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Food Safety and Standards Authority of India

सत्यमेव जयते

स्वास्थ्य एवं
परिवार कल्याण मंत्रालय
MINISTRY OF
HEALTH AND
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MINISTRY OF HEALTH AND FAMILY WELFARE
GOVERNMENT OF INDIA

REGULATING HEALTH SUPPLEMENTS AND NUTRACEUTICALS: AN EVOLVING LANDSCAPE

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1. Background

- The term “nutraceuticals” was introduced by Dr. Stephen DeFelice in 1989 and came from two words “nutrition” and “pharmaceutical” which means “it is food or part of a food which provides health benefits.” However, there is no international accepted definition of nutraceutical.

- The health supplements and nutraceutical industry is currently a booming industry worth billions and is expected to experience rapid growth in the coming decade. Because consumers are becoming more aware of potential health benefits and the importance of wellness, there has been an increase in popularity of food products like Dietary supplements, Health Supplements and Nutraceuticals. Across the globe, this market is expanding quickly, with regulations constantly evolving. In some countries, these items are classified as pharmaceuticals, while in others they are considered dietary supplements. Hence, the regulatory provisions vary between countries. Other challenges include identifying authentic raw materials, ensuring purity, efficacy and safety, lack of evidence and testing methods, false advertising, heavy metal contamination and supplement-drug interactions. Therefore, it is imperative to explore the emerging regulatory landscape for Health supplement and Nutraceutical and similar product across the globe.

2. Global Regulatory Landscape

Certain nations permit the use of supplements solely for general health and wellness, while others authorize their use for medical purpose. Regulatory standards differ significantly from one country to another. The regulatory framework of controlling dietary supplement/Health supplements/Nutraceuticals are summarised below:

United States of America

- The US FDA regulates these products as dietary supplements under the Federal Food, Drug and Cosmetic Act (the FD&C Act) as a food. Unlike FDA's regulation of drugs, where safety and efficacy need to be proven before approval, dietary supplements are primarily regulated through post-market surveillance and do not require prior approval1. No premarket approval is required to market dietary supplements in the United States. However, it is the manufacturer's responsibility to ensure that their product is safe for the population and that the conditions of use are indicated on the label.

European Union

- Food supplements are regulated as food products in EU. Food supplements are defined as concentrated sources of nutrients (i.e. mineral and vitamins) or other substances with a nutritional or physiological effect that are marketed in “dose” form (e.g. pills, tablets, capsules, liquids in measured doses).

- There is no central authorization before marketing for dietary supplements in the EU. EU Member States can request notification when a particular food supplement is placed on the market in their territory, so that the Member State's competent authority can monitor its use in the territory.

[1]S. Thakkar et al., Regulatory landscape of dietary supplements and herbal medicines from a global perspective, Regulatory Toxicology and Pharmacology, Volume 114, July 2020, 104647

- Safety and Efficacy of Food Supplements are evaluated by the European Food Safety Authority (EFSA as an independent source of scientific advice that produces opinions which then are used by the European Commission to adopt legislation1.

Canada

- Nutraceuticals come under the category known as Natural Health Products and regulated under the Natural and Non-prescription Health Product Directorate (NNHPD), which operates under the authority of Health Canada. Natural Health Products are a subset of drugs under the Food and Drugs Act1. They are regulated by Natural Health Product Regulations (NHPR). Natural health products (NHPs) are defined as vitamins, minerals, herbal remedies, homeopathic medicines, traditional medicines such as Traditional Chinese Medicines, probiotics, and other products like amino acids and essential fatty acids.

- It is mandatory for NHPs to apply for premarket authorization and submit all relevant material for assessment by Health Canada prior to going on sale. Because of this, Health Canada can monitor and the production and post-marketing procedures

Australia

- Most natural products such as herbal, vitamin, mineral, and nutritional supplements are treated as "complementary medicines" and termed as the "therapeutic goods," regardless of whether they are "Classified as Supplements" or "Classified as Medicines".

- These products are regulated under the Therapeutic Goods Act (TGA), which was established in 1989, which also regulates medicinal products. Some products could be in both "Classified as Supplements" and “Classified as Medicines" categories1.

