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# Health Supplements and **Nutraceuticals**

**Emerging High Growth Sector in India** 





Ministry of Food Processing Industries

Government of India





# Health Supplements and Nutraceuticals

**Emerging High Growth Sector in India** 



Published for the Ministry of Food Processing Industries (MoFPI) by Ernst & Young LLP (EY) and Confederation of Indian Industry (CII)

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# Contents

1	Glossary of terms	7
2	Executive summary	8
3	India's health supplements and nutraceuticals market- An overview	11
4	Demand drivers for health supplements and nutraceuticals in India	19
5	Supply drivers for health supplements and nutraceuticals in India	27
6	India's regulatory framework- A quick overview	33
7	Outlook	43





#### Foreword

Food processing is considered as one of the fastest growing industries in India. The growth of the industry is supported by the availability of a large raw material production base. India is the largest producer of milk, bananas, mangoes, guavas, papaya, ginger, okra, second largest producer of wheat, rice, fruits, vegetables, tea, sugarcane and cashew nut and the third largest producer of cereals, coconut, lettuce, chicory, nutmeg, mace, cardamom and pepper globally.

Given the natural supply advantage and a population of 1.3 billion people (that spend a high proportion of their disposable income on food), there is a potential to nurture mutually beneficial relationships with global food processing, food retail and related supply chain organizations who could realize significant business growth opportunities in India, through new technologies, innovations and other methods of value additions.

Further, India's geographical location gives it a unique advantage when it comes to exports, having convenient connectivity to Europe, Middle East & Africa from the western coast, and Japan, Singapore, Thailand, Malaysia, Korea, Australia & New Zealand from the eastern coast.

Food processing is a priority sector for the Indian Government, as well as one of the focus sectors in the Make in India initiative. Further, the availability of affordable credit and other fiscal incentives has also led to India being considered as one of the most favourable markets.

In light of the above factors, and with total consumption of the food and beverage segment in India expected to increase from US\$ 369 billion to US\$1.142 trillion by 2025, output of the food processing sector (at market prices) is expected to increase to US\$ 958 billion for the same period. These estimates clearly evidence the vast market opportunity offered by the Indian food processing, food retail, transport, logistics and related infrastructure sectors to players in the food processing value chain.

We trust that this report would be a useful guide for international as well as domestic food processing, food retail and related supply chain companies that are looking to invest or expand their presence in India.



#### **Preface**

India, the fastest growing economy in the world, houses over 1.25 billion people and, as per the UN, is forecasted to become the most populated country by 2024<sup>1</sup>. With the growing population, India, a developing country, faces challenges to ensure that there is not only adequate food supply but it also meets the required nutritional levels.

While undernourishment in India has been reducing (from 17% in 2008 to 15% in 2016<sup>2</sup>), malnutrition and dietary risks associated with diseases remain prevalent globally, including in India. Further, rapid urbanization, changing lifestyles and lack of awareness with respect to the required nutrition intake have led to a greater need for nutraceuticals and health supplements in the Indian market.

Quality healthcare is the foundation of any prosperous nation. As per Global Nutrition Report - 2016, annual Gross Domestic Product losses from low weight, poor child growth and micro nutrient deficiencies average 11% in Asia and Africa – greater than the loss experienced during the 2008-2010 financial crisis.

Nutrition care, which forms an integral part of preventive healthcare, is undergoing a transformation in India. Today, given the change in the dietary habits, increase in awareness on account of a rapidly growing middle class population, and changes in consumer preferences when it comes to health, food alone is unable to fully service the nutritional needs of the body. Thus, complementing it with health supplements and nutraceuticals has become critical.

"Health supplements and nutraceuticals– Emerging high growth sector in India", is a study assessing the current health supplements and nutraceuticals market in India and the key growth drivers of this market in India. It is hoped that investors would explore, invest and partner in the Indian health supplements and nutraceuticals market which truly stands at an inflexion point, poised to grow.

<sup>1</sup> World Population Prospects: The 2017 Revision by the Department of Economic and Social affairs of the United Nations 2 Global Hunger Index 2016- http://ghi.ifpri.org/countries/IND/ - accessed on 4 October 2017





## 1 Glossary of terms

Abbreviations	Full form	
APAC	Asia Pacific	
CAGR	Compounded Annual Growth Rate	
DIPP	Department of Industrial Policy & Promotion	
DMMA	Drug Marketing and Manufacturing Association	
FDI	Foreign Direct Investment	
FEMA	Foreign Exchange Management Act, 1999	
FIFP	Foreign Investment Facilitation Portal	
FIPB	Foreign Investment Promotion Board	
FSS Act	Food for Safety Standards Act, 2006	
FSSAI	Food Safety and Standards Authority of India	
FY	Financial Year	
GDP	Gross Domestic Product	
GOI	Government of India	
INR	Indian Rupees	
mcg/d	micrograms per day	
mg/d	Milligrams per day	
NSSO	National Sample Survey Office	
R&D	Research and Development	
RDA	Recommended Dietary Allowance	
UN	United Nations	





## 2 Executive summary

The term "health supplements and nutraceuticals" is evolving and the nomenclature for "health supplements and nutraceuticals" varies across countries. For e.g., Canada naming them natural and non-prescription health products<sup>1</sup>, the USA calling them dietary supplements<sup>2</sup> and Japan naming them "foods with health claims<sup>3</sup>". This has resulted in different countries including different categories for defining "health supplements and nutraceuticals".

