Regulatory Perspective of Nutraceuticals in India

Interlink's white paper

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Executive Summary

Nutraceuticals, defined as any food or part of food which provides health benefits including prevention or treatment of disease, have emerged as a necessity for consumers in developed as well as developing countries. With changing lifestyle and related diseases, functional ingredients such as vitamins, minerals, amino acids, fatty acids and probiotics, etc. have also become a part of this category.

World wide regulatory authorities are focusing on the Product Quality and Safety as these products are meant for human consumption. As food products are reaching from one country to another, maintaining safety and quality standards as per various regulatory guidelines set by the respective governments becomes important; which can be a real driver for the industry growth.

In Indian context, along with FSSA, getting implemented, the nutraceutical producers must be in tune with

- need for product evaluation,
- types of licenses required to import or manufacture and market a product in India
- requirements for label claims

This white paper gives a snapshot of what is happening on the Indian regulatory front and requirements to be met before entering Indian market.

Happy reading!

Dr. R. B. Smarta

Life, whether human or animal, is nourished by food, and its components like macro and micro nutrients. Though the food which we have been eating for years together is considered to be safe, different technologies have led to development of new foods where some of the existing characteristics of foods can get altered, either in a positive or a negative way. But on the whole, these foods can be looked at as supplementation to daily diet to have some positive effects. As per the Food Safety Standard Act, 2006 (Chapter 4, Section 22) it has been recommended that Food should be classified as follows

- Novel foods
- Genetically modified food
- Irradiated food
- Organic foods
- Foods for special dietary use
- Functional foods
- Nutraceuticals
- Health Supplements

This makes it very clear that Nutraceuticals are a part of the food segment and it should not be considered as a form of pharmaceutical or drug formulation.

Nutraceutical factsheet

Nutraceutical business : global and Indian

Globally the nutraceutical market was estimated to be US$ 140.1 billion in 2010. Of this USA and Europe formed the largest markets accounting to 36 percent and 25 percent respectively. Exhibit 1 portrays global neutraceutical market.

US: In 2010, the US nutraceutical market stood at US $ 50.4 Billion and was by far the largest nutraceutical market in the world. The dietary supplements segment was growing at roughly 3.1 percent while the functional food and beverages segment was growing at 5.6 percent. Currently, companies in the US are looking to diversify their products and are leaning more and m o r e towards natural nutraceutical ingredients in their product offering, mainly due to the increasing consumer demand for all-natural, non-modified functional ingredients.

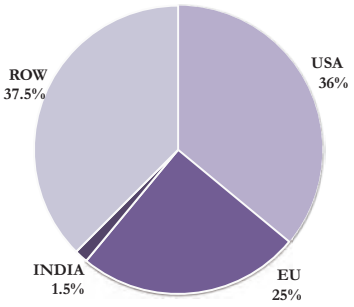
Europe: The total European industry was valued at US $ 35 Billion in 2010. Companies in Europe believe that product and ingredient innovation is the way forward for the nutraceutical industry. Germany, Netherlands and Sweden have emerged as the key nutraceutical innovation hubs in Europe, while Great Britain and Spain have emerged as key test markets for new products.

India: In 2010, the Indian nutra industry was estimated at US $ 2 Billion, roughly 1.5 percent of the global nutraceutical industry. The existence and consumer belief thealternate medicines share in India could provide a platform for the nutraceutical industry to capitalize on. Currently, an Indian nascent market is trying to incorporate traditional herbal ingredients (usually ayurvedic) into the nutraceutical portfolio. Example: Chyawanprash supplements (market size US $74.5 Million in 2010). Broad segments of Indian nutraceutical industry include Dietary supplement (40%) and Functional food and beverage market (60%) (Refer exhibit 2). In India, functional foods and beverages are expected to see increased consumption over the next five years resulting in this segment garnering greater product share (67%) in the market as opposed to dietary supplements (33%). The total Indian nutraceuticals market in 2015 is expected to be approximately US $ 5 billion.

