Nutraceuticals and Functional foods are the products whose safety for human consumption is very essential, since these products are directly consumed by the consumers and if they are miss-handled or of poor quality or standards they can have adverse effects on consumers.

The main aim of regulating these products is to ensure safety of the consumer’s health. Apart from this, the regulations help in bringing about fair trade, harmonization, uniformity in practices, price control etc.

**Regulatory scenario in India**

In India the regulatory body which legalizes nutraceutical products is the Food Safety and Standards Authority of India, commonly referred to as FSSAI which has been established under the Food Safety and Standards Act, 2006. FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption. The Ministry of Health & Family Welfare, Government of India is the Administrative Ministry for the implementation of FSSAI.

Prior to the establishment of FSS Act 2006, there were a number of different Acts for different types of foods or other related products. Thus FSS Act was established to be a single reference point for all matters relating to food safety and standards, by moving from multi-level, multi-departmental control to a single line of command. The Food Safety and Standards Regulations 2011 notified in the Gazette of India came into force on August 5, 2011, to regulate manufacture, distribution and sale of nutraceuticals, functional foods and dietary supplements in India.

**Benefits of the FSS Act**

It unifies the earlier eight different laws, this has been a step towards harmonization, alignment of international regulations, science-based standards, clarity and uniformity on novel food areas, help to curb corruptions.
FSSAI Initiatives

FPAS system
FSSAI went for online registration process for product approval. FSSAI Product Approval System (FPAS) was launched to make product approval & registration easier.

Establishing food parks
The Ministry of Food Processing Industries, Govt. of India has already taken up initiatives such as approving a number of food parks and coming up with schemes for the development of food processing to address the constraints in food processing sector. This initiative was taken in order to attract investments.

Paradox
On one hand there have been some good initiatives from the FSSAI’s side but on the other hand we also witnessed uprest regarding regulations was wherein the sudden implementation of reforms and regulations had given food importers a real tough time. Over 200 tonnes of foodstuff imported to India was stuck at the Indian seaports and airports due to Food Safety & Standards Authority of India’s (FSSAI) zero-tolerance policy towards non-compliance of its regulations. The imports mainly contain chocolates, nutritional supplements, snack items etc.

In case of exports there has been some haziness regarding the certification process for their products has dealt a serious blow to Indian exporters of dietary supplements and nutraceuticals, who are now unable to ship newer products abroad or renew licenses for older ones. Apart from this the uncertainty over the licensing authority, is hampering the exports significantly.

International Regulatory Scenario

Some of the global food and nutrition policy related bodies are: WHO (World Health Organisation), CODEX (Codex Alimentarius), WTO (World Trade Organisation), FAO (Food and Agriculture Organisation).
Every country has its own regulation and nomenclature for nutraceuticals and allied. When considering the entry into global nutraceuticals market, understanding these varying regulations becomes quintessential. Some countries have notification based approach for market entry (Mexico, Chile) while some have registration based approach (India, Brazil, Colombia and Argentina).

Some countries consider nutraceuticals in food category while others consider in drugs category.

Examples:

1. In the USA, the Food and Drug Administration (FDA) regulates nutraceuticals under a different set of regulations when compared with those covering “conventional” foods and drug products. According to the Dietary Supplement Health and Education Act from 1994 (DSHEA), it is the manufacturer's responsibility to ensure that a nutraceutical is safe before it is marketed.

2. FDA is authorized to take action against any unsafe product after it reaches the market. Manufacturers have to make sure that the information on the product label is truthful and not misleading, but they are not obliged to register their products with the FDA nor get FDA approval before producing or selling nutraceuticals.

3. In Europe the food legislation is largely under the umbrella of European Food and Safety Authority (EFSA). This legislation focuses on “food supplements”, which are defined as concentrated sources of nutrients (e.g. proteins, minerals and vitamins) and other substances with a beneficial nutritional effect.

4. New products from Europe are presumed to have passed stringent European development and quality requirements. As a result, European nutraceutical companies, which are generally considered leaders in innovation, enjoy a perception of producing the highest quality products.

5. In Canada and Australia, nutraceuticals are regulated more closely as a drug than as a food category.

6. In India these is a regulatory body FSSAI for regulation of nutraceuticals and allied products.
Product Approval requirements across the world

The illustration below depicts the product approval requirements of various countries.

Characteristics of Good/ideal regulations

The regulations should be such that they support and provide real value to the consumers as well as they should facilitate the growth of the industry and should be business friendly. Enlisted below are some of the characteristics of good regulations.

- Developed with all relevant groups in society
- Supported by good science
- Developed on a risk based approach
- Backed by industry
- Enforceable
- Promote public health
- Protect consumers
- Stimulate innovation and research
- Stimulate economic growth

Way Forward

The nutraceuticals industry in India has knowledge as well as the science and tradition of natural medicines. But this science and knowledge should reach the consumers i.e. it should
be made available to the population. For this purpose regulations are important. OR This should be the approach of regulatory bodies while setting up regulations. **India still needs to have regulations that are industry friendly and such regulations that facilitate or mediate the growth of SME’s (Small and Medium sized enterprises).**

Now with the foreign companies looking at India as a potential hub for Nutraceuticals, our regulations should be conducive to the foreign investors. We need to have stability and certainty with respect to regulations and guidelines (including defined and time efficient regulatory and product approval system).

Also the FSSAI need to have certain regulations and guidelines in place for the digital or online retail of nutraceuticals, dietary supplements and allied products.

- *Published in NuFFooDS Spectrum Magazine*

**References**

- Nuffoods Spectrum, Budget – Way forward, Dr. R.B. Smarta.
- Regulatory and Product Approval Challenges: Are they Key Impediments in setting up Nutraceuticals Manufacturing in India? Ric Hobby, Chairman, IADSA, 6th FICCI-HADSA International Annual Conference.
- News-Medical net, Nutraceutical Regulation, Dr. Tomislav Mestrovic.