RNI NO: MAHENG/2007/23118

June 1-15, 2022 |₹60

All Your Ingredients In One Magazine

Ingredients SOUTH ASIA

A Saffron Media Publication
Vol. 15, Issue 17, Pages-44

Emerging regulatory scenario and future course

DR SANJAY AGARWAL

NUTRACEUTICALS are currently the principal dietary supplements for India's health-conscious population. Nutraceuticals, also known as nutritional supplements, have quickly become a standard in the healthcare industry, available in various formats such as tablets, syrups, gummers, and capsules. As a result of the Covid-19 pandemic, the nutritional supplement business will expand by 35% (CAGR) from $4 billion in 2015 to 18 billion in 2025. This article aims to provide a quick review of the FSSAI updated regulations for nutraceuticals.

Market Analysis of Nutraceuticals from an Indian Perspective

Every day, the global demand for nutritional supplements grows. The demand in India is currently growing at a rate of 26 percent per year, the same as Japan. The majority of new businesses have started manufacturing nutraceuticals in India. The rise of the Indian nutritional supplement sector was primarily due to drug firms and FMCG suppliers. Beverages, including dietary supplements and functional foods make up India's nutraceuticals market.

Mineral and vitamin supplements account for over 64% of the Indian nutritional supplement market. The Indian nutraceuticals business, which had surpassed the $1.5 billion mark in 2013, has grown to $2 billion in 2014. Furthermore, by 2025, this industry is expected to reach $18 billion.

What are the Nutraceutical FSSAI regulations?

The Food Safety and Standards Authority of India has established guidelines for the licensing and registration of businesses in the food sector. The FSSAI has set several regulatory standards for the clearance of nutraceuticals in the Indian market. The Act is divided into 21 chapters, with the fourth article discussing nutraceuticals and other functional foods.

The Food Safety and Standards Authority of India has established guidelines for the licensing and registration of businesses in the food sector. The FSSAI has set several regulatory standards for the clearance of nutraceuticals in the Indian market

The 21 simple combination of minerals and vitamins formed in capsules, tablets, or syrup formats must not be included in any of the categories of such regulations required when minerals and vitamins are added, according to the FSSAI's Nutraceuticals Regulations, 2016.

Although there has been a revised nutraceutical update that the FSSAI has proposed, I thought of taking more into consideration.

FSSAI Revises Nutraceutical Regulations

In 2018, the Food Safety and Standards (Health Supplements, Nutraceuticals, Special Dietary Use Foods, Food for Special Medical Purpose, Functional Food, and Novel Food) Regulations, 2016, went into effect. The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food) First Amendment Regulations, 2021 were recently amended by the FSSAI with the prior consent of the Central Government.

These regulations cover eight categories of

CONTINUED ON p18▶

Probiotics are microscopic living organisms

CONTINUED FROM p17

functional foods: Health Supplements; Nutraceuticals; Specialty Food Containing Plant or Botanicals; Foods Containing Probiotics; Food for Special Dietary Use; Food for Special Medical Purpose; Foods Containing Prebiotics; Novel Foods.

From April 1, 2022, all Food Business Operators (FBOs) must comply with the provisions of these laws.

The following are the significant changes in the first amendment:

- These laws cover dosage formats such as tablets, capsules, and syrups for combining vitamins and minerals, including the use of a single vitamin and mineral, at amounts equal to or less than one Recommended Dietary Allowance (RDA).
- These laws on 'Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food, and Novel Food' do not apply to infants under the age of 24 months with the formation of a separate regulation on 'Food for Infant Nutrition, 2020.'Foods suitable for infants up to the age of 24 months are specified in the Food Safety and Standards (Food for Baby Nourishment), 2020).
- Cereal grains, fruits, vegetables, legumes, spices, and processed substances such as extracts may be utilised as a supplement or nutraceutical. However, touting specific health advantages of such foods would necessitate previous Food Authority approval.
- Except for botanical extracts, any "single pure chemical entity" stated in these regulations is not permitted without prior Authority clearance.
- Ingredient or product claims must be approved.
- Claims of disease risk decrease are omitted.
- Food for Special Dietary Use (FSDU) for athletes must be used only under the supervision of a physician, professional dietician, or nutritionist.
- For athletes, Food for Special Dietary Use (FSDU) must only be in oral formats.
- For a sportsperson, Food for Special Dietary Use (FSDU) is a formula for substituting all meals in the daily diet for slimming, weight management, and weight control objectives.
- All advertisements for Food for Special Dietary Use (FSDU) should state that the product should be taken only under medical advice.
- Nutrients must be added in quantities equal to, or less than one Recommended Dietary Allowance (RDA). Prior Food Authority clearance is necessary based on acceptable scientific proof that the food is exceptionally prepared for weight loss and intended as a complete replacement of a full meal with larger RDA in food format (except capsule, tablet, syrup).
- When using vitamin esters, derivatives, salts, and mineral salts and chelates, food industry owners must notify the Food Authority in writing. When necessary, they must additionally offer extra safety data or information.
- Amino acid esters, derivatives, isomers, and salts that are suitable can be employed. When using esters, salts, isomers, and products, food business authorities, or FBOs, must disclose them in writing. They must also present extra safety data or any other document in such circumstances.