Nutraceutical ingredients

Developing nations like India, China and Brazil have emerged as key sourcing destinations for agri-based raw materials, while Europe has evolved into a

Exhibit 1 : Global nutraceutical market



nutraceutical ingredient hub. Indian nutraceutical ingredient market is around US $250 million comprising of vitamins and minerals (36%), probiotics (9%), omega 3 fatty acids (5%) and others (50%).

Globally, the ingredient trend is shifting towards natural ingredients. In order to make product successful in various regions, manufacturers are focusing on cultural customization to suit specific regions and specific target groups.

Major nutraceutical ingredients used world wide are Vitamins, Minerals, PUFA or specialty lipids, Phytochemicals, Prebiotics, Probiotics, Amino acids, Peptides, Proteins, Fibers, Carotenoids, Polyols and others like CoQ10, Glucosamine, Chondroitin, Lipoic acid, Inositol, etc.

Ingredients and disease conditions

Usually each formulation, be it a functional food or dietary supplement, is a combination of 2-3 ingredients. Some of the key target areas for nutraceutical ingredients are

Cardiovascular Disorders: Omega-3, Phytosterols, Fiber, Antioxidants
Weight Management: Herbal Extracts, Fiber, Proteins, Fatty Acids
Cognitive: Omega-3, Antioxidants, and Amino Acids
Bone and Joints: Omega-3, Vitamins, Minerals, Protein, Amino Acids, Antioxidants, Botanicals

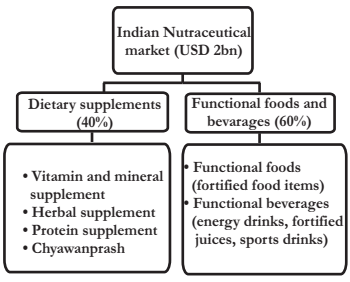
Regulatory guidelines

Because nutraceuticals are not a part of pharmaceuticals and drugs formulation, rules and regulations also tend to be different for this segment. Indian government has recently implemented the new law FSSA (Food Safety and Standards AOI). As a result, there exists a confusion in minds of new entrants regarding do's & dont's of Indian regulatry system.

Historical perspective

All along before Food Safety and Standards Act, 2006 was passed, neutraceuticals were regulated under Prevention of Food Adulteration Act and Rules (PFA). As on date, the regulations for foods and beverages are in a state of transition from PFA to the new FSSA.

Exhibit2 : Segments of Indian Nutraceutical market



Pre 2005

Multitude of laws and ministries were governing food and food processing such as

1. The Prevention of Food Adulteration Act, 1954
2. The Fruit Products Order, 1955
3. The Meat Food Products Order, 1973
4. The Vegetable Oil Products (Control) Order, 1947
5. The Edible Oils Packaging (Regulation) Order, 1998
6. The Solvent Extracted Oil, De-oiled Meal, and Edible Flour (Control) Order, 1967
7. The Milk and Milk Products Order, 1990
8. Essential Commodities Act, 1955 relating to food

There were varied standards of food under these laws regarding manufacturing, processing, packaging, etc.

2005-2006

A need felt for integrating all existing laws under one law as number of committees, including the Standing Committee of Parliament on Agriculture in its 12th Report submitted in April 2005, have emphasized the need. A Group of Ministers (GOM) was appointed by Government of India to propose the Integrated Food Law. Food Safety and Standards Bill, 2005 was introduced in parliament and referred to the recommendations made by Standing Committee on Agriculture. The Indian Food Safety and Standards

Bill (FSSB) 2005 was passed by parliament and signed by President on 23rd August 2006, promising a major impact on the Indian Food Processing Industry. The Food Safety and Standards Act aims to integrate the food safety laws in the country in order to systematically and scientifically develop the food processing industry and paradigm shift from a regulatory regime to self-compliance. As part of the process of consolidation, the act proposes to repeal above mentioned eight existing law related food safety. Two main objectives of the Act are

- To introduce a single statue relating to food
- To provide for scientific development of the food processing industry

The Act aims to establish 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. It incorporates the salient provisions of the Prevention of Food Adulteration (PFA) Act, 1954 and is based on international legislation, instrumentalities and Codex Alimentarius Commission.