In India, FSSAI regulates the health supplements and nutraceuticals through Food and Safety Standards Act, 2006 and the regulations framed thereunder. India has 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 in the Gazette of India on 23 December 2016. The regulations covers eight categories of food and is defined based on their contents and use. Further, FSSAI, vide its directions issued on 19 May 2017, has released the Food Safety and Standards (Fortification of Foods) Regulations, 2017. This regulation prescribes standards for fortification of oil, salt, milk, vanaspati, atta, maida and rice and has been made operationalized by FSSAI w.e.f 17 April 2017. While different countries legislations including India have different definitions of health supplements and nutraceuticals, globally, the term can be divided into 3 segments i.e., functional/ fortified food, functional beverages and dietary supplements.

Ideally, intake of nutrients through food should be sufficient to prevent curative measures such as pharmaceuticals and traditional medicines being used in large quantities. However, in the absence of requisite nutrition through food, an external intervention in the form of health supplements and nutraceuticals has become imperative in India.

There are four key demand drivers which has resulted in need for health supplements and nutraceuticals:

- 1. Malnutrition status in India and micro-nutrient deficiency
- 2. Affordability: Increasing costs of hospitalization are driving consumers towards health supplements and nutraceuticals
- 3. Affluence of working population with changing lifestyles and dietary patterns and increase in disposable income
- 4. Awareness: Increasing concern about nutrition, awareness and access to information have led to an increase in use of health supplements and nutraceuticals

<sup>&</sup>lt;sup>1</sup> Website of Government of Canada – Link - <a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation.html</a>

<sup>&</sup>lt;sup>2</sup> Website of U.S. Food and Drug administration – Link - <a href="https://www.fda.gov/food/dietarysupplements/">https://www.fda.gov/food/dietarysupplements/</a> -

<sup>&</sup>lt;sup>3</sup> Website of Burdock group - <a href="http://burdockgroup.com/international-regulations-on-dietary-supplements-challenges-and-opportunities/">http://burdockgroup.com/international-regulations-on-dietary-supplements-challenges-and-opportunities/</a>

The above links were accessed on 4 October 2017



Along with the demand drivers, the supply side drivers have also ensured that India becomes a critical market for the global players in this sector. The supply drivers are:

- Strong macro-economic indicators
- Strategic location
- India transforming into a global manufacturing hub
- Low labor cost
- Strong technical and skilled capabilities
- Availability of ingredients
- Accessibility of products through e-commerce
- India is a global hub for companies to set up R&D facilities
- India's vision and commitment to world class infrastructure.

While the global nutraceuticals market is expected to grow at a CAGR of 6.5%<sup>4</sup>, the DMMA estimates that the Indian nutraceuticals market is likely to grow by 16% CAGR over the next five years<sup>5</sup>. All three segments of the Indian health supplements and nutraceuticals market i.e. fortified/functional packaged food, dietary supplements and functional beverages are registering a double digit growth<sup>6</sup>. The Indian consumer base is only set to increase and there are tremendous opportunities for the existing as well as new entrants to exploit the Indian market. The Indian government is taking and implementing several path breaking reforms to make India a better place for doing business. The strong and favorable demand, supply drivers along with India's regulatory framework builds a very strong case for doing business in India. In all probability, there could not be a better timing to enter this market in India than now.



<sup>&</sup>lt;sup>4</sup> Global Nutraceuticals Market - 2015-2019 - technavio

<sup>&</sup>lt;sup>5</sup> https://timesofindia.indiatimes.com/city/ahmedabad/nutraceuticals-market-in-india-to-double-by-

<sup>2020/</sup>articleshow/57103090.cms

<sup>6</sup> Sector Capsule: Fortified/functional packaged food in India, Vitamins and Dietary Supplements in India, Energy Drinks in India, and sports drinks in India by Euromonitor International 2017





### 3 India's health supplements and nutraceuticals market- An overview

The term "heath supplements and nutraceuticals" is evolving and the nomenclature varies across countries. For e.g., Canada naming them natural and non-prescription health products, the USA calling them dietary supplements and Japan naming them "foods for special health use". This has resulted in different countries including different categories for defining "health supplements and nutraceuticals".

A snapshot of how different countries use the nomenclature "health supplements and nutraceuticals":

#### Canada

Known as: Natural and non-prescription health products

The definition covers naturally occurring substances that are used to restore or maintain good health. They are often made from plants, but can also be made from animals, microorganisms and marine sources.

