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systems management in the
context of modern global
challenges
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Vlasenko Iryna

*Doctor of Medical Sciences, Professor
Department of Commodity Science,
Expertise and Commercial Business*

Sirenko Svitlana

*Candidate of Technical Sciences, Docent
Department of Commodity Science,
Expertise and Commercial Business*

Semko Tatyana

*Candidate of Technical Sciences, Docent
Department of Tourism, Hotel and
Restaurant Business
Vinnytsia Institute of Trade and
Economics of Kyiv National University of
Trade and Economics
(Vinnytsia, Ukraine)*

**HARMONIZATION
PROBLEMS OF
THE EUROPEAN
UNION AND CHINA
COUNTRIES
LEGISLATION
FOR TRADE WITH
UKRAINE**

Problem formulation. In today's context, the issue of Ukrainian standards harmonization with the countries of the European Union and the PRC is a pressing issue. Harmonization of standards will allow to expand the market and increase the volume of Ukrainian products production, to activate trade relations between the countries, which will ultimately be in the interests of everyone – the state, business, consumers. The safety requirements for which foodstuffs must be produced and which they must meet in order to reach the European and Chinese markets are very high, which to some extent can guarantee the maximum protection of consumer's health. The more national food producers will produce their products in accordance with the best international practices, for example, will introduce HACCP and traceability system, system of rapid notification of dangerous products and their withdrawal from the market, the more protected consumers will be in our country.

Purpose – comparison of microbiological indicators in the European Union and the People's Republic of China (PRC), comparison of a number of food safety indicators, as well as hygienic criteria for food production in EU and PRC countries.

Materials and methods. Applied general scientific and special

methods of cognition of economic processes: analysis and synthesis, systematic approach, comparison and generalization. The methodological basis of the work is the official EU and PRC documents, EU Commission Regulation of 15 November 2005 № 2073/2005, which sets microbiological criteria for EU foodstuffs, and in national standards of the PRC (GV series documents).

Main material presenting.

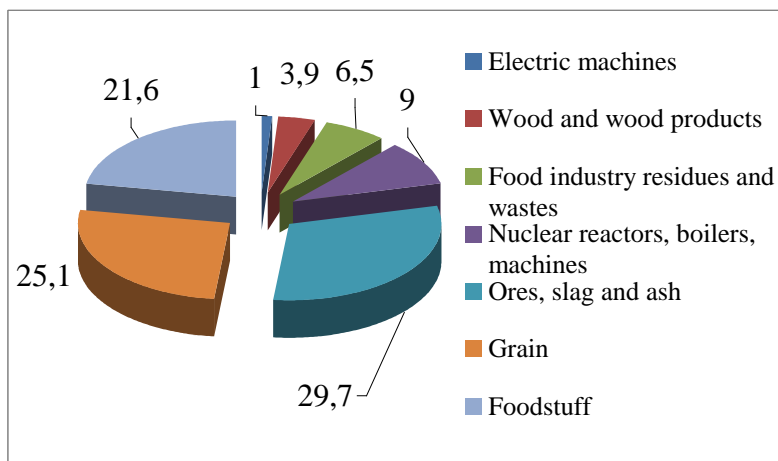


Figure 6.3 Share of total exports of Ukraine to China in 2018

As can be seen from Figure 6.3, share of food products in the export structure of Ukraine to China is 26.1%. Ukraine’s exports to China in 2018 amounted to \$ 2, 2 billion.

As can be seen from Figure 6.4, Ukraine practically does not export finished foods to the EU countries. Only individual producers have quotas for export and their share in the overall structure of exports is very small.

Harmonization of requirements will allow food market operators to export food products to the PRC or EU countries, as it will eliminate differences in:

- 1) requirements for the content of pathogens in different food categories;
- 2) sampling rules;
- 3) approaches to the normalization of certain positions.

