



**Mr. Ashish Bahuguna**  
Former Chairperson, FSSAI

“Industry should partner with Government and sections of the civil society to address the apprehensions and issues that nutraceuticals and dietary supplements sector is facing”.



**Mr. Simon Pettman**  
Executive Director, IADSA

“The Resource centre is a first of its kind initiative, we hope it would become a key structure globally and a reference point in India and outside the country”.



**Professor David Richardson**  
Visiting faculty  
(University of Reading UK)

“Claims should be truthful and meaningful for consumers to reflect the strength of the evidence and biological plausibility of the food and health relationship.”



**Mr. Pawan Agarwal**

CEO, Food Safety and Standards Authority of India (FSSAI)

## Foreword

The Resource Centre for Health Supplements & Nutraceuticals (ReCHaN) was established by CII in partnership with the International Alliance of Dietary/Food Supplement Associations, (IADSA) with the aim to foster an innovation friendly environment and a culture of food safety and quality among manufacturers, businesses, consumers and regulators. This Resource Centre in collaboration with Food Safety and Standards Authority of India (FSSAI) has been working towards achieving global excellence in a science-based ecosystem for the sector.

In its endeavour to catalyse global excellence in capacity building, over the last one year, ReCHaN has initiated a series of scientific dialogues in the area of Claims Substantiation and Usage of Vitamins and Minerals with global experts. Additionally, Guidance Documents on “Compliance” and “Good Manufacturing Practices” have been developed specific to the sector. Training Packages comprising the Training Manual & Training Presentation on Food Safety Management Systems (FSMS) for Regulators, Designated Officers, Food Safety Officers and Food Business Operators have been developed and Trainings were conducted across India along with FSSAI. These training packages will also be utilised under FSSAI’s Food Safety Training and Certification (FoSTaC) initiative.

ReCHaN has also initiated a consumer awareness program on Health Supplements and Nutraceuticals “Know Your Supplements”

I am hopeful that this partnership with ReCHaN will go a long way on further strengthening the science based ecosystem for this sector.



# ReCHaN

Resource Centre for Health supplements and Nutraceuticals

## Vision

Drive science base food safety inputs on health supplements and nutraceuticals to foster a culture of food safety and quality among manufacturers, businesses, consumers, and other stakeholders.

## Instituting FSSAI-ReCHaN collaboration



A MoU was signed between Food Safety and Standards Authority of India and ReCHaN (Resource Centre for Health Supplements and Nutraceuticals) on 23<sup>rd</sup> March 2018 to enable a science-based ecosystem for the sector.

## Key Focus Areas

The key focus area of ReCHaN includes capacity building, supporting best practices and contributing to the nutrition policies in India.

### Capacity building:

Help consumer benefit from safe and quality products and facilitate handholding for Food Businesses.

### Supporting best practices:

Science-based approach for developing effective regulatory standards and Food Safety & Management Systems.

### Comprehensive policies through measuring impact:

- Establishing an outline of the priority areas to potentially include in policy.
- Mapping of the potential role of Nutraceuticals & Health Supplements in contributing to nutrition and health policy goals in India.

## India: An emerging global leader in the Supplement Sector

The global supplement and nutraceutical market have grown over the past decade at a rate few would have predicted. Consumers across the world are increasingly looking to take more control of their health in a bid to keep healthy, active and productive. Projections by Nutrition Business Journal see this growth continuing at 6% globally.

This has been accompanied by the development of specific regulation for supplements to help ensure the quality, consistency and safety of products entering the market. Historically, in many countries' supplements were seen as a side-line of food or pharmaceutical categories, not requiring specific legislation themselves. No longer. Due to their specific requirements, health supplements require their own legislation, and this has been recognised by most governments across the world.

For many years the United States has been the dominant country in the supplement market. Clear, specific legislation developed in 1994 provided the US industry with a clear basis for investment in the category, whether in science, manufacturing or international trade. The EU's Food Supplement Directive of 2002 did likewise in Europe.

The implementation last year in India of the Health Supplements and Nutraceutical Standards should be seen as an equivalent point of global significance. By establishing a clear regulatory framework, the starting gun was fired for increased investment in the category and for India taking on a growing leadership role in this area. And while many elements of this legislation can be seen in regulation elsewhere in the world, some elements are both innovative and exciting. For example, the list of botanical ingredients, many of which come from a traditional Ayurveda background, not only creates a solid basis for the development of this category in India but is a key step towards Indian botanicals becoming increasingly significant worldwide.

Through our work in ReCHaN, IADSA has been delighted to have the opportunity to play our part in efforts to make the new regulatory framework in India a success. We believe that the work carried out over the past 18 months is not just important in India but is ground-breaking in the world. In no other country does such a Resource Centre exist that can help generate tools to help support both government and industry. We also know this is the beginning of the journey and we look forward to working with the FSSAI and our partners in India over many years to continue to make this a success and help project Indian innovation on the global scene.

