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Review of Dietary Supplement Regulation

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ABSTRACT

Human health condition significantly depends on the food they consume. Up to 50% of diseases are likely related to food and nutrition.[1] The growing trend of using dietary supplements to fill nutritional deficiencies, which aims to improve human health and prevent diseases, is evident. Governments of different countries set rules and regulations for the dietary supplement business to provide the public with quality and safe products, to grow the domestic economy, to attract foreign investment, and/or to set barriers and protect local production. Frameworks of regulations in individual states are more or less similar. However, their approaches might be radically varying. The business of these products is susceptible to the ever-changing regulatory environment and, therefore, affects product safety, quality, and, ultimately, the public interest. Thus, recommendations based on scientific analysis are essential for achieving the goal of caring for public health and improving well-being through the use of dietary supplements. The article discusses and analyzes the main aspects of legislative regulations of supplements in different countries, including Georgia.

Keywords: Dietary supplement; food claim; food supplement; health claim; nutrition; regulation.

INTRODUCTION

The increase in public interest in the use of dietary supplements is due to many factors, including the aging of the population.[2,3] A remarkably rapid growth in dietary supplement use was observed during the public health crisis of COVID-19.[3]

Although additional opportunities for the development of the functional food and nutritional supplement industry will increase health costs proportionately, it is clear that people are increasingly seeking to improve their quality of life rather than simply meeting their basic health needs. As a result, the dietary supplement market has grown significantly over the past few decades and is likely to continue. Many regulatory bodies are developing strict, comprehensive rules and standards around the world to ensure the quality and safety of dietary supplements. Individual restrictions vary from country to country, often making it difficult to manufacture and export the products, especially if regulations need to be clarified or products need to meet updated regulations in the importing country.[4] Such reviews promote the examination of the impact of regulations on the business and consumption of dietary supplement products, market access, and industry profitability.

REVIEW

Definition of the dietary supplements

For the time being, there has yet to be a global consensus on the definition of the Dietary Supplements (DS) category, and this disagreement consequently refers to the differences and ongoing discussions on the issues of the regulations. The situation is further complicated when most DS products, besides vitamins and minerals, belong to traditional health and healing systems such as Chinese medicine and Indian medicine Ayurvedic/Unani/Siddha.[5]

In order to develop a traditional medicine strategy for 2014-2023, the World Health Organization considers DS as traditional and complementary medicines. WHO recognizes an essential shortcoming of its classification - the definitions are substantially different according to individual countries. The difference in approaches is caused by the fact that individual supplements may be an integral part of traditional food in different cultures.[4] The decisive factor for classifying a product as a DS is the substance, the nature of its action, and the recommendation for use. Table 1 lists the names of supplement products according to the regulations of individual countries.[6-13]

TABLE 1. Dietary Supplement name by the countries

Country	Name
Australia	Complementary medicines (CM)
Canada	Natural health product (NHP)
China	Health food (HF)
Europe Union (EU)	Food supplement (FS)
Georgia	Food supplement (FS)
Japan	Foods with health claims (FHC)
South Korea	Health functional food (HFF)
USA	Dietary supplement (DS)

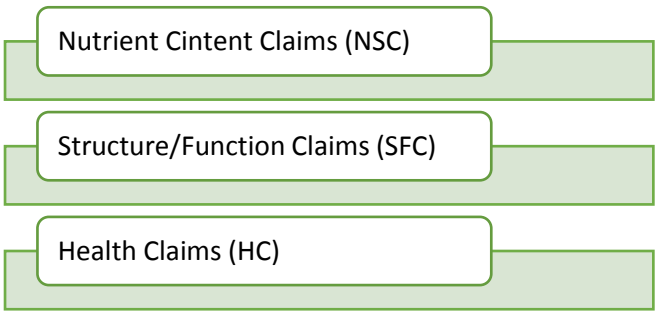
International regulations on dietary supplements

The international regulation of DSs is the Codex Alimentarius, a collection of standards, guidelines, and codes of practice. It was adopted by the Codex Alimentarus Commission (CAC), the central body of the food standards program at the Food and Agriculture Organization (FAO) of the United Nations and WHO. In 2005, the Codex adopted guidelines for vitamin and mineral food supplements, which apply only to supplements containing vitamins and/or minerals where these products are regulated as food. They also cover the issues of supplement composition, safety, purity, and bioavailability.[14,15]

