Regulating the Market of Food Additives: World and Domestic Experience

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Abstract. The paper analyzes the domestic and foreign market of food additives and the risks associated with dietary supplements. Using research materials by world companies, the authors describe the main directions for regulating this market in developed countries. Nutritional supplements are located between food and pharmaceutical products. They are designed to treat acute malnutrition or specific dietary problems. The main share of food additives is distributed through pharmacies. Only one-third is provided through direct sales and other channels. The content of food additives must be strictly regulated at the state level and meet the standards of composition, purity, and safety. The international regulation of the food additives market is based on compliance with the Codex Alimentarius International Food Regulations (a set of averages). In some countries, the principle is established by national standards and laws. The purpose of the regulation is to distribute food additives that meet market standards and avoid significant risks (quality problems, health problems, climate change, and unethical behavior). The production and sale of food additives require strict control over product labeling, analysis of the composition, warning of side effects (prohibition of use), effectiveness (utility), and distribution channels.

Keywords: Dietary supplements · Dietary supplement market · Dietary supplement market regulation · Food nutrition improvement

1. Introduction

The research object is the market of biologically active additives (BAA) in Russia and abroad. The study aims to analyze the global market of dietary supplements and measures to regulate it. In Russia, as in many other countries, people have a deficit diet – a lack of iodine, vitamins C, D, and B, calcium, iron, selenium, dietary plant fibers, and other components. In countries with developed market economies, the population is well informed about this problem and regularly takes various food supplements and fortified foods to balance it. Dietary supplements are taken by up to 90% of Japanese people, 75% of Indians, 67% of Chinese, and 66% of Americans. According to the Russian Public Opinion Research Center [VCIOM], only 2% of Russians regularly use dietary supplements, and another 23% do it periodically. Even though it is difficult to predict market development in the short term, the dietary supplement market remains attractive in the long-term forecast since it is still far from saturation [1]. Over the past three decades, the use of nutritional supplements increased worldwide from $ 12 billion in 1990 to $ 180 billion in 2020. This figure is projected to reach $278 billion by 2024.
2. Materials and Methods
The primary data analysis methods are traditional (qualitative) content analysis of interviews and documents and quantitative analysis using application software packages.

Many studies and statistical materials are devoted to the issues of market research on food additives. Sociological and economic research of this market segment is carried out by such large companies as DISCOVERY Research Group, “DSM Group” JSC, VCIOM, etc.

3. Results
A dietary supplement is a product taken orally, containing a “dietary ingredient” intended to supplement a diet. The European Union (EU) has given the following definition: “As a supplement to a normal diet, food operators sell food additives containing concentrated sources of nutrients (or other substances) with a nutritional or physiological effect. Such dietary supplements can be sold in a “metered-dose” form, such as pills, tablets, capsules, liquids in measured doses, etc.” The classification of dietary supplements into specific groups is complicated by many products involved, their different contents, range of action, and complications. It is challenging to compare consumption because definitions have changed over time, as in the National Health and Nutrition Survey (NHANES). Dietary supplements are commonly used to treat acute malnutrition or specific nutritional problems, especially in developing countries, and are considered special-purpose products.

The market for vitamins and dietary supplements consists of four segments: “Dietary supplements,” “Children’s vitamins,” “Tonics,” and “Vitamins.” The largest market segment includes dietary supplements. According to the forecasts, the average annual growth rate of the market of vitamins and nutritional supplements will be 2%.

Compared with foreign markets, not all trade channels are represented in Russia due to regulatory restrictions and the underdevelopment of specific trade formats. According to market participants, the current distribution of shopping channels is as follows: 60% – pharmacies, 12% – food retail, and 18% – direct sales [2].

For pharmacies, dietary supplements remain the most critical category of non-pharmaceutical pharmacy assortment, accounting for 4% of total sales. According to the Russian pharmaceutical market audit conducted by the DSM Group, 268 million packages of dietary supplements worth 31.5 billion rubles were sold through pharmacy chains in 2016 [2]. For 2017, the figures were 340.7 million packages of dietary supplements worth 51.2 billion rubles. That is, the market for nutritional supplements increased by 4.6%. However, in 2018, the market of nutritional supplements grew by 0.5% in rubles and decreased by 5.5% in packages compared to 2017.

In addition to the seasonal fluctuations and a decrease in the real income of Russians, a considerable role in the fall in pharmacy sales of food additives was played by tightening advertising regulations and allowing the sale of dietary supplements in any retail outlet.

To maintain competitive prices, pharmacies have to reduce the mark-up for this group of products. At the end of 2017, the mark-up for dietary supplements was 38.4%, while, in 2016, the same indicator was at the level of 40.8%. On average, one package of domestic dietary supplements cost 150 rubles in 2017. In 2018, the price increased to 160 rubles (retail price). The cost of a package of foreign dietary supplements averaged 378 rubles.

Traditionally, universal supplements of the group [V] “dietary supplements acting on the body as a whole” are the most popular (the share of 30.2%). During the study, this group of dietary supplements increased in sales by 1.7%. The most popular brands in the group [V] were “Solgar” produced by “Solgar Vitamin and Herbs” and “Femibion” of the manufacturer “Merk Selbstmedikation.”

The second place was taken by the group [A] “dietary supplements acting on the digestive system,” showing an increase in sales by 1.8%. In this group, the most popular positions are “Phytolax” of the domestic manufacturer “Evalar” and “Maxilac” of “Genexo.”