### Mr. Simon Pettman

Executive Director  
International Alliance of Dietary/Food Supplement Associations (IADSA)

## Key Initiatives

### Scientific Interface

### Building capacity through Technical Workshops

### Stakeholders Forums

### Consumer awareness

### Guidance Document and FosTaC toolkit

## I. Promoting Scientific interface to share global best practices

### Claims Substantiation

ReCHaN organised its first interactive session on 10th April 2018 on Claims Substantiation with members of Scientific Panel of Food or Health Supplements, Nutraceuticals, Foods for Special Dietary uses, Foods for Special Medical Purpose, Functional Food and Novel Food of FSSAI and Experts from Standards, Regulation and FSMS Division.

International Experts, **Dr Andrew Shao, International Expert (Regulatory and Policy)** and **Dr David Richardson, Visiting Professor, University of Reading** covered basic principles of claims, Codex framework for health claims, basic scientific substantiation principles and resources, application of evidence-based medicine approach to health claims for nutrients and bioactives.

### Vitamins & Minerals in Health Supplements & Nutraceuticals

The Second scientific interface of ReCHaN was held on "Regulatory approaches for establishment of maximum levels for Vitamins & Minerals in Health Supplements & Nutraceuticals" at FSSAI on 25th July 2018.

International Experts like **Dr B.H. Lim, International Expert** and **Mr. Basil Mathioudakis, International Expert, Food Legislation** made presentation on key global principles for food safety and setting maximum amounts of vitamins and minerals in health supplements.

Dr B.H. Lim mentioned that ASEAN member states have made significant progress on establishing a new regulatory framework for health supplements in the region.



“He highlighted that these are based on risk analysis in the vast majority of jurisdictions across the world and stressed the importance of these principles being applied coherently across the board.”

### Mr. Basil Mathioudakis

International Expert  
Food Legislation

## II. Building capacity through Technical Workshops based on Guidance document on Good manufacturing practices and compliance document

### Technical workshops were conducted for:

- Food Business Operators
- Designated Officers
- Food Safety Officers

A 2-day workshop for Food Business Operators on "Regulations & Food Safety Management Systems for Health Supplements & Nutraceuticals" was conducted in New Delhi, Ahmedabad, Mumbai and Chennai. **There were more than 180 participants from 91 companies** from various core areas involved in manufacturing, regulatory, production etc.

The Capacity Building Program for training of FBOs was organised with an objective to develop understanding on:

Regulatory  
Compliance

Labelling  
Requirements  
& Information  
on Labels

Basics of  
Food Safety for  
strengthening  
Health

Supplements  
& Nutraceuticals  
Industry

Good  
Manufacturing  
and Hygiene  
Practices

Risk  
Assessment

# Technical Workshops on Regulations & Food Safety Management Systems for Health Supplements & Nutraceuticals



■ Delhi ■ Ahmedabad ■ Mumbai ■ Chennai

### III. Stakeholders Forums to create a platform for exchange of scientific dialogues among stakeholders with global experts

#### Scientific Framework for Substantiation of Health Claims

1<sup>st</sup> Stakeholder Forum focused on “Scientific Framework for Substantiation of Health Claims” on 1<sup>st</sup> May 2018. Professor David Richardson, visiting faculty - University of Reading (UK) emphasised during the presentation that the Claims should be truthful and meaningful for consumers to reflect the strength of the evidence and biological plausibility of the food and health relationship. The session provided a platform for all relevant stakeholders including regulatory agencies, Research Institutes, Industries, Academia, scientific community to strengthen the sector.



Mr. Pawan Agarwal, Chief Executive Officer, Food Safety and Standards Authority of India addressing the Forum.

#### Key Insights

Scientific substantiation for Claims should consider:

- Generally accepted scientific evidence
- The totality of the available scientific data and weight of evidence, and recognize the strengths and limitations of various sources of evidence

The creation of a harmonised, scientifically robust, transparent and proportionate framework for the assessment of health claims is a critical regulatory and policy issue.

#### Regulatory approaches to the establishment of maximum levels for Vitamins & Minerals in Health Supplements & Nutraceuticals

The 2<sup>nd</sup> Stakeholder Forum on “Regulatory approaches to the establishment of maximum levels for Vitamins & Minerals in Health Supplements & Nutraceuticals” was organised at FSSAI. Scientists and experts from ICMR and National Institute Nutrition (NIN) participated in the forum. International experts included Basil Mathioudakis, key architect of global regulations in health supplements and nutraceuticals, particularly in the EU and Dr B.H. Lim, a leading expert in this area from the ASEAN region. The focus of the session was 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.