> The viable number of added probiotic organisms in food should be 108 CFU in the suggested serving size per day

Probiotics and prebiotics are two types of probiotics.

Prebiotics are a form of fibre that the human body cannot digest and that probiotic bacteria feed on. Probiotics are microscopic living organisms such as bacteria and yeast. Both prebiotics and probiotics may encourage the growth of beneficial bacteria and other microorganisms in the stomach.

The following are included in the new amendment.

- The viable number of added probiotic organisms in food should be 108 CFU in the suggested serving size per day.
- Adults should not consume more than 40g/2000 kcal of prebiotics per day.

Aside from that, changes can be found in schedules 1 and 4. Schedule 1 has the newly added vitamins and minerals, whereas Schedule 4 contains the updated botanical component list.

Additions to Schedule 1 (List of vitamins and minerals and their components)

The following are the new vitamin and mineral forms included in the regulation:

- ***Vitamin D:*** Vitamin D3 (cholecalciferol) - Lichen/Algae sources are allowed. However, the Food Authority will need to approve the lichen/algae species first.
- Tocotrienols (vitamin E)
- Calcium comes from algae, such as red seaweed.
- Calcium is found in corals, shells, pearls, conchs, oysters, and milk in natural forms.
- Copper-oxide (copper (II) oxide, cupric oxide, and black copper oxide) is a kind of copper.
- Selenious acid (selenium)

Revisions – Schedule – IV (List of plant or botanical ingredients)

- The FSSAI has revised the IV List of plant or botanical ingredients. The daily consumption range for adults (in terms of raw herb/material) has been changed for most Botanicals.
- The list of Botanicals has been updated to add new botanicals.
- Certain botanicals, such as Areca catechu L. (Supari: Seed) and Carissa spinarum L., have been removed from the list (Karawan: Fruit).

As previously stated, all Food Business Operators (FBOs) must comply with the provisions of these laws beginning April 1, 2022. As a result, all FBOs must evaluate their botanical product compositions and make changes to comply with the amended requirements.

Futurist Approach: The FSSAI is working to improve the regulatory system for health supplements and nutraceuticals.

FSSAI is expected to improve the regulatory environment to oversee the country's health supplement and nutraceuticals industry. It will be accomplished through international collaboration and the adoption of global best practices.

"By 2025, India's health supplement and nutraceutical sector will have grown to a size of US$10 billion." FSSAI is preparing to strengthen the regulatory ecosystem through cross-border collaboration and learning from international best practices as the sector evolves, according to a statement. These rules apply to eight different types of foods and include specific criteria for their content, claims, and labelling, among other things.

"The regulations permit the manufacture and sale of the above-mentioned foods in the form of tablets, capsules, and syrups, provided they meet the quality requirements and standards set forth in the Indian Pharmacopoeia," according to the FSSAI.

According to the regulations, food formulation will be based on medicine or nutrition and supported by objective scientific evidence. According to information, hormones, steroids, and psychotropic chemicals are not permitted in these foods.

In collaboration with the International Alliance of Dietary/Food Supplement Associations, FSSAI and the CII (Confederation of Indian Industry) established the Resource Centre for Health Supplements and Nutraceuticals (ReCHaN) for this aim (IADSA).

(The author is a leading pharmaceutical consultant)