in it [26]. As regards the above-mentioned issue, the Russian Federation strictly adheres to abandoning one-side administratively-oriented informing and to implementing a dialogue, risk communications, and searching for a social consensus in the food safety sphere [27, 28].

However, Russia is still an integral part of the Eurasian Economic Union even when protecting interests of the country citizens; and the Eurasian Economic Union has declared a strategic goal to join efforts for protecting consumers' health and rights on the overall territory of the unified economic space and consumer market. The Council that comprises heads of competent authorities responsible for sanitary and epidemiologic welfare of the population living in the EAEU member states was created and has been operating quite successfully ever since. Most urgent and acute issues related to consumer products safety are constantly being discussed; all the concerned parties are looking for consensus and mutually beneficial solutions.

Development of risk assessment methodology is a well-known and very promising way to reach a new level in predicting threats and hazards and taking efficient preventive actions that will help to preserve population health (Figure 2).

Russia takes active part in developing approaches to solving nutrition-related problems on the international level. The Russian Federation constantly participates in activities performed by international organizations (the WHO, the FAO, the UNICEF, the UNEP etc.) when considering nutrition-related issues as well as those related to food products quality and safety. The country has declared the following priorities in its policy for assisting international development at regional and global level: assistance in providing food security and safe nutrition as well as agricultural development of states that are recipients of this assistance. Russia makes a considerable contribution into global food security cooperating with international organizations.

Goals and tasks fixed in the UN decade of Action on Nutrition program in nutrition sphere are becoming integral components of national agenda and programs all over the world, and in the Russian Federation as well. Population health should always remain a top priority. When solving issues related to providing people with sufficient nutrition, one should prevent any increase in health risks caused by microbiological, chemical, or radiation contaminants in food products. Up-to-date tools for risk assessment should become a solid base for building up national strategies and plans aimed at struggling against malnutrition in all its forms as well as at providing food safety and quality. In this relation it seems strategically significant to develop methodology for health risk assessment completing the following:

– to unify national information databases and to create global ones that contain information on food products quality and related risks;

– to develop risk prediction techniques including those based on application of genetic and mathematic modeling and biological analysis;

– to update methods for predicting individual health risks together with creating personified programs of medical and preventive support;

– to develop methodology for creating a system of evidence that proves damage to health in case a health risk is realized;

– to create risk-oriented models for managing food products quality including those incorporating control and surveillance activities;

– to form a global information and communication field that contains data on food-related health risks for consumers; the field will provide relevant support to risk management actions.

We should further develop methodology for assessment and prediction of food-related risks, update techniques for managing such risks, and it will eventually allow us to achieve our primary goal, namely, to preserve population health and to provide more comfortable and safe living standards for people both in Russia and all over the world.

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