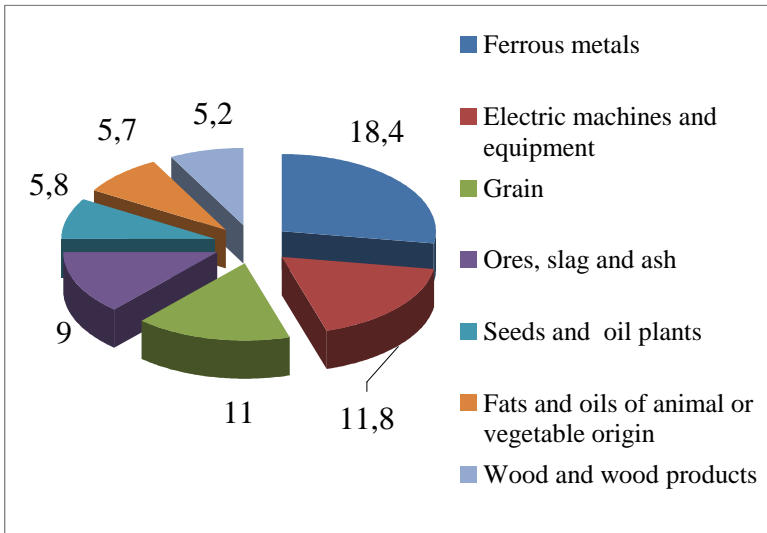


Figure 6.4 Share of total exports of Ukraine to the EU in 2018

In addition, this will eliminate other differences in European and Chinese approaches and techniques regarding food safety at different stages of production. Compliance with requirements will make it easier for national food producers and exporters to enter the PRC and EU markets.

Unlike EU legislation, there is no single regulatory document in the PRC that sets microbiological criteria for food of all categories, as is done in the EU in Regulation № 2073/2005. Instead, there are number of documents in the PRC regarding different categories of food [1-4]. These documents have been adopted at different times, mostly since 2010. They are updated periodically, due to the continuous improvement of the Chinese food safety monitoring system and its compliance with international standards, as well as the requirements of the EU, US, Canada, Australia, New Zealand, Japan, Hong Kong and Taiwan.

At the same time, China's basic document setting maximum levels for pathogens in food products is China's national standard GB 29921-2013, which came into force on July 1, 2014. GB 29921 applies to general standards and may apply to pre-packaged foods. GB 29921 requirements should be applied if the values in GB 29921 and other PRC standards differ.

It should be noted separately that in the case of food exports to the

PRC, the Chinese side is usually guided not only by its own standards and standards, but also by European or American ones, especially where there are no national requirements.

When comparing food safety indicators in the EU and the PRC, a number of differences were identified [5-6]:

1) there is no single consolidated document in the PRC that regulates hygiene requirements for all categories of foodstuffs that may contain potential risks and threats;

2) there are no or differing positions in the Chinese standards on foodstuffs that are subject to mandatory control compared to Regulation № 2073/2005;

3) Chinese standards sometimes have lack of product detail categories and subcategories compared to Regulation № 2073/2005;

4) a number of product categories available in Chinese documents are absent from European ones, such as casein, cereal products, legumes, chocolate and cocoa products, nuts and seeds;

5) the overwhelming number of product categories does not include the list of pathogens that must be monitored;

6) in some cases there is a discrepancy in the maximum permissible standards for the content of pathogens in food;

7) Chinese standards sometimes do not meet the European standards for the number of samples required;

8) for a number of items existing in the EU (eg. raw meat of poultry and poultry that require heat or special treatment and are not intended for direct consumption), there are no microbiological requirements in the PRC;

9) Based on the hygiene standards of the PRC, China does not have a system for monitoring the presence of pathogens and other micro-organisms in food during their production; such control is regulated only for ready-to-sell (pre-packaged) food / semi-finished products.

Given the fact that the names of the categories and products themselves differ significantly, Ukrainian exporters need to consult substantially with Chinese partners on a case-by-case basis.

1. The purpose of implementing standards. Pathogens often cause a variety of diseases for both humans and animals. Among the pathogens found in food are salmonella, paragemolytic vibrios, Escherichia coli, Staphylococcus aureus and more. According to statistics, the number of diseases caused by foodborne pathogens in the PRC annually in the PRC is about 40-50% of all reported cases.

The Law on Food Safety stipulates that food safety standards

determine the permissible levels of content in food and related products of pathogens, plant protection residues, veterinary residues, heavy metals, contaminants and other substances harmful to the human body. There are more than 500 applicable standards in the PRC regarding restrictions on the content of pathogenic microbes in foods, with indicators sometimes duplicated, overlapping, contradictory, or simply lacking.

In order to control the contamination of food by pathogens and prevent the occurrence of diseases caused by food in microbes, as well as to combine all the scattered standards for the permissible content of pathogenic microbes, the State Committee for Health and Birth Control Food Safety Prepare Draft Standard GB29921-2013 “Maximum Allowable Levels of Pathogens in Food”. The document was reviewed and agreed by the Committee on the Evaluation of State Standards for Food Safety and released on December 26, 2013. It entered into force on 1 July 2014.

GB29921 regulation relies to general standards and may apply to pre-packaged foods. All relevant rules that differ from this standard must be complied with. All requirements for the permissible content of pathogens in foodstuffs specified in other standards should be abolished or aligned with this standard.