These include vitamins, minerals, herbal remedies, homeopathic medicines, traditional medicines, probiotics, and other products like amino acids. It also includes non-prescription and disinfectant drugs in addition to natural health products

#### The USA

Known as: Dietary supplements

The definition covers products containing vitamins, minerals, herbs, amino acids, and enzymes.

New ingredients (post 1994) to be added into dietary supplements need to go through the New Dietary Ingredient Notification ('NDIN') process.

#### European Union

Known as: Food supplements

The definition covers the following products:

Concentrated sources of nutrients; or

Other substances with a nutritional or physiological effect

#### Russia

Known as: Biologically active supplements

The definition covers products containing:

 $\label{thm:micro} \mbox{ Mineral substances, micro and macro elements; some amino}$ 

acids; some mono and disacchardies; food fibres;

microorganisms present in human body, vitamins, subject to upper limits



Known as: Foods with Health Claims

The products are divided into two categories:

- 1) Food with nutrient function claims; and
- 2) Food for specified health uses

#### Australia

Known as: Complementary medicines

The definition covers herbal, vitamin, mineral, and nutritional supplements



Website of Government of Canada – Link - https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/regulation.html Website of U.S. Food and Drug administration – Link - https://www.fda.gov/food/dietarysupplements/ -

Website of European Food Safety Authority - Link - https://www.naz.gov/nood/nutera/supplements

Website of Burdock group - http://burdockgroup.com/international-regulations-on-dietary-supplements-challenges-and-opportunities/

Website of Natural product insider - Link - https://www.naturalproductsinsider.com/articles/2016/10/overview-of-the-russian-supplement-market.aspx

The above links were accessed on 4 October 2017 Health supplements and nutraceuticals- Emerging high growth sector in India



In India, the FSSAI regulates the nutraceuticals through FSS Act and the regulations framed thereunder. As per the press note on Nutraceutical Regulations issued by the FSSAI, India has 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 in the Gazette of India on 23 December 2016. The said regulations covers 8 categories of food. The definition includes the use of each categories and the content of the food.



Snapshot of definitions of eight categories of food as used in the said regulations:

Category Definition	<ol> <li>Foods for special dietary uses or</li> <li>Nutraceuticals or</li> <li>Health supplements</li> </ol>	4) Foods for special medical purpose	5) Foods with added probiotic ingredients	6) Food with added prebiotic ingredients	7) Novel Food	8) Specialty food containing plant or botanical ingredients
Contents	Specially processed or formulated foods that contain one or more of the following ingredients:  " Plants or botanicals " Mineral or vitamins " Substances from animal origin " Dietary substance	Specially processed or formulated	Food with live micro- organisms beneficial to human health	Food that contains added prebiotic ingredients which are nonviable food components	Does not contain any of the foods and ingredients prohibited	Food which is shown to be containing plant or botanical ingredients
Use	<ul> <li>To satisfy particular dietary requirements</li> <li>Not to cure or mitigate any specific disease, disorder or condition as may be permitted by the regulations</li> <li>Does not include drugs, ayurvedic, siddha and unani drugs as defined under Drugs and Cosmetics Act, 1940</li> <li>Does not include narcotic drugs or a psychotropic substance as defined in Narcotic drugs and Psychotropic Substance Act</li> </ul>	For particular dietary use  Dietary management under medical advice  Exclusive or partial feeding or specified persons  Other medically determined nutrient requirements	Confers one or more specified or demonstrated health benefits in human beings	Confer health benefits to the consumer by modulation of gut micro biota	Food for which standards are not specified but is not unsafe	Having history of safe usage



Further, FSSAI has released the Food Safety and Standards (Fortification of Foods) Regulations, 2017 which are operational w.e.f 17 April 2017. The said Regulations define fortified food as food that has undergone the process of fortification. The regulations prescribe standards for fortification of oil, salt, milk, vanaspati, atta, maida and rice and defines fortification to mean deliberately increasing the content of micronutrients (i.e. vitamins, minerals or trace elements that are vital to development, disease prevention and wellbeing of human beings) in a food so as to:

- improve the nutritional quality of food; and
- to provide public health with minimal risk to health

For this purpose, oil, salt, milk, atta, maida and rice are specifically defined under a separate Regulation issued by FSSAI i.e. Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011

While different countries legislations including India have different definitions of health supplements and nutraceuticals, globally, the term can be divided into 3 segments.

