

FSSAI facilitates CII & IADSA to set up nutraceutical resource centre

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With a view to bring in the best global practices towards the harmonisation of nutraceutical regulations, FSSAI, the country's apex food regulator, has facilitated the Confederation of Indian Industry (CII) to establish a Resource Centre for Health Supplements and Nutraceuticals (ReCHaN) in partnership with the International Alliance of Dietary/Food Supplement Associations (IADSA), particularly on vitamin and mineral content in health supplements in India.

In July 2018, FSSAI had signed a Memorandum of Understanding (MoU) with ReCHaN to support the best practices and enable effective science-based standards and regulations in the country. The resource centre, established by CII and IADSA, over the last one year, has been working efficiently to help establish a robust ecosystem towards maximising the full potential of the health supplement and nutraceutical sector.

Pawan Kumar Agarwal, chief executive officer, FSSAI, said, *"The health supplement sector is very important for the country, not only from the industry growth, but also from the public health point of view. FSSAI has taken up the task and is collaborating with various countries to create a data bank of knowhow on the subject of health supplement and nutraceuticals."*

Shweta Khandelwal, senior research scientist and associate professor, Public Health Foundation of India, said, "Dietary supplements are considered safe within a broad range of intake and safety problems with the supplements are relatively rare. ReCHaN was created to strengthen and cultivate a culture of food safety and quality among various stakeholders in the nutrition supplements and nutraceuticals segment. Since it represents both industry and food regulators (government), along with some independent experts, it is likely to boost the quality of products being manufactured and supplied in the markets."

Explaining the regulatory difference between the health supplement space from other food Khandelwal said, "Supplements sector is different than drugs or food because supplements are not seen as a danger to health, they are not regulated as strictly as drugs."

"Proper research should be performed to develop effective dietary supplements and scientists must invest time and funds in research related to the formulation of dietary supplements. Online promotion is one of the major regulatory problems concerning supplements," she

added. “Unfortunately, supplements sold on the Internet have low barriers of entry, and almost anyone can establish a store on the Internet and sell anything they want anywhere in the world,” Khandelwal said.

Agarwal said, “This sector poses new set of challenges not seen in the traditional food processing sector. FSSAI is gearing itself to face the challenges by learning from abroad. Indian opportunity in this space is particularly large due to plants and botanicals that are traditionally used in Ayurveda are included in the regulations.”

Thus, the apex food regulator, in order to bring in more clarity with respect to health supplements and nutraceuticals, will be notifying the claims regulations soon. Agarwal has said that the work related to these regulations is underway, and the notifications on the claims regulations are expected to be out in a few months.

He said, “Claim regulations on the health supplements would soon be notified. These regulations would help industry to grow further, and at the same time, safeguard consumer interest.”

Interestingly, two guidance documents on compliance and good manufacturing practices has been by ReChaN for the functioning of food businesses.

According to Khandelwal, the guidance documents provide a lot of fragmented material comprehensively. She added, “These two documents can serve as hand-holders, knowledge enhancers for people unfamiliar with or unaware about certain regulatory or advisory aspects. However, it is important to have an internal quality control, feedback and monitoring mechanisms set up to see how people are actually using those.”

By 2025, India’s health supplement and nutraceutical sector is poised to be a \$10 billion industry. Looking at the growth prospects, the country apex food regulator is gearing itself to strengthen the regulatory ecosystem through cross-border collaboration and learning from international best practices.

Analysing the health and nutraceutical value, growth and potential, Khandelwal stated, “It is a growing industry. People are becoming more aware of the role of several therapeutic benefits of many ingredients and have started consuming those.”

“Thus, this industry has seen a huge rise in the volume of demand for health and nutrition supplements. Being a public health nutritionist, I would however add a word of caution. These fractions also are quite potent and may furnish an undesirable outcome if consumed erratically and without physician’s advice,” she added.

“People should bear in mind that in general, a balanced diet provides all nutrients in moderation and because of its natural form and better bioavailability, benefits the body much better than synthetically-formulated concoctions,” Khandelwal said.

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, which were to come into force from January 2018, allowed the manufacturing and sale of the above category of foods in the form of tablets, capsules and syrups, and must fulfill quality requirements and standards as specified in the Indian Pharmacopoeia.

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 FSSAI.

Recently, the regulator also prohibited the use of 14 ingredients under nutraceutical regulations due to the lack of scientific data for safe usage.