- Low risk medicines are “listed” while higher risk medicines must be “registered”; The products that are “newly registered” must be evaluated for their quality, safety and

Japan

- Foods in Japan are regulated as either “foods in general” or “foods with health claims.” There are three different categories of “foods with health claims”.

(1) “Foods with nutritional function claims.” (FNFC) which are mainly vitamins and minerals

(2) “Food for Specified Health Uses” (FOSHU) for other functions: This category permits formulating productswhich have been pre-reviewed and evaluated by the Japanese authority including their health benefit that can be claimed.

(3) “Foods with Function Claims” (FFC).

- These categories are regulated in various ways, ranging from strict routes for FOSHU to short routes for FFC. Health Foods may only be marketed as FOSHU if the information on the product labels has been submitted for review.

- Manufacturers should provide evidence of product safety and effectiveness for approval. In 2015, new labelling guidelines for FFCs were approved, which include a simplified marketing process for submitting advance notifications and less stringent requirements than FOSHU products.

India

- Currently in India food supplements are regulated as food by FSSAI and are regulated under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022 (here after Nutraceutical Regulation) .The regulation covers five categories of food : Health Supplements, Nutraceuticals, Food for Special Dietary Use (FSDU) and Foods for Special Medical Purpose (FSMP), Pre-biotic Food and Probiotics Food. These products are intended for persons above the age of two years and can be marketed in forms such as capsules, tablets, pills, sachets and in any other format as measured unit quantities except those formats that are meant for parenteral administration. The products falling under these regulations shall not include drugs as defined in Drugs and Cosmetics Act, 1940, hormones or steroids or psychotropic ingredients. The labelling, presentation and advertisement of these product shall not claim that the product has the property of preventing, treating or curing a human disease, or refer to such properties.

3. Regional Approch/Issues

Food supplements, which are products derived from food sources that offer health benefits beyond basic nutrition, face several global challenges. Followings are some key issues:

1. Lack of Harmonization/ Diverse Regulatory Framework

- **Different classifications:** Dietary supplements are classified differently across countries—some classify as food, others as drugs, or as a separate category altogether (e.g., Natural Health Products in Canada). Such a situation creates difficulties to cross-border trade and commerce leading extensive registration processes of a product in one nation under entirely different category in another nation. However, there is a need to recognize national regulations as they cater to the socio-economic as well as cultural and concern related aspects.

- **Diverse definitions:** The definition a dietary supplement varies widely. For example, in the U.S., a dietary supplement can include vitamins, minerals, herbs, amino acids, and other substances, whereas other countries may have narrower or broader definitions.

- **Different approval processes:** Some countries, like the U.S., allow dietary supplements to be marketed without pre-approval, while others, like Japan (for FOSHU products) or Canada, require rigorous pre-market approval. This inconsistency can lead to the same product being available in one market but not in another.

- **Varying standards for evidence:** The scientific evidence required to support health claims varies greatly. In the EU, claims must be backed by substantial evidence and be pre-approved, while in other regions, less stringent standards may apply. This can lead to discrepancies in the quality and reliability of claims made on similar products in different markets.

- **Misleading claims:** The lack of harmonization can lead to products being marketed with claims in one country that would not be allowed in another. This can mislead consumers about the safety and efficacy of the products they purchase, especially in a global marketplace where consumers may buy products online.

- **Safety concerns:** Supplements that are considered safe and are readily available in one country might be restricted or banned in another due to safety concerns or different interpretations of the available evidence. This results in safety risks for consumers. There is a need to develop a mechanism of consultation between nations before such restrictions or banning of nutraceutical/ supplements are undertaken with a view to obtain expert opinion from other nations. The mechanism to exchange available history of use documents/ safety profile data and quality data from other nations need to be evolved.

- **Inconsistent labelling requirements:** Countries have different requirements for labelling dietary supplements, including how ingredients are listed, the health claims allowed, and required warnings or disclaimers. These differences complicate the process of creating a unified product for international markets.

2. Quality, Safety and Efficacy:

The use of dietary supplements was basically permitted to address micronutrient deficiencies. However, because of the widespread consumption of processed and nutrient-deficient foods there use has become quite widespread. Therefore, there is need for assessment of safety, efficacy, and quality of the food supplements in the market.