2. *Standards requirements.* Until the entry into force of the standard (01.07.2014), food manufacturers and distributors could, at will, comply with this standard and the authorities encouraged them to do so. Since its entry into force, manufacturers, food safety authorities and inspection bodies have been required to comply with this standard. Pathogenic microbial content is monitored according to the methods described in GB29921.

Manufacturers and distributors must adhere strictly to the standards and rules of food production and distribution, or take measures to strictly control pathogens during production and distribution to ensure that products meet the requirements of GB29921.

China’s State Committee on Health and Birth Control will monitor and evaluate the implementation of this standard and as a result propose adjustments to improve the standard.

3. *Principles and procedure for defining standards.*

1) The main purpose is health protection. The purpose of GB29921 is to control the contamination of food products by pathogens and to prevent diseases caused by them. The Editorial Expert Group analyzed the causes of foodborne microbial diseases and, based on international

management experience, undertook a comprehensive risk assessment of the pathogenic microorganisms – food line. Based on the results of the monitoring and risk assessment, maximum levels of pathogenic microorganisms in high-risk foodstuffs have been determined to reduce the risk of foodborne diseases.

2) Definition of indicators by scientific approach. Based on the monitoring and assessment of the risks associated with the presence of pathogens in food, the Editorial Expert Group conducted a comprehensive analysis of:

- the potential adverse effects of pathogenic microorganisms or their products on human health
- the content of pathogenic microorganisms in the raw material;
- changes occurring with pathogens at each stage of food processing, storage, sale and consumption.

At the same time, the ratio factors of the consumer groups of each product category and the cost (economic effect) of ensuring compliance with the standard on the permissible norms of the content of pathogenic microbes were fully taken into account. In general, this has led to the application of a scientific approach to the determination of acceptable levels of pathogens in food.

3) Consideration of foreign assessments and standards – improvement of standards. GB29921 took into account the results of a risk assessment related to the presence of pathogens in food by relevant international organizations such as CAC, ICMSF, etc., and the principles used to set standards. The regulations, standards and standards of the US, EU, Australia, New Zealand, Japan, Canada and some other countries and regions regarding restrictions on the content of pathogens in food have also been taken into account.

4) Consideration of proposals from all stakeholders, ensuring openness and transparency. In the process of standard formation, meetings and seminars were repeatedly convened to hear proposals from relevant agencies, research organizations, industry professional associations and enterprises, and open Internet surveys. On this basis, the text of the standard was finalized and the process of its approval was open and transparent.

4. Areas of application and main content of standards. GB29921 can be applied to pre-packaged foods. GB29921 establishes permissible levels of five pathogens (Salmonella, Listeria monocytogenes, Escherichia coli, Staphylococcus aureus and Paragemolytic Vibron) in 11 food categories.

Manufacturers and distributors of pre-packaged foods must adhere strictly to the hygiene rules for the production and distribution of food to minimize the risk of contamination with pathogens.

Canned foods must meet the requirements of commercial sterility, so this standard does not apply to them.

5. The main categories of food to which the standard applies:

1) Meat products cooked (thermally processed) or intended to be eaten raw: products made from prepared (marinated, stewed, smoked, fried, steamed, boiled, etc.) and raw (fermented or processed by special technology) meat (pork), beef, lamb, chicken, rabbit, dogfish, etc.), suitable for direct consumption.

2) Aquatic fishery products: cooked (thermally processed) aquatic fishery products (products made from fish, crustaceans, molluscs, invertebrates, echinoderms and other aquatic organisms that have been heat treated – steamed, boiled, baked, fried – fried suitable for direct consumption); intended for consumption of raw aquatic animal products (products that have been purified but not heat-treated and are fit for direct consumption, including live, fresh, frozen fish (fish pieces), shrimp, cephalopods, live crabs, live molluscs, as well as products made from live snails, crabs, shellfish, caviar by non-thermal processing (pickles, marinades, alcohols – suitable for direct consumption); intended for consumption vegetable products of watercraft – algae (products made from algae, suitable for direct consumption, which have undergone some processing, including thermal – cooked, deep-fried).

3) Egg products intended for consumption: products suitable for direct consumption made from poultry eggs, including cooked eggs.

4) Cereal products: prepared (thermally processed) cereal products (including baking); cooked (thermally processed) flour-rice products with stuffing (filler); instant flour meal: products prepared from rice, wheat, other cereals, root crops, corn, etc., with or without filling, suitable for direct consumption (cereals, cereals / cereals / instant noodles, etc.), and products made by baking, with a basis of cereals, fats, eggs, sugar and food additives, suitable for direct consumption (cakes, cakes, cookies, bread, etc.).

5) Intended bean products (fermented and unfermented): fuji (soybean salted beans), fermented black bean sauce, natto and other products prepared by wet fermentation, as well as soy milk, tofu (soy cheese), solid soy cheese, soy protein, and other wet-fermented products.