Mr. Pawan Agarwal, Chief Executive Officer, Food Safety and Standards Authority of India addressing the Stakeholders Forum.

#### Key Insights

Setting of maximum amounts of vitamins and minerals in health supplements are based on risk analysis in the vast majority of jurisdictions across the world.

The RDA being a reference point, cannot be used as the basis for setting maximum levels



## IV. Sensitizing consumers on myths and facts



Posters developed on Health Supplements and Nutraceuticals

A consumer awareness programme was initiated on “**Know your Supplements**” during the Eat Right Mela, New Delhi. A Guidance Kit on consumer awareness was developed and distributed during the Eat Right campaign which includes information leaflet on Health Supplements & Nutraceuticals like what are Health Supplements & Nutraceuticals, basic information about identification and labelling of Supplements, difference between medicines and health supplements, how to check authenticity of supplements.

To support this initiative, an animated video was also developed educating consumers on the basic aspects of the sector in both Hindi and English language. The kit was intended to create a sensitization on the myths and facts about Health Supplements & Nutraceuticals and their impact on overall health. The initiative was appreciated by all the stakeholders.

## V. Aligning Guidance documents as FosTaC toolkit for formalising the dissemination channel

With an objective for providing the foundation level requirements/practices or manufacturing within the Indian food system based on the core elements of Indian standards & international best practices, achievable for all, ReCHaN has disseminated two Guidance documents and a toolkit across the country through practical Training modules for Food Business Operators and Regulatory officers.

### Guidance documents:

Health Supplements and Nutraceuticals

1. Guidance Document on **Good Manufacturing Practices:** The GMP guidance document is aimed at enabling small and medium enterprises to implement food safety practices during the manufacturing processes.
2. **Compliance Guidance:** The Compliance Guidance Document provides key regulatory requirements and understanding of Global practices.



Release of ReCHaN Guidance Documents on Compliance & Good Manufacturing Practices by Mr. Ashish Bahuguna, Chairperson, FSSAI.

### Toolkit

A Tool kit was developed comprising of FSMS FosTaC training manual and Training presentation for Food Safety Supervisors Special course on Health Supplements, to train food business operators across the country.



Release of FSMS training manual for Food Safety Supervisors Special Course

# In News

Menu Nutraceuticals World MAGAZINE NEWS EXCLUSIVES NUTRACEUTICALS MARKET

**BREAKING NEWS**  
**ReCHaN Issues Guidance for Supplement Companies in India**  
 As new regulations come into effect the Resource Centre for Health Supplements and Nutraceuticals published two new guides.



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NEWS / BUSINESS NEWS / INDIA BUSINESS NEWS / WORKING TO STRENGTHEN REGULATORY SYSTEM FOR HEALTH SUPPLEMENT

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**Working to strengthen regulatory system for health supplement, nutraceutical sector: FSSAI**

PTI | Jul 29, 2018, 16:12 IST

New Delhi, Jul 29 () With the country's health supplement and nutraceutical industry poised to grow to USD 10 billion by 2025, food regulator FSSAI has said it is gearing to strengthen the regulatory ecosystem through cross-border collaboration and learning from global best practices.

**hindustantimes**

**FSSAI to notify claim regulations on health supplements and nutraceuticals**

According to country's apex food regulator, Food Safety and Standards Authority of India, health supplements and nutraceutical industry is a rapidly growing market in India, poised to be worth -10 billion by 2025



In 2014, the regulator began the process of regulating in the sale of these products by way of rules under eight categories of foods. (Shreerajiv Photo)

The government is in the process of notifying claim regulations on health supplements and nutraceuticals – a mix of nutritional and pharmaceutical products – keeping in mind global practices.

According to country's apex food regulator, Food Safety and Standards Authority of India, health supplements and nutraceutical industry is a rapidly growing market in India, poised to be worth -10 billion by 2025.

**NutFOODS Spectrum**

ReCHaN publishes guidelines to help health supplement industry to adapt to new regulations

1 August 2018



Two new guides have been published in India to help the country's health supplement industry adapt to recently implemented regulatory requirements. The documents have been produced by ReCHaN – the Resource Centre for Health Supplements and Nutraceuticals – which was established in July 2017 through a partnership between the Confederation of Indian Industry (CII) and the International Alliance of Dietary/Food Supplement Associations (IADSA).

The publication is significant because they are seen as a key stepping stone towards a harmonised regulatory ecosystem across India's supplement industry and will assist in the

**INDIA**

**"An Integrated Health Supplement Resource Centre"**

**NEW DAY FOR HEALTH SUPPLEMENTS IN INDIA**

In December 2018, the Health Supplements and Nutraceuticals Regulations were published in India and became effective this year. The need for these had been established in the original Food Safety Act of 2006, but it was to take 10 years for them to become a reality.