Following three major concerns with respect to food supplements

- **Quality:** The quality of a dietary supplement is determined by precisely identifying and testing the purity of each ingredient used, and whether or not it contains the ingredients that are listed on the label. As the number of dietary supplements produced and consumed rises, concerns regarding the identity and purity of the bioactive compounds used in these products have also grown in importance. This area needs a greater cooperative approach amongst scientist of different nations.

- **Safety:** Safety is the ability of a dietary supplement to not negatively impact a consumer's health. A dietary supplement is considered safe if it doesn't contain any harmful ingredients or exceeds the safe upper limits for any given nutrient. Availability of history of safe use documentation along with the ingredients, levels and processing methods need discussion and recognition.

- **Efficacy:** Efficacy is the measure of a supplement's capacity to live up to the promises made on the label and whether or not it can genuinely improve the health of the consumer. The food supplement industry is expected to address the issue of efficacy through relevant testing protocols and human intervention studies by conducting.

3. Claims and Misleading information

- **Misleading claims:** Claims such as goods can prevent, cure, or treat illnesses are misleading. Many claims on dietary supplement are not backed by strong scientific evidence. While some supplements are supported by research, others are based on anecdotal evidence or studies that lack rigor.

- **Health risks:** False or overstated claims have the potential abuse or overuse of the supplements. Serious health risks may arise, particularly if the supplements have an adverse effect on prescribed medications or pre-existing medical conditions

4. Testing methods

Several challenges are faced in testing, which can impact the reliability, safety, and efficacy of these products. Some of the key challenges include:

- **Standardization of methods:** There is often a lack of standardized testing methods for nutraceuticals, which can lead to variability in results. Different laboratories may use different techniques or protocols, making it difficult to compare results across studies or ensure consistency in product quality.

- **Complexity of ingredients:** Nutraceuticals often contain complex mixtures of active ingredients, which can be challenging to analyse accurately. The presence of multiple compounds and potential interactions between them can complicate testing and make it difficult to isolate and measure individual components.

- **Matrix effects:** The complex matrix of nutraceutical products (e.g., powders, capsules, liquids) can affect the accuracy of testing methods. Matrix effects can cause interference with the detection and quantification of active ingredients.

- **Adulteration and contamination:** Nutraceutical products can be adulterated with unapproved substances or contaminated with harmful impurities. Detecting and quantifying such contaminants requires sophisticated testing methods and can be challenging due to their potential low concentrations.

5. Consumer's issue:

Nutraceuticals can contain a wide range of ingredients, and consumers may struggle to understand what these ingredients are, their potential effects, and appropriate dosages. This lack of knowledge can lead to improper use or mixing with other supplements or medications. Nutraceuticals can interact with prescription medications or other supplements, leading to adverse effects. Consumers may not be aware of these interactions, which can pose health risks. Consumer awareness is one important aspect which needs to be addressed.

4. Scope

1. To create a strong regulatory framework, encourage innovation and scientific research, ensure product quality, and raise customer awareness.

2. To explore the latest developments in bioactive ingredient combinations, delivery methods, and formulation and to tackle the growing issues faced by the nutraceutical and health supplement industries.

3. To develop adequate pre-market approval procedures, labelling specifications, testing, certification systems, and post-market monitoring in the global context.

4. To bring clarity between health supplements / nutraceuticals and drugs and other functional bioactive food products vis-a-vis medicine.

5. To explore ways and means to exchange experts across nations with a view to build skills, competency in this area.

6. To recognize and promote cross border trade and commerce of nutraceuticals/ supplement with history of safe use and traditional foods and to develop framework for such commerce.

5. Expected Outcome

- Awareness and understanding of international regulatory provisions by stakeholders.
- A deeper comprehension of the challenges faced the field of nutraceutical research as well as upcoming advancements and policies.
- Harmonization of standards to encourage worldwide trade in health supplements and nutraceuticals.
- Creating a dynamic regulatory framework to keep up with new, innovations and scientific advances.
- Increasing consumer awareness.
- Facilitate international trade and prevent fraud.