- Foods for special dietary uses
- 2) Nutraceuticals
- 3) Health Supplements
- 4) Food for special medical

8 categories of food defined under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 and fortified foods defined under Food Safety and Standards (Fortification of Foods) Regulations, 2017

- 5) Food with added probiotic ingredients
- Food with added prebiotic ingredients
- 7) Novel food
- 8) Specialty food containing plant or botanicals
- 9) Fortified food

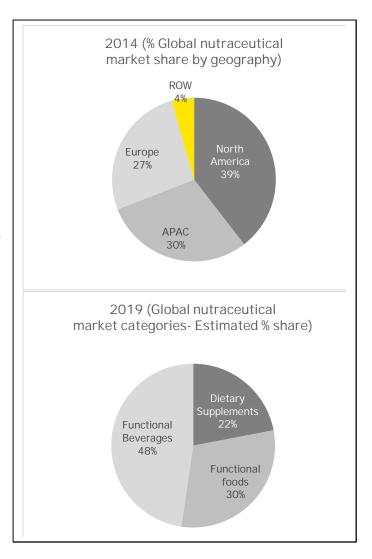
Globally, for convenience and in common parlance, various stakeholders categorize 'health supplements and nutraceuticals' into 3 segments as under:

#### **Segments**

- 1) Functional/ fortified Foods
  e.g., nutrition fortified foods like fortified flour, fortified oil, fortified malted powder, breakfast cereals, probiotic foods like yogurt, etc.
- 2) Functional beverages e.g., sports and energy drinks, fortified juices, glucose powder, etc.
- 3) Dietary supplements e.g., vitamin supplements, minerals supplements, macronutrients, antioxidants, tonics, herbal extracts like Chyawanprash, non-herbal extracts like cod liver oil, etc.



- The global nutraceuticals market was estimated at US\$ 169.32 billion in 2014 and is growing at a CAGR of 6.5%<sup>7</sup>
- The global nutraceuticals market was dominated by North America in 2014 followed by APAC and Europe. However, due to the increasingly health conscious population, and an increase in the disposable income of consumers in the emerging economies, the APAC region is expected to witness significant growth<sup>9</sup>
- Amongst the segments, functional beverages would have approximately 48% of the share by 20199
- India's nutraceuticals market is expected to double in size to US\$ 4 billion by 2020 on account of the strong demand for dietary supplements from the upper and middle class<sup>8</sup>
- The DMMA projects around 16% CAGR until 2020<sup>10</sup>



Source: Global Nutraceuticals Market - 2015-2019 - technavio

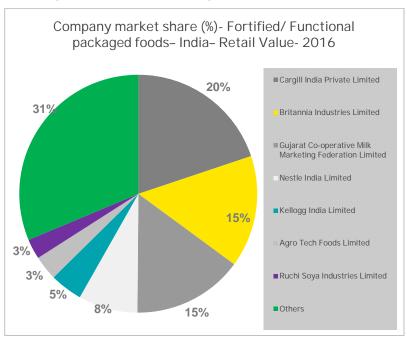
<sup>&</sup>lt;sup>7</sup> Global Nutraceuticals Market - 2015-2019 - technavio

<sup>&</sup>lt;sup>8</sup> http://www.thehindubusinessline.com/news/indias-nutraceutical-industry-set-to-double-to-4-bn-by-2020-dmma/article9537453.ece



#### Market share in each segment along with key industry players

- 1. Fortified/ functional packaged food in India9
- With 11% current value growth in this segment from 2015, the market size of this segment is approximately INR 132.6b in 2016
- Probiotic drinking yogurt sees strongest current value growth of 28% in 2016
- Cargill is the leader in this segment based on the market share



Today, Britannia is a leading food company in India with over Rs. 8500 crores in revenue, delivering products in over 5 categories through 4.2 million retail outlets to more than half the Indian population. Our core emphasis across portfolios is on healthy, fresh and delicious food and we are the First Zero Transfat Company in India. 50% of our product portfolio is enriched with micro-nutrients.

Source -Website of Britannia - Link http://britannia.co.in/about-us/overview - accessed on 4 October 2017

Company Name	Few products	
Kellogg	Kellogg's Cornflakes, Oats	
Abbot	PediaSure	
Agro Tech Foods	Sundrop	
Britannia Industries	Cheese, Nutrichoice biscuits, Tiger Glucose Biscuits	
Cargill	Gemini, Sweekar	
GlaxoSmithKline Consumer Healthcare	Horlicks	
Nestlé	ActiPlus Dahi, CEREGROW, MILO, Baby & Me	
Ruchi Soya Industries	Nutrela	
ITC	Sunfeast	
National Dairy Development Board	Dhara	
Gujarat Co-operative Milk Marketing Federation	Amul	
Mother Dairy Fruit & Vegetable	Nutrifit	
Yakult	Probiotics	
Pepsi Co	Quaker Oats	
Patanjali	Choco Flakes, Corn Flakes, Oats, PowerVita	
Heinz	Glucon D, Glucon C	
Baggrys	Cornflakes, Oats	
Mondelez	Bournvita Malt Drink	
Mead Johnson	Enfagrow	
General Mills	Natures Valley Granola Bars	

FMCG continues to be an exciting arena. With predicted good monsoons, growth for the FMCG sector is expected to come from rural markets. This along with rising per capita income of Indians will accelerate the FMCG industry growth. At present, GSK Consumer Healthcare has 64% market share in HFD category, significantly ahead of competition. Two of our products Horlicks and Boost are among the top 3 brands in HFD segment with Horlicks continuing to be the market leader. This clearly demonstrates that customers have faith and trust in Company's brands within the competitive market dynamics. Focus on innovation, consumer insight and R&D resulted in key product launches maintaining GSK at the top.