Transition perspective - the ideal scenario

Food safety and standards act - 2006

The Food Safety and Standards Act, 2006 consolidates eight laws governing the food sector and establishes the Food Safety and Standards Authority of India (FSSAI) to regulate the sector and other allied committees. The FSSAI would consist of a Chairperson and 22 members. The Chairperson would be either an eminent food scientist or a civil servant not below the rank of Secretary. Seven of the members would be ex-officio, not below the post of Joint Secretary, from various ministries. Five members would be appointed by rotation every three years from the States and Union Territories. The Authority would have two representatives each from the food industry and consumer organizations, three food technologists, two members from a farmer's organization and one from retail organization. FSSAI will be aided by several scientific panels and a Central Advisory Committee to lay down standards for food safety. These standards will include specifications for ingredients, contaminants, pesticide, biological hazards, labels and others. Everyone in the food sector is required to get a license or a registration that would be issued by local authorities. Temporary stall holders are exempted from the license but need to get their businesses registered with the local municipality or *Panchayat*.

The law will be enforced through State Commissioners of Food Safety and local level officials. The Act empowers the FSSA and State Food Safety Authorities to monitor and regulate the food business operators. The Commissioner of Food Safety of each state appoints a Designated Officer (DO), not below the level of Sub-Divisional Officer, for a specific district whose duties include issuing or canceling licenses, prohibiting sale of food articles that violate specified standards, receiving report and samples of food articles from Food Safety Officers and getting those analyzed. The State Commissioner, on the recommendation of the Designated Officer, decides whether a case of violation would be referred to a court of ordinary jurisdiction or to a special court. The Act provides for a graded penalty structure where the punishment depends on the severity of the violation. Offences such as manufacturing, selling, storing or importing sub-standard or misbranded food could incur a fine. Offences such as manufacturing, distributing, selling or importing unsafe food, which result in injury, could incur a prison sentence. The sentence could extend to life imprisonment in case the violation causes death. Petty manufacturers who make their own food, hawkers, and vendors to the temporary stall holders could be fined up to INR 25,000 if they violate the specified standards.

Current scenario

The Food Safety and Standard Rules, 2011 have been issued and have become effective from 5th May, 2011. The Food Safety and Standard Authority has also issued regulations with respect to Licensing and Registration of food business, Packing and Labeling, Food products standard and additive etc. The Acts, Rules and Regulations are now implemented from 5th August, 2011. Thus, there is now one single legislation and specified authorities to regulate manufacture, distribution and of sale nutraceuticals, functional foods and dietary supplements in India. However, due to lack of clarity of specific regulations for registration of nutraceuticals, permitted additives, etc, entrepreneur intending to launch nutraceutical in India is still faced with following challenges:

- Drugs defined under Section 3(b)(i) of the Drugs and Cosmetics Act, 1940 and also

Ayurvedic, Siddha and Unani drugs are specifically excluded from the scope of the definition of nutraceutical and health supplement under Section 22 of the act. The definition of drug under Drugs Act is very exhaustive and taking recourse to the definition of drug, regulatory officers are categorizing nutraceuticals, especially manufactured and marketed in tablet, capsule or liquid oral dosages form containing vitamin and minerals as drugs on the basis of even structure function claims.

- The regulatory officers also take a view that as empty gelatin capsule itself is covered by the definition of drug: any product marketed in capsule form will also be considered as drug.
- Some commonly used colors and additives such as binding agents, granuating agents used in formulating tablets do not find place in the list of permitted food additives under the regulations.
- Though the structure function claims are permitted, there is no clarity as to the permitted structure function claims for nutraceuticals and dietary supplements.