Overview of regulations in the European Union (EU)

In the EU, the regulatory framework for supplements is considered under general food legislation through the European Food Safety Agency (EFSA), and compliance with Good Manufacturing Practices (GMP) and Hazard Analysis and Critical Control Points (HACCP) procedures is mandatory for manufacturing processes. The main ingredients of food supplements are vitamins and minerals, regulated by several European Commission directives (EC). The European Medicines Agency is responsible for evaluating the safety and efficacy of herbal preparations used as medicines.[16] The EC 1924/2006 directives establish guidelines for food supplement labeling. The EFSA can also assess the scientific evidence supporting a health claim.[14,15] Figure 1 demonstrates the categories of product health claims in the EU.

FIGURE 1. Supplements categories by health claims in the EU



In order to ensure the proper functioning of the internal market of food supplements, the EU has a positive list of safe ingredients, where vitamins and mineral ingredients are primarily included in inorganic form. This is an obstacle for manufacturers to approve their products in which the ingredients are often in organic form. Manufacturers can apply to the EFSA to add ingredients to the list, but the process is usually long and expensive; the review is rigorous and often rejected.[17]

According to Directive 2015/2283/EC, special legislative measures apply to novel foods used in the EU on May 15, 1997. The directive envisages the listing of new ingredients in the production of supplements. Despite the conservative position of the EC and EFSA towards the regulation and applications of food supplements, recent regulation changes indicate some industry opportunities.

In 2018, the definition of novel food supplements includes supplements derived from clones, engineered nanomaterials, and traditional food sources, the safety of which has been proven by at least 25 years of use in third-world countries. According to the updated rules, the approval process for novel food supplements and the period required for the authorization was reduced from 3 years to 18 months, which allows manufacturers to bring the product to the market as soon as the product type - "novel food" (not in use until 1997) is approved.[18]

Overview of the regulations in Georgia

According to the Law of Georgia on Medicines and Pharmaceutical Activities (LGMPA), a biologically active supplement (BAS) is considered a means of maintaining physiological conditions. Unlike medicines, their authorization is voluntary; it is not mandatory for a manufacturer or importer, and the submission for approval depends only on their initiative. If a supplement is not approved as a pharmaceutical according to LGMPA regulations, it cannot refer to diseases in the advertisement and present them as a pharmaceutical product.[19]

Supplements not registered as pharmaceutical products are regulated under the competence of the Ministry of Agriculture and Food of Georgia, the National Food Agency, whose guiding legal document is the Resolution of the Government of Georgia No. 360 of July 12, 2022 - Technical Regulation - Regarding the Approval of Food Supplements, which came into the force in May 2023.[6]

The mentioned regulation considers food supplements under the general food legislation. Like the EU regulation, food supplement manufacturing processes require compliance with good manufacturing practice (GMP) and Hazard Analysis and Critical Control Points (HACCP) procedures. Within six months of the regulation, 2360 product names had already been listed in the National Food Agency register.[20]

Overview of the regulations in the USA

The sale of DSs in the USA is under the Dietary Supplement Health Education Act of 1994 (DSHEA). Manufacturers of DSs are not required to prove safety or efficacy; DSHEA is believed to reduce FDA oversight and focuses on the industrial performance of the USA economy.[21,22] Supplements and their ingredients are regulated as food and are not allowed to be used to treat or prevent any disease. The FDA's primary responsibility is to ensure the safety and purity of dietary supplements on the market and to withdraw from the market any product that may be