Chairman, GlaxoSmithKline Consumer Healthcare Ltd at its 58<sup>th</sup> AGM for FY 2016-17

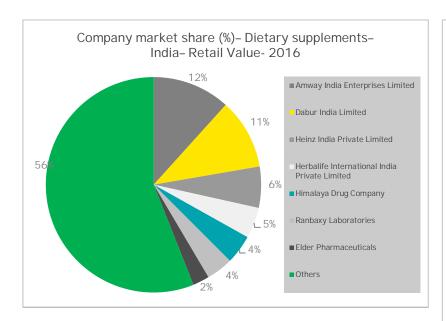
16

Health supplements and nutraceuticals- Emerging high growth sector in India

<sup>9</sup> Sector Capsule: Fortified/ functional packaged food in India by Euromonitor international dated 21 June 2017



- 2. Dietary supplements in India<sup>10</sup>
- Vitamins and dietary supplements registered a growth of 13% in 2016
- Fish oils/ omega fatty acids recorded fastest growth of 16% in 2016
- " Amway is the leader in this segment based on the market share



"India is a key market for Amway. It is one of our top 10 markets and we believe there is great potential for growth here. In order to support that growth, we must invest and are doing so in several ways. We have invested Rs. 1000 crore in India, including Rs. 600 crore in a state-of-the-art manufacturing facility in Tamil Nadu, to produce world-class products for the Indian market. This plant represents the largest investment of our global \$335 million manufacturing and R&D expansion, approximately 30% of the total spend. Our investments don't end there. We will continue to invest on multiple fronts" - Global President, Amway

Source - Amway Company's web-site - Link http://www.amway.in/store/amway/en/INR/staticpages/amwayImageLink/16\_Feb\_2016\_2

Accessed on 4 October 2017

Company Name	Few products	
Amway	Nutrilite - range of products	
Aventis Pharma	Seacod Capsules	
Dabur	Dabur Glucose - D	
Danone	Protinex	
Novartis	Calcium Sandoz	
Herbalife International	Herbal life Protein Powder	
Himalaya Drug Company	Himalaya Pure Herbs	

"At present, our nutrition business is about 80 per cent of our overall business in India and the rest from the dairy segment. Going forward this proportion will continue. We plan to double our nutrition business between now and 2020 and so should our dairy business," Danone India Managing Director

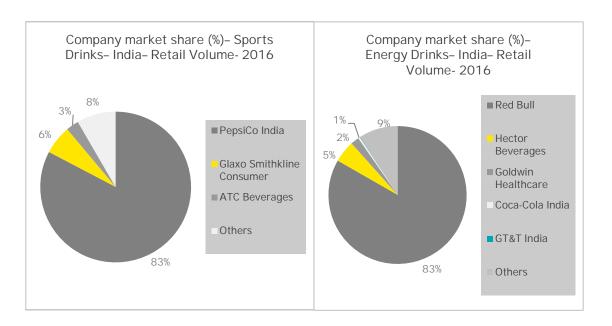
Source - Economic Times - Link http://economictimes.indiatimes.com/industry/cons -products/food/danone-to-double-india-business-by-2020-lines-up-10-newproducts/articleshow/56596098.cms

Accessed on 4 October 2017

<sup>10</sup> Sector Capsule: Vitamins and Dietary Supplements in India by Euromonitor International dated 19 September 2016



- 3. Functional beverages in India<sup>11</sup>
- Functional drinks market grew by 15.6% in 2014. By 2019, functional drinks market is expected to have a value of US\$ 432.6 million (an increase of 69% since 2014)
- Energy drinks is the largest segment accounting for 63% of the total market value
- Red Bull is the leading player with a 83% value share in energy drinks
- PepsiCo with Gatorade is the leading player in sports drinks with 83% value share in 2016



Company Name	Few products	
Red Bull	Red Bull Energy Drink, Red Bull Sugar Free	
Coco-Cola	Minute maid juices	
PepsiCo	Gatorade, Fruit juices such as Tropicana and Tropicana 100%	
GlaxoSmithKline	Lucozade	
Goldwin Healthcare	Cloud 9 Energy Drink	
Hector Beverages	paperboat thandai, chilli guava	
Patanjali	Aloevera Fibre Juice	
Dabur	Fruit juices and Real and Real Activ Brands	

"India is just hitting the tipping points as the per capita consumption of juices is increasing. Tropicana is one of our fastest growing brands and nearly 70% of the brand's growth this year has come on the back of innovations.