To overcome these difficulties, it would be necessary to amend Schedule K of the Drugs and Cosmetics Rules, 1945 to provide for specific exemption to nutraceuticals, dietary supplements and health supplements from the scope of Drugs and Cosmetics Act, 1940 and Rules, 1945.

It is also essential to have specific regulations as regards product approval, approval of claims, permitted additives, quantity of vitamins and minerals etc. for nutraceuticals as it is necessary to treat this segment as independent and unique entity under the Food Safety Standard Act, 2006.

Regulatory requirements for India entry

As the nutraceutical regulation is evolving in India, with FSSA getting recently implemented there is a possibility that some of the content is conflicting / confusing, but for Indian industry to take a shape, these have to be streamlined.

In order to enter Indian nutraceutical market, some of the very important areas to focus include product evaluation, actual product analysis, procuring licenses and developing India specific health and label claims.

1. Product evaluation

In Indian conditions, the formulations behave very funnily and get mixed up in classifications. Hence, the due-diligence in terms of carving a specific amount for each ingredient and the combination of ingredients becomes very crucial.

In order to perform product assessment as per Indian regulatory definition, it is of utmost importace to examine each active ingredient and additive in the

context of permissibility, standards and dosage of vitamins / minerals allowed as per the Therapeutic, Prophylactic or Recommended Daily Allowance for Indians. Also manufacturers are unclear whether their products will be classified as food or food supplement or drug in the context of the Prevention of Food Adulteration Act, 1954 and Rules, 1955, Food Safety and Standards Act, 2006 and Drugs and Cosmetics Act, 1940 and Rules, 1945.

The Food Safety and Standards Rules, 2011 highlights regulatory enforcement structure and procedures which Central Government proposes to make. The structure has a hierarchy from commissioner of Food Safety to number of officers like designated officer, food safety officer, food analyst, etc. who will be involved in the product analysis process at different points.

Various steps in the product analysis include

1. Developing extracts of documents and authenticating the same by concerned authority
2. Sample collection (in the presence of witnesses)
3. Sample dispatch to concerned authority (different process for bulk package and single package)
4. Food analysis
5. If analysis is not complete within stipulated period of time, further action plan by designated officer
7. Adjudication proceedings (holding enquiry, appeal procedure, hearing, etc.)

Exhibit : 3 Key ingredients with health claims used by Indian nutraceutical players

INGREDIENT	HEALTH CLAIM AS PER INDUSTRY SOURCES
Ginseng	Believed to cure lethargy, arthritis, impotence, senility. Also has effective anti-aging properties
Lactobacillus and bifidobacterium	Lactobacillus and bifidobacterium improve intestinal microflora and aid better digestive abilities. They help to prevent diarrhea, other gastrointestinal infections, irritable bowel syndrome, and other inflammatory bowel disease
Beta glucan	Beta glucan is a soluble fiber that soaks up the cholesterol in our digestive system and help Reduce the amounts of 'bad' (LDL) cholesterol in the body
Phytoestrogens	Reduces the risk of many kinds of cancers, cholesterol and risk of coronary heart disease, chances of osteoporosis.
Tocopherols	Known for their cholesterol lowering ability. Prevent or delay heart disease and related complications, cataracts and macular degeneration, prostate and other cancers. Retard the aging process. Boost immune function. Promote healing of burns, eczema, skin problems.
Beta-carotene	Helps prevent night blindness and other eye problems, skin disorders, enhance immunity, protects against toxins and cancer formations, colds, flu, and infections. Beta-carotene is also a powerful antioxidant and helps guard against cancer and CVD.
Ashwagandha	Used to treat fevers, and to protect against infection or illness. It has also been used to boost the immune system, improve memory, and to promote overall wellness. Very effective in reducing inflammation, treating tumors, decreasing stress and as an antioxidant.