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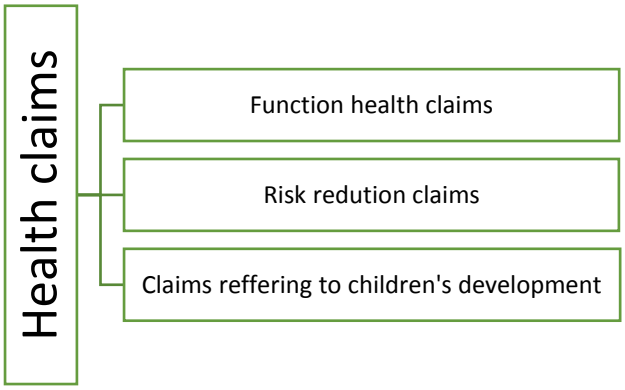
potentially dangerous to the consumer. Regulations mandate the provision of Good Manufacturing Practices and Good Distribution Practices for DS manufacture, as well as labeling, packaging, and record-keeping requirements. Premarketing approval for DSs is required, although the manufacturer must ensure the safety of the products. The addition of any new food ingredient(s) to a DS product must be notified to the FDA through the New Dietary Ingredient Notification (NDIN) process; if the product ingredient was in use before 1994, notification to the FDA is not mandatory.[23] The regulation prohibits the sale of DSs with a therapeutic use claim, such as use for treating or preventing a specific disease. However, it is possible to label the application categories shown in Figure 2.[9]

FIGURE 2. Claim types of dietary supplements in the USA



The main difference between SFC and HC is that SFC must not refer to the effect of a nutrient or ingredient on a disease or health condition. Some experts, including Peter Cohen, question the effectiveness of the US approach. According to him, the USFDA begins withdrawal of class I products when there is a reasonable possibility that the product will cause serious adverse health effects or death. Cohen also revealed that most of the banned supplements were still on the market six months after the ban, and two-thirds of them contained a pharmaceutical substance.[24]

Overview of the regulations in China

In 1996, the Ministry of Health (MOH) of China first approved this product category under health food. In 2003, the China Food and Drug Administration (CFDA) took over the regulation of health food from the Ministry of Health. Since then, the CFDA has been a part of the State Administration of Market Regulation (SAMR) and the regulatory body of drugs and medical products in China (19). In 2005, the Ministry of Health's original definition of health food was expanded into two categories: vitamin and mineral supplements and functional health food. The CFDA has approved and published a list of health foods by benefit groups (immunity-boosting, antioxidant activity, improving memory, reducing eye fatigue, improving sleep, promoting digestion, etc.).[25]

On July 28, 2015, the China Food and Drug Administration (CFDA) issued new projects on changes to the health food regulatory system, which include the registration and reporting process, the creation of a catalog of applications, and the catalog and labeling of health food ingredients. Based on the existing registration procedure, a new system has been added to the regulatory scheme, which provides the printing of the "blue hat" logo on health foods successfully registered by the State Administration of Market Regulation (SAMR), which is an alternative framework to the longer, more complex and expensive registration process of health foods. The principal changes in 2015 included:

- A new notification system for health food catalog recognized (domestic products),
- Vitamin and mineral products (imported products) and
- Provincial food and drug administrations were established to control the domestic production of healthy food.[25]

The newly added Functionality Catalog and Food Supplement Ingredient Catalog expand the scope of CFDA regulations, allowing the CFDA to provide more comprehensive oversight of the final product and the ingredients. The government is trying to focus more on product safety and scientific evidence of function.[12,26]

Overview of the regulations in Japan

In Japan, the Ministry of Health, Labor, and Welfare (MHLW) distinguishes two categories of foods: (i) Foods in general and (ii) Foods with Health Claims (FHC). The Consumer Affairs Agency administers the second category. FHC is further divided into subcategories. Introduced in April 2015, a separate labeling category, Food with Functional Claims (FFC), includes a simplified approval process and less stringent requirements than FOSHU products, potentially boosting Japan's health food market. Figure 3 shows the three types of Foods with Health Claims.[27] A relatively simple lower-level regulatory process and lower costs for verifying scientific evidence are sufficient to approve products in this category, which presents opportunities, especially for small and medium-sized companies. In addition, the Japanese government has lowered the minimum nutritional value threshold for FNFC products, allowing more products, even those with low levels of specific vitamins and minerals or other derived nutrients, to qualify for application.

