



NUTRACEUTICALS Basic Research/Clinical Applications

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GLOBAL REGULATORY STATUS AND CHALLENGES



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Nutraceuticals

Global Regulatory Status and Challenges

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Regulatory Requirements and Challenges for Nutraceuticals

Ramesh Pennamareddy, Shivkumar Somani, and Kandi Purushothama Reddy

Chapter 8 Regulatory Frameworks and Guidance for Food Products Registration, Safety, Labeling, and Consumer Protection Guidelines: A Comprehensive Review on German Standards

Nikunjana Patel, Nishit Parekh, and Sanjeev Acharya

Chapter 9 Regulatory Landscape of Nutraceuticals in the European Union: Compliance and Standards

Arindam Chatterjee, Mayank Bansal, Rakesh Kumar Gupta, Devid Chutia, Deepak Sharma, and Madan Mohan Gupta

Chapter 10 Regulatory Requirements for South Africa for Marketing and Importing Nutraceuticals, Herbal Products, and Functional Foods

Pravin Semmarayan, Deon du Rand, and Megan Saffer

Chapter 11 Regulatory Provisions for Food Supplements in India

Maitreyi Zaveri and Bhavita Dhru

Chapter 12 Navigating Regulatory Requirements: A Comprehensive Guide to Nutraceuticals and Traditional Chinese Medicine

Risha Fillah Fithria and Jinfu Peng

11 Regulatory Provisions for Food Supplements in India

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11.1 INTRODUCTION

Nutraceuticals are products which are very rich in nutrients and provide lots of nutritional benefits, like the prevention of many diseases. *Nutraceutical* is made up of the word *nutrient*, which is a nutritious food or food component, with *pharmaceutical*, which is a medical drug. They help in improving and maintaining human health, and also, the prevention of some lifestyle diseases, like diabetes, cancers, and osteoporosis, is covered by nutraceuticals.

Today, the market of nutraceuticals is rising, and the request for these products is increasing, since consumers always look for health products to supplement their diet and to enhance their health. People need this for many reasons, such as lifestyle changes and the consumption of food and dietary habits of people. Nutraceuticals are widely available in many forms, and their use varies from country to country. It may range from isolated nutrients to food supplements, processed foods, and plant preparations and may be formulated in oral dosage in the form of pills, capsules, powders, and syrups, and also as dietary supplements, prebiotics, probiotics, and functional food. Different countries have their own regulations and legislative requirements. Some countries follow stringent regulations, whereas in some countries, well-structured and streamlined regulations for nutraceuticals are lacking.

All categories of nutraceuticals/dietary supplements clutch the market.

The terminology and definition of dietary supplements vary throughout the world, with developed countries having regulations in place, followed by some stringent laws and regulatory requirements, whereas in developing countries, the regulations are constantly evolving. [1]

11.1.1 THE FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA (FSSAI)

In India, FSSAI (Food Safety and Standards Authority of India) regulates all the activities of manufacturing, storage, packaging, import, and sale to ensure the availability of food and food products within the country. FSSAI, which regulates food and food products for special dietary purpose, also regulates many categories of food, such as nutraceuticals, health supplements (HS), food for special dietary use (FSD), and food for special medical purpose (FMP), which includes all the products that contain vitamins, minerals, amino acids, etc. FSSAI was established under the Food Safety and Standards Act (FSS Act) of 2006, which consolidated various acts and orders that up until then had handled food-related issues in various ministries and departments. FSSAI was created to lay down science-based standards for articles of food and to regulate all their aspects (manufacture, storage, distribution, sale, and import), to ensure the availability of safe and wholesome food for human consumption. [2–3]

11.1.2 HISTORY OF FOOD REGULATION IN INDIA [4]

India is the world's largest producer of fruits and vegetables, and by the mid-1990s, the food processing sector laws were framed in a veritable grid of regulations including a multitude of state laws as well as the following national laws.