2. Licenses

Though new FSSA promises to simplify Licensing and Registration processes for nutraceuticals, the actual process vary depending on number of parameter

To get the product registered in India, number of licenses (almost 4-5)will be required depending on the actual product status like

- Whether company wants to sell bulk drug or finished formulation
- Whether company is importing finished product or bulk ingredient?
- Whether product to be imported is with or without India specific label

Glossary

FSSAI	Foods Safety and Standard Authority of India
FSSA	The food Safety and Standards Act
FSSB	Food Safety and Standards Bill
GOM	Group of Ministers
PFA	Prevention of Food Adulteration Act
DO	Designated Officer
INR	Indian Rupees
USFDA	United States Food and Drug Administration
FDA	Food and Drug Administration
OTC	Over the Counter
DMR	Drug Magic Remedy
NRVs	Nutrient Reference Values
LDL	Low Density Lipoprotein
ASCI	Advertisements Standards Council of India
ICMR	Indian Council of Medical

and will the claims be developed in India?
- Whether the company has packaging license?
- Whether it requires manufacturing license?
- Whether it requires marketing license?

Number of documents will have to be furnished by the food importer to the government authority along with registration application dossiers.

Interlink through its regulatory product offerings provides regulatory support for following licensing procedures which need to be taken care of before launching these products in India.
- Import licensing
- Manufacturing licensing
- Marketing licensing and
- Other State and national level clearances/licenses required from regulatory side.

3. Health and label claims

Developing health and label claims specific to Indian regulatory guidelines is the major element to be focused while entering Indian market.

International as well as national clients have number of questions about

- Indian labeling and packaging requirements
- Packing of consignment
- Need for sample material and declaration for registration
- Composition of consigntment and approach for the same
- Label contend
- Structure-function claim and label claim

Based on the results of regulatory assessment of the product, India specific label content and claims are developed. nwe entrant should also consider Exhibit 3 showcases some of the health claim used in India. The requirements to be met to make specific product claims

Conclusion

Globalization of the nutraceutical and functional food industry presents significant challenges to stakeholders, not the least of which is the regulatory variance between countries active in the marketplace. Nutraceuticals are playing crucial role in developments of future therapeutics but it depends on control of purity, efficacy and safety.

Hence, when any new entrant wants to enter Indian nutraceutical market, it is very important to comply with regulatory framework so that business is run smoothly. The focus areas should be product evaluation for each active ingredient in the context of permissibility, standards and dosage of vitamins / minerals allowed, product classification as per various Indian Healthcare Laws (legal definition of the product), India specific label claims and advertising.

References

- *Ministry of food processing industry website "http://mofpi.nic.in/ContentPage.aspx?CategoryId=147"*
- *The Food Safety and Standards Act, 2006 – Bare act with short comments, 2009, Professional Book Publishers, Delhi.*
- *Nutraceuticals – Critical supplement for building a healthy India, 2009, E & Y-FICCI report*
- *Industry Insight – Nutraceuticals, August 2010, Cygnus Report.*
- *Interlink Knowledge Bank*
- *Expert Interviews*
- *Global Nutraceutical Industry: Investing in Healthy Living, Frost - FICCI report, 2011*
- *Chaturvedi, S. et al (2011), Role of Nutraceuticals in Health Promotion, International Journal of PharmTech Research, Vol. 3, No.1, pp 442-448*

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"Despite consolidation of all food laws in a single legislation Food Safety and Standards Act, 2006, the confusion exists in the minds of new entrants as well as existing players as regards regulatory requirements for Nutraceuticals, health supplements, functional foods. The regulatory white paper on the subject is a commendable step by Interlink and the crisp, precise information will be value addition and guide to the manufacturers, marketers and distributors"

Mr. Sudhir W Deshpande
Former Joint Commissioner,
FDA. Maharashtra.

"The white paper has tried to crisply bring out the relevant issues and questions that need to be addressed by the FSSAI while framing the regulations for the "Nutraceutical/Functional Foods sector" in India. I hope the FSSAI does so and the sector needs to interact with the FSSAI to get these clarifications when the draft regulations are announced"

Dr. DBA Narayana
Retired Director, Regulatory Affairs,
Foods, Home & Personal Care,
Unilever Research, Bangalore, India.

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