6) Chocolate and cocoa products: chocolate, including cocoa butter

substitutes, toppings and creams; cocoa products (liquid, solid, cocoa powder).

7) Fruit and vegetable products (including pickled): products intended for direct consumption made from vegetables and fruits: frozen vegetables / fruits, dried vegetables / fruits, fruit in vinegar, oils or salts, jams, jams, jam, candied fruits, syrup fruits, pickled vegetables, vegetable pastes and sauces (except tomato), fermented vegetables and fruits.

8) Beverages (except bottled drinking water and aerated drinks): fruit and vegetable juices, protein drinks, water-based mixed drinks, tea, coffee, vegetable drinks, dry drinks, other drinks.

9) Frozen beverages (ice cream, food ice): all types of ice cream and food ice, made on the basis of drinking water, sugar, dairy, fruit, legumes, food fats and oils, with the addition of food additives.

10) Seasonings: soy sauce (fermented and mixed), soy paste (fermented and mixed), seasonings from aquatic products (fish, oyster, shrimp sauce), combined seasonings (mayonnaise, broths, juices and other condiments with animal and plant bases). This standard does not apply to spices and seasonings.

11) Nuts and seeds: nuts and seeds paste, pickled nuts and more.

6. *Determination of indicators for pathogens within the standard.*

1) *Salmonella* (2nd risk group). Indicators of the standard were approved taking into account similar standards in force in the CAC, ICMSF, EU, Australia, New Zealand, USA, Canada, Hong Kong SAR (Hong Kong), Taiwan. General requirements: $n = 5$, $c = 0$, $m = 0$.

2) *Listeria monocytogenes* (2nd risk group). Due to the lack of sufficient clinical observation data in the PRC, the indicators of the standard were approved taking into account the reporting data of FAO, WHO, as well as the standards in force in CAC, ICMSF, EU, etc. General requirements: $n = 5$, $c = 0$, $m = 0$.

3) *Escherichia coli* O 157: H7 (2nd risk category). Although no cases of mass destruction of finished meat and meat products by the micro-organism have been reported in the PRC, this standard has been adopted at a high level to reduce the risk of disease. General requirements: $n = 5$, $c = 0$, $m = 0$.

4) *Staphylococcus aureus* (3rd risk group). For China, it is one of the main agents of food poisoning associated with the enterotoxins it produces. Indicators of the standard were approved taking into account similar standards in force in CAC, ICMSF, Australia, New Zealand, SAR Hong Kong (Hong Kong), Taiwan. General requirements (for 8

product categories): $n = 5$, $c = 1$, $m = 100$ CFU / g (ml), $M = 1000$ CFU / g (ml); for seasonings: $n = 5$, $c = 2$, $m = 100$ CFU / g (ml), $M = 10,000$ CFU / g (ml).

5) *Paragemolytic Vibriion* (3rd risk group). For the coastal and some inland regions of the PRC, it is one of the main agents of food poisoning. It is predominantly found in water-based products and – crosswise – in meat products. Indicators of the standard were approved taking into account similar standards in force in ICMSF, EU, Canada, Japan, Australia, New Zealand, Hong Kong SAR (Hong Kong). General requirements: $n = 5$, $c = 1$, $m = 100$ MPN / g (ml), $M = 1000$ MPN / g (ml).

7. *Other*. The permissible standards of pathogenic microorganisms for milk, dairy products, special supplementary foods are determined by separate state standards for food safety.

As the risk of contamination by pathogens of such products (or raw materials) as honey, fats and oils, emulsified fats, marmalade, candy, edible mushrooms, etc., is extremely low, in view of CAC, ICMSF rules and regulations, it has not been decided to set appropriate standards so far these products. However, the indicators and standards of the standards can be refined and modified based on the results of monitoring and risk assessment.

Contamination of food by the *Shigella* micro-organism can occur as a result of contact with dirty hands or carriers, improper treatment of drinking water, sewage leakage, etc.

Based on the situation in the PRC and long-term monitoring data, it is extremely infrequent to detect this microorganism in food. In view of the regulations and regulations in force in the CAC, ICMSF, EU, USA, Canada, Australia, New Zealand, this item was not included in the list of food content restrictions under this standard.

Conclusions.

Standards harmonization of the Ukraine with the countries of the European Union and China will allow to expand the market and increase the volume of Ukrainian products production, to intensify trade relations between the countries, which will ultimately be in the interests of the state, business and consumers. It is important to eliminate differences in the requirements for the content of pathogens in different food categories, sampling rules, other differences in European and Chinese approaches and techniques related to food safety at different stages of production markets of the PRC and EU countries.

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