In the third place was the group [G] “dietary supplements affecting the reproductive system,” which showed a decrease in sales (-1.3%). The rating was headed by a drug affecting the female reproductive system – “Indinol” from the manufacturer “Miraxbiopharma.” The second and third places in this group
Low vitamins focuses on vitamins and minerals used as ingredients in food additives. In the EU, food additives are ingredients, and recommended uses. Before it can be removed from the market, the FDA has the burden of proving that a particular food additive is unsafe for consumer use.

Seven subgroups showed negative dynamics. The largest decrease in sales was observed in such groups as:

- [J] “dietary supplements used in viral, bacterial, and fungal diseases” (-19.5%) (the sales leader of the group, the brand “Daisy,” fell by 25.4%);
- [V] “dietary supplements acting on the hematopoietic system” (-16.2%) (hematogen in various embodiments is not so popular among buyers);
- [W] “dietary supplements for weight loss and cleansing of body” (-11.8%) (falling sales of the mainline “TurboSlim” (7.2%).)

On the contrary, sales of the group [T] “dietary supplements used for poisoning and intoxication,” increased by 14.5%. The sales volume of the “White Coal” increased by 36.2% over the year.

In contrast to the market of medicines, biologically active additives are dominated by utilizing domestic production. Russian dietary supplements account for 54.4% of costs and 80.7% of natural sales.

According to the calculations of “DISCOVERY” Research Group, the volume of production of dietary supplements in Russia in 2019 amounted to 5,894.4 tons or $ 199 million. In 2018, the growth rate was 22.2% of the natural volume of production.

In 2018, the import of dietary supplements to Russia accounted for 6,519.9 t or $ 156 million. “Solgar Vitamin and Herbs” was the largest importer of nutritional supplements to Russia in 2018.

In 2018, the export of biologically active additives from Russia amounted to 1,435.9 t or $ 20 million. The largest exporter of biologically active additives from Russia was the “Laboratory of Modern Health” LLC. Central international, and national authorities regulate food additives.

International regulation is established by the Codex Alimentarius International Food Regulations. It is a set of standards, guidelines, and codes of practice adopted by the Codex Alimentarius Commission (CAC). The Commission is central to the Joint FAO/WHO food standards program, which was established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to protect consumer health, harmonize food standards, and promote acceptable practices in the food trade. The Commission has 187 member states and organizations. In 2005, the Code adopted “Guidelines on vitamins and mineral supplements.” They apply only to supplements containing vitamins and minerals, where these products are regulated as food. Guidelines relate to the composition of accessories, including their safety, purity, and bioavailability.

Many developed countries adopted laws on the control of pharmaceuticals and the promotion of clean foods. For example, in the US, under the “Dietary Supplement Health and Education Act of 1994” (DSHEA), the FDA has the burden of proving that a particular food additive is unsafe for consumer use before it can be removed from the market.

In Canada, dietary supplements are regulated by the “Natural and Non-prescription Health Products Directorate Authority” (NNHPD). All products and their manufacturers must have the license and provide detailed information about medicinal ingredients, sources, doses, activity, non-medical ingredients, and recommended uses.

The primary EU legislation is Directive 2002/46/EC, concerning dietary supplements containing vitamins and minerals. The rules of the European Commission are aimed at ensuring the safety of food additives and proper labeling. In the EU, food additives are regulated as food products. The legislation focuses on vitamins and minerals used as ingredients in food additives.

In Australia, most dietary supplements are regulated by complementary medicines, including vitamins, minerals, and herbal, aromatherapy, and homeopathic products. The listed category refers to low-risk ingredients. Manufacturers are required to collect evidence of safety and effectiveness. However, this is not formally evaluated.
In China, dietary supplements are regulated as a healthy food. The new Chinese law “On food safety,” adopted in 2015, indicates that every food supplement must receive a certificate of approval of a healthy diet from the Chinese Food and Drugs Administration (CFDA).

The Japanese Ministry of Health, Labor, and Welfare (MHLW) classifies food into general foods and food with health claims (FHC). The latter (including dietary supplements) are managed by the Consumer Affairs Agency and require standardization and certification. Nutritional supplements are included in healthy functional foods (HFF) in South Korea, regulated by the Ministry of Food and Drug Safety (MFDS) under HFF safety assurance activities. The nutrients, functional ingredients, raw materials, ingredients, and components are evaluated and approved by the Korean Food and Drug Administration (KFDA).

4. Discussion
Despite the dynamic development of the food additive market in recent years, the increasing use of food additives has raised public health concerns about their effectiveness and safety in both the short and long term. Researchers identify several risks associated with the help of dietary supplements:

- Quality issues. A study of multivitamin and mineral supplements showed significant differences between the number of different components listed in the drug description and those contained in the supplements themselves;
- Unhealthy food additives were sold to children in the form of sweetened lollipops or sweets, which can be harmful to health;
- Climate change may affect the production and composition of crop-based additives and may change the impact of heat on consumers using specific additives;
- Food additives in developing countries. Improved food supply and nutritional diversity would reduce any need for food additives in developing countries;
- Unethical behavior. The temptation to gain fame and fortune by creating dietary supplements that would solve fundamental nutritional problems has proved too vital for some people.

5. Conclusion
Most countries have relatively loose rules that put market access and industry profits ahead of public health benefits. The EU and Japan have stricter regimes compared to other countries or international groups. The business of producing and selling dietary supplements with its risk of complications and side effects deserves stricter regulation and control over product labeling, warning about side effects (prohibition, if they are significant), and effectiveness (if there are health claims).

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