While these rules are still in the process of being notified, they will contribute to meet further expansion of the country's health supplement market. The need for these had been established in the original Food Safety Act of 2006, but it was to take 10 years for them to become a reality.

Indian food regulator is developing guidelines for the Health Safety Standards Authority of India (FSSAI) and there are FSSAI officers in every state that play a critical role in implementation. In addition, there are health supplement market or regulatory officers in every state who play a critical role in implementation. Ensuring compliance with the health supplement regulations is a key challenge for manufacturers and distributors. Ensuring regulatory compliance is a key challenge for manufacturers and distributors.

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Tuesday, January 8, 2019

**NUTRITION**

**FSSAI facilitates CII & IADSA to set up nutraceutical resource centre**

Thursday, 15 August, 2018, 08:00 AM [IST]

Shraddha Joshi, Mumbai

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 effectively to help

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**Nutraceuticals Market to Cross \$319.6 Billion Revenue by 2023 Witnessing a CAGR of 6.70%, Predicts Market Research Future**

Nutraceuticals Market Research Report Insights and Industry Analysis by Type (Functional Beverages, Functional Foods and Dietary Supplements), Ingredients (Vitamins and Minerals), Distribution Channel (Store Based and Non-Store Based) and Region, Competitive Market Share, Trends, and Forecast, 2017-2023

August 28, 2018 08:45 ET | Source: Market Research Future

Pune, India, Aug. 28, 2018 (GLOBE NEWSWIRE) -- A study conducted by Market Research Future (MRFR) reveals that the nutraceuticals market will expand at a compound annual growth rate of 6.70% from 2017 to 2023. Towards the end of the review period, the global nutraceuticals market is anticipated to surpass a valuation of USD 319.6 billion. Global consumption of nutraceuticals has continued to grow over the past few years, and consumer preference is influencing the growth of the nutraceuticals market. The increased level of awareness among consumers about nutritional and health benefits of nutraceuticals is also partly responsible for recent rise in their popularity. Moreover, nutraceuticals are now finding application in a broader range of processed food items.

Nutraceuticals are viewed to have high food value and thereby added to different types of food products increasing their nutritional offerings. From functional food to dietary supplements and health drinks, nutraceuticals are being added to a range of commercially manufactured items. Adding extra nutritional value to a food item often improves its marketability. Nutraceuticals are added to food products in the form of powder and liquid. Nutraceutical pills and capsules are also available for direct consumption purposes.

**Key Players and Competition Tracking**

Abbott Nutrition Manufacturing Inc. (U.S.), Cargill Inc. (U.S.), BASF SE (Germany), GlaxoSmithKline Plc (UK), Archer-Daniels-Midland Company (U.S.), DSM Nutritional Products, Inc. (The Netherlands), E. I. du Pont de Nemours and Company (U.S.) are among the leading companies operating in the global nutraceutical market.

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**Latest Industry News**

- Food Safety and Standards Authority of India (FSSAI) India's apex organization for food safety has reportedly assisted Confederation of Indian Industry (CII) to set up a Resource Centre for Health Supplements and Nutraceuticals (ReCHaN) in collaboration with the International Alliance of Dietary/Food Supplement Associations (IADSA) in India. The move will be primarily focused on meeting global quality standards for vitamins and mineral ingredients in health supplements marketed in the country.
- Canada based medicinal cannabis expert 1010 Nutraceuticals Inc. has reportedly joined forces with the University of Sherbrooke to conduct a special study on medicinal and industrial applications of cannabis.



## A Joint Initiative

The International Alliance of Dietary / Food Supplements Associations (IADSA) and Confederation of Indian Industries (CII) have established a collaborative initiative under the Resource Centre on Health Supplements and Nutraceuticals (ReCHaN)

### IADSA

International Alliance of Dietary/  
Food Supplement Associations

IADSA brings together associations from 6 continents in the food supplement sector to coordinate discussions in Codex Alimentarius and support governments and the private sector on appropriate and effective regulation and policy.

As a leading international expert association, IADSA aims to build science based interactive platforms for policymaking and harmonized approaches to legislation.



Confederation of Indian Industry

CII (Confederation of Indian Industries) a premier business association of industries serves as a reference point for Indian industry and the international business community.

CII has set up a Food and Agriculture Centre of Excellence (FACE) to contribute to the ongoing policy dialogue related to agriculture and food-security concerns.

CII through the Food and Agriculture Centre of Excellence (CII-FACE) provides an integrated approach of action-oriented programs and capacity building addressing issues from the farm gate to consumers.

It works in partnership with government, FSSAI, Industry and other stakeholders.

## OUR PARTNERS



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