These changes and the new FFC category help local small companies and farmers distribute their products more quickly and efficiently. It also allows foreign manufacturers to test the ground before incurring the time and investment costs required to obtain FOSHU approval.[27-30]

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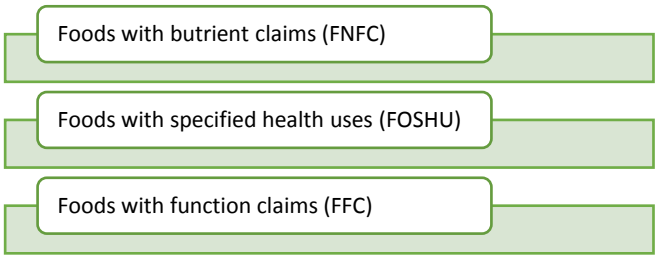
FIGURE 3. Types of foods with health claims in Japan



Overview of the regulations in Australia

In Australia, most dietary supplements are regulated under the complementary medicine category, which includes vitamins, minerals, herbal remedies, aromatherapy, and homeopathic products. However, some products may be considered unique and regulated under food competence. Complementary medicines containing low-risk ingredients may be registered on a list where manufacturers do not need to collect evidence on safety and efficacy. The category of complementary medicines falls under the Therapeutic Goods Act 1989 (TGA). The TGA also applies to medicines. Medicines subject to the TGA are regulated at a federal level, while foods, including those with health claims, are predominantly regulated by territorial regulatory authorities. As there is sometimes a coincidence between food and medicine, the legislation provides a guidance tool for the food-drug interface, helping manufacturers determine product compliance with TGA rules.[11]

Overview of the regulations in Canada

In Canada, DSs are considered a subcategory of drugs and are regulated by Health Canada's Natural and Non-Prescription Health Products Directorate (NNHPD). Natural health products (NHPs) include minerals, herbal products, and homeopathic medicines and can be formulated in pharmaceutical-like dosage forms. In addition to post-marketing monitoring, Health Canada evaluates all NHPs before they enter the market and inspects the manufacturing process. Licensing is subject to the manufacturer and all manufactured products, except for products manufactured by a health care practitioner on a personalized basis, except retailers of natural health products (NHPs). Details to consider in licensing include information on medicinal ingredients, origin, dosage, action, non-medicinal ingredients, and recommended use(s). The safety and efficacy of NHPs and health claims must be supported by adequate evidence.[8]

Like Australia, Health Canada helps manufacturers determine which regulations their products must comply with. For most food-like NHPs, the product definition fits into the food category and is therefore regulated as food. Like the European Union, Canada has a new food category includes genetically modified foods. Similar to the US, nutrient content claims are in practice in Canada.

Overview of the regulations in South Korea

South Korea, dietary supplements are grouped under the Health Functional Food (HFF) category, which is regulated by the Ministry of Food and Drug Safety (MFDS) HFF Act to ensure safety.

Individual ingredients that make health claims must be approved by the KFDA (Korea Food and Drug Administration), which is different from Japan, where approval is required for the final product. KFDA is also authorized to evaluate and approve nutrients, functional ingredients, raw materials, and components. MFDS assigns the health claim symbol "HFF" to a limited number of products.[13]

The different DS claims by individual jurisdictions are given in Table 2.

TABLE 2. Categories of supplement claims by country

Country	Categories of claims
Australia	Foods
	Complementary medicine (CM)
Canada	Nutrition claims
	Health Claims
China	Nutrient supplements
	Functional health food
EU	Nutrition claims
	Health claims
Georgia	Nutrition claims
	Health claims
Japan	Foods with nutrients function claims (FNFC)
	Foods with specified health uses
South Korea	Health and functional foods
USA	Nutrient content Claims
	Structure/function Claims
	Health Claims

CONCLUSION

Thus, the review of the regulations in individual countries reveals that, unlike pharmaceuticals, dietary supplements are relatively loosely regulated. In many jurisdictions, dietary supplement use is permitted without the prescription or recommendation of a practitioner. In such cases, the product claim is defined by a small list of conditions and the promotion of health and well-being. In other jurisdictions, particularly where traditional forms of health and healing are approved, traditional and complementary medicine products are often prescribed and, in some cases, prescribed only by experienced practitioners.[8,11]

The requirements are relatively stricter in the European Union, Japan, and some international groups. The need to regulate the food supplements sector forces the governments of individual countries to take practical steps towards the standardization of food and medicine

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regulations, but the need for greater cooperation and convergence of approaches between the official agencies of different countries is the principal issue. Improvements in e-commerce regulation of dietary supplements also require cooperation. The problem is that supplements can be purchased over the Internet with little regulatory oversight, and e-commerce can be widely used to promote and sell dietary supplements of unproven value.

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