

FSSAI strengthens regulatory system for health supplements as it is poised to grow to USD 10 Billion by 2025

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India's health supplement and nutraceutical industry is rapidly growing and is poised to be USD 10 Billion industry by 2025. As this sector grows, FSSAI is gearing itself to strengthen the regulatory ecosystem through cross-border collaboration and learning from international best practices.

In December, 2016, FSSAI had notified the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016. These regulations cover eight categories of foods and carry detailed requirements about their composition, claims, labels etc. These foods are health supplements, nutraceuticals, foods for special dietary use, food for special medical purpose, speciality food containing plants or botanicals, foods containing probiotics, foods containing prebiotics and the novel foods. The regulations allow the manufacturing and selling of the above category of foods in the form of tablets, capsules and syrups and must fulfil quality requirements and standards as specified in the Indian Pharmacopoeia. As per these regulations, the formulation of articles of food shall be based on the principles of sound medicine or nutrition and supported by validated scientific data, wherever required.

A mere combination of vitamins and minerals formulated into tablets, capsules or syrup is not food unless vitamins and minerals are added to an article of food based on a food format. These foods are not permitted to contain hormones, steroids or psychotropic ingredients. These foods may use approved colours and additives as permitted in Schedule VF of these regulations, natural, nature identical or synthetic flavours as permitted in the Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

The quantity of nutrients added to the articles of food shall not exceed the recommended daily allowance (RDA) as specified by the Indian Council of Medical Research (ICMR) and accepted by the FSSAI. These regulations have into force from 1 January 2018.

Since, this is new and emerging area, FSSAI has begun its efforts to bring in global best practices towards harmonisation of regulations on the issue, particularly on vitamins and minerals content in health supplements and nutraceuticals in India. For this purpose, FSSAI had nudged CII to establish 'Resource Centre for Health Supplements and Nutraceuticals (ReCHaN)' in partnership with International Alliance of Dietary/Food Supplement Associations (IADSA).

ReCHaN has initiated a series of scientific dialogues involving stakeholders on international best practices with global experts. The second in the series of these dialogues was held this week on the issue of "*Regulatory approaches to the establishment of maximum levels for Vitamins & Minerals in Health Supplements & Nutraceuticals*". Scientists and experts including those from ICMR and National Institute Nutrition (NIN) participated in the forum. International experts included Basil Mathioudakis, key architect of global regulations in the space of health supplements and nutraceuticals, particularly in the EU and Dr B.H. Lim, a leading expert in this area from the ASEAN region.

In order to strengthen the regulatory system for health supplements in the country, the Resource Centre had earlier developed two guidance documents on compliance and good manufacturing practices. Now, it has developed the training manual and presentation deck on food safety management system for use under the FSSAI's Food Safety Training and Certification (FoSTaC) initiative. These would be used both for food businesses and the regulatory staff.

FSSAI and ReCHaN have been conducting a series of training sessions for regulatory staff on issues of regulatory compliance including labelling, FSMS, enforcement and licensing in health supplement space. Since the regulatory issues in the health supplement space are somewhat different from other food sector, hence the regulatory staff are finding these training sessions very useful.

Speaking on the occasion, Pawan Agarwal, CEO, FSSAI pointed out that the health supplement sector is very important for the country not only from the industry growth perspective but also from public health point of view. This sector, however poses new set of challenges not seen in the traditional food processing sector. He added that FSSAI is gearing itself to face the challenges by learning from abroad. He further added that Indian opportunity in this space is particularly large due to plant and botanicals that have traditionally been used in Ayurveda are included in the regulations. Finally,

he informed that claim regulations on the health supplements would soon be notified. These regulations would help industry to grow further while at the same safeguarding consumer interest.