There is clearly a big opportunity to drive penetration of juices at the right price points in smaller towns and rural regions and we will focus on this in coming years. We are looking at launching tasty and functional juices that will address nutrient deficiencies with fortification"

Vice-President - Nutrition Category, PepsiCo India

Source - PepsiCo India website - Link - http://www.pepsicoindia.co.in/Download/print-media/PepsiCos%20affordable%20fruit%20juice%20products%20boost%20growth%20.pdf - accessed on 4 October 2017

18

Health supplements and nutraceuticals- Emerging high growth sector in India

<sup>&</sup>lt;sup>11</sup> India - Functional Drinks - Executive summary (Aug 2015) by MarketLine; Sector Capsule: Sports Drinks and Energy Drinks in India by Euromonitor International dated 23 March 2017 and 7 April 2017 respectively



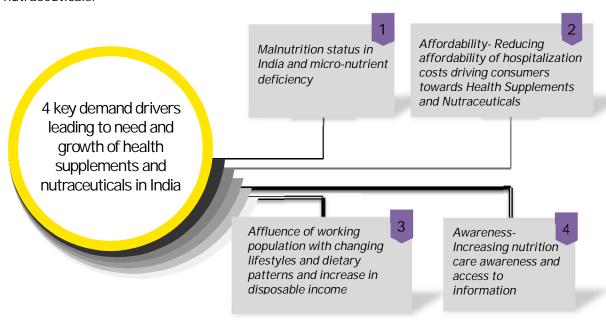


# 4 Demand drivers for health supplements and nutraceuticals in India

India is expected to become the most populated country in the world by 2024<sup>12</sup>. India is undergoing significant demographic transition as population between the age 15 to 59 years has increased from 57% in 2001 to 60% in 2011 and is expected to be approximately 63% by 2021<sup>13</sup>. To reap benefits from the demographic dividend, it is important that India has a healthy population. India's Economic Survey 2015-16 devotes an entire chapter dealing with malnutrition, opening with the following statement which elicits India's commitment to overcome the global problem:

"Imagine the government were an investor trying to maximize India's long-run economic growth. Given fiscal and capacity constraints, where would it invest? This chapter shows that relatively low-cost maternal and early-life health and nutrition programs offer very high returns on investment because: (i) The most rapid period of physical and cognitive development occurs in the womb, so in utero and early-life health conditions significantly affect outcomes in adulthood; and (ii) The success of subsequent interventions—schooling and training—are influenced by early-life development. Despite recent progress, India generally under-performs on maternal and child health indicators: pre-pregnancy weights and weight-gain during pregnancy are both low. India is already halfway through its demographic dividend, and taking full advantage requires a healthy and educated population. Making these investments in maternal nutrition and sanitation, and enhancing their effectiveness by working to change social norms, can help India exploit this window."

There are four key demand drivers in India which has resulted in need for health supplements and nutraceuticals:



#### 1. Nutritional status of the population of India

The GOI along with industry players have taken several steps to improve country's nutritional status and also create an awareness amongst the masses about the importance of nutritional food intake for e.g., around 17% of the population was undernourished in 2009 which has reduced to 15% in 2016. This scenario results in enormous opportunities for the health supplement and nutraceutical companies who are playing a critical role in gradually, improving the nutritional status of India.

<sup>&</sup>lt;sup>12</sup> World Population Prospects: The 2017 Revision by the Department of Economic and Social affairs of the United Nations

<sup>13</sup> Youth in India - 2017 - Central Statistics Office - GOI

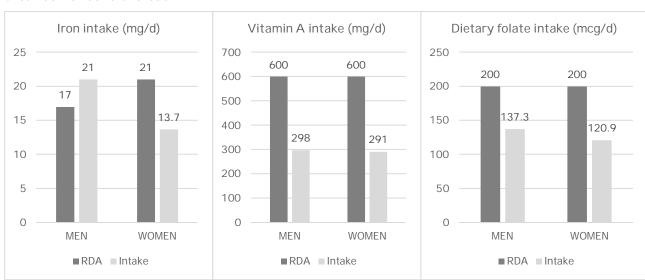


#### Malnutrition

Forms of malnutrition	Indicators	Number/ %	
Adult overweight	<ul> <li>▶ Women (age 15-49 are overweight)</li> <li>▶ Men (age 15-49) are overweight</li> </ul>	20% 19%	
Adult with low BMI	<ul> <li>Women (age 15-49) having low BMI - (BMI&lt;18.5kg/m²)##</li> <li>Men (age 15-49) having low BMI - (BMI&lt;18.5kg/m²))¹</li> <li>Adolescent girls aged 15-18 years have BMI below normal²</li> </ul>		22.9% 20.2% 45%
Non- communicable diseases	<ul> <li>Diabetes type 2 patients <sup>3</sup>,</li> <li>Heart disease patient in India<sup>5</sup>,</li> <li>Deaths in India due to non-communicable diseases <sup>4</sup></li> </ul>		50 million 30 million 60%
Children under 5 – Stunted, Wasted	<ul> <li>Children under five are stunted<sup>1#</sup></li> <li>Children under five are wasted #</li> <li>Are underweight <sup>1#</sup></li> </ul>		38.4% 21% 35.7%
Source:  1. National Family Health Survey of India – 2015-16; 2. RSoC, 2014  3. India-spotlight-index-2016; 4.Global Status Report on NCD – 2014;  5. Press Information Bureau – GOI – September 2015		# Below -2 standard deviations, ##Excludes pregnant women an months	based on the WHO standard d women with a birth in the preceding 2

#### Micronutrient deficiency<sup>14</sup>

The micronutrient rich foods are being consumed in low proportions in India. Further these micronutrients deficiencies are not restricted to rural areas but also in urban areas for e.g., in Tier 1 cities like Mumbai and Delhi the vitamin deficiency covers almost 70% of the adults. In fact, in Delhi, over 90% of pregnant women, children and elders have vitamin D deficiency. Therefore, significant micronutrient deficiencies exist in urban as well as rural areas.



The iron intake by pregnant women is less than 50% of the RDA.

In case of women the intake of iron is very less which has led to over 50% of women in India suffering from anemia.

Vitamin A intake by men and women is less than 50% of the RDA. More than 50% of preschool children suffer from Vitamin A deficiency.

Vitamin A deficiency leads to night blindness, increased susceptibility to infections, impaired immune response.

Dietary folate intake by men and women is approximately 50% of the RDA (for pregnant women the same is less than 50% of the intake).

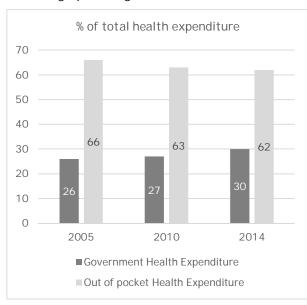
Low folic acid intake results in increased cardiovascular diseases and colorectal cancer. Further, pregnant women have increased risk of having a baby with neural tube defect.

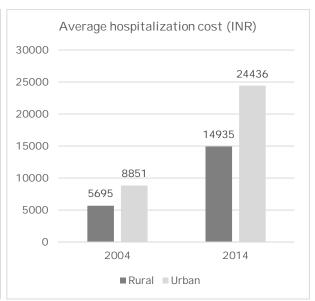
<sup>&</sup>lt;sup>14</sup> Need for Fortification report as downloaded from FSSAI website http://ffrc.fssai.gov.in/fortification/data/NeedforFoodfortification\_final.pdf - Accessed on 4 October 2017



#### 2. Affordability

While increasing nutritional deficiency is leading to increase in health issues and diseases in India, the hospitalization costs of family also increases. Out of pocket health expenditure constitutes around 62% of the healthcare expenditure in India as compared to 11% in the US, 10% in the UK, 25% in Brazil and 32% in China<sup>15</sup>. Further, average cost of in-patient treatment both in rural and urban India has increased at a double digit pace of growth in the last one decade.





Source: WHO - Global Health Expenditure Database - Link http://apps.who.int/nha/database/ViewData/Indicators/en - Accessed on 4 October 2017 NSSO 2004 and 2014

Out-of-pocket expenditure is any direct outlay by households, including gratuities and in-kind payments, to health practitioners and suppliers of pharmaceuticals, therapeutic appliances, and other goods and services whose primary intent is to contribute to the restoration or enhancement of the health status of individuals or population groups. It is a part of private health expenditure.

Therefore, there is now a mindset shift driving Indian consumers towards taking preventive health measures and availing of health and wellness related services in order to lead healthier lifestyle and prevent spiraling sick care costs. While the average hospitalization cost may be low in India as compared to other countries, however given the low per capita income in India, for majority of the population of India the hospitalization cost is high. This in turn is also leading the consumers to undertake physical activity through fitness centers such as gym and slimming centers [growing at CAGR of 18%], sports activities, undertaking regular health check-ups at diagnostic centers, consulting a dietician, increasing own awareness through doctors consultation or through internet, use of health tracking equipment and wearable like Fitbit, Garmin, Misfit, etc. With the shift in mindset towards preventive healthcare due to high cost of hospitalization, the consumer base in India consuming the health supplements and nutraceuticals is increasing.

Health supplements and nutraceuticals- Emerging high growth sector in India

<sup>&</sup>lt;sup>15</sup> WHO - Global Health Expenditure Database - Link http://apps.who.int/nha/database/ViewData/Indicators/en - Accessed on 4 October 2017



#### Awareness

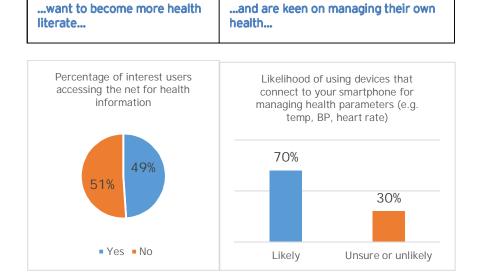
While there is a clear need for the health supplements and nutraceuticals in India, the demand for these products is getting a significant boost due to increasing awareness about the products and their benefits which if consumed with the regular diet may be an important step to preventive healthcare.

The Indian consumer's awareness is increasing due to strong and effective initiatives by the GOI and industry players.

- The Indian regulator FSSAI is running a pilot program to train domestic workers to make them aware about practices that need to be adopted for safe, hygienic and nutritious food at home
- FSSAI launched an initiative on "safe and nutritious food at home" tomorrow to create awareness about healthy food items and ways to test common adulterants at home
- FSSAI is banking on resident welfare associations and other local bodies to disseminate information on safe and nutritious food. The regulator plans to reach out to 400 million households in the country under its drive
- Cargill India is working together with the government in Madhya Pradesh to improve food security and nutrition in the state, which has one of India's highest concentrations of hunger and malnutrition
- Britannia Industries through its Britannia Nutrition Foundation distributed iron fortified biscuits through government to 43,000 children in India
- Nestle during the year 2016-17 conducted sessions on nutrition counselling for consumers in modern trade outlets, government offices and corporate offices. The objective was to help the participants to make tastier and healthier food choices for a healthy lifestyle

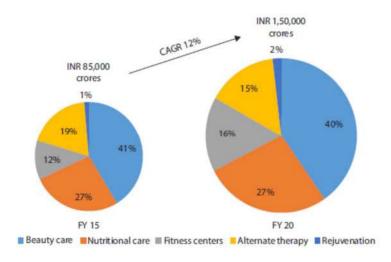
Interestingly, the increase in awareness of health supplements and nutraceuticals products along with their uses is also growing by accessing the information through internet.

As per the EY survey and its report "Re-Engineering Indian Health Care", almost 50% of the respondents accessed internet for health awareness. Further, 70% of the respondents were likely to use devices that connect to smartphones for managing heath parameters.



Awareness on health supplements and nutraceuticals products are also increasing due to increase in the number of nutritional care professionals/ service providers i.e. dietician and nutritionalist. The nutritional care segment is growing at a CAGR of 12% and has a 27% market share in the wellness industry consisting of beauty care, fitness centers, alternate therapy and rejuvenation.

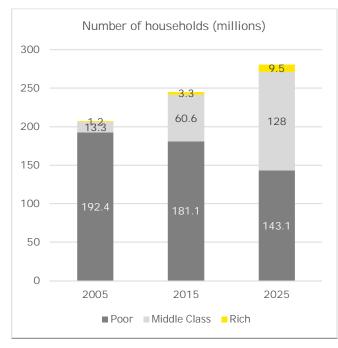




Source: EY Report on Value Added Services - Wellness and Preventive Healthcare - December 2016

#### 4. Affluence

- Increase in working population: The population of India between age 15 to 59 years has increased from 57% in 2001 to 60% in 2011 and is expected to be approximately 63% by 2021<sup>16</sup>. This has resulted in increase in working population of India resulting in large base of informed consumers in India who have disposable income to spend on a healthier life.
- Increase in middle class: India is expected to have middle class larger than the US or EU. Therefore India's consumption will be dominated by young middle class.
- Growing disposable income: With change in lifestyles has resulted in dietary changes with increase in consumption of food and beverages with high salt and sugar and with low micronutrient contents. This has resulted in nutritional deficiencies leading to the need for health supplements and nutraceuticals products. If India continues its recent growth trend, average household incomes will triple over the next two decades and it will become the world's fifth largest consumer economy by the year 2025<sup>17</sup>.



Source: McKinsey Global Institute

 $http://www.mckinsey.com/assets/dotcom/mgi/interactives/india\_consumer\_market/India\_Interactive1.swf~Accessed on 4~October~2017~accessed on 4~October~2017~$ 

<sup>&</sup>lt;sup>16</sup>Youth in India- 2017- Central Statistics Office- GOI

<sup>&</sup>lt;sup>17</sup>The Bird of Gold, McKinsey Report



- Wellness: The enormous opportunities in India's health supplements and nutraceuticals market is not only due to the state of inadequate intake of nutrients but also due to the fact that there is a growing fitness need which has led to the rise in slimming centers and gyms. In its current form, wellness industry includes five major sub segments: the beauty care, nutrition care, fitness centers, alternative treatments, therapy and rejuvenation. During FY15, the Indian wellness industry was estimated at INR 850b. Bolstered by increasing awareness, push from the insurance industry and government, it is expected to grow at a CAGR of 12% for the next 5 years. From its current size this industry can achieve INR 1,500b by FY 20<sup>18</sup>. The growth of the wellness center has also contributed to the demand in the health supplements and nutraceuticals products in India especially in the urban areas.
- Sports: India's growing interest in sports, not only in cricket but also in other sports such as badminton, athletics, football, tennis, wrestling, kabbaddi, swimming, etc., has resulted in increase in consumption of health supplements and nutraceuticals especially sports drinks.



Source: EY report - Sports in India - July 2017

To take advantage of the demand drivers, the Indian health supplements and nutraceuticals players are continuously innovating by launching new products to meet the specific nutrients requirements and taste preference of the consumers of all age levels and thereby increasing their market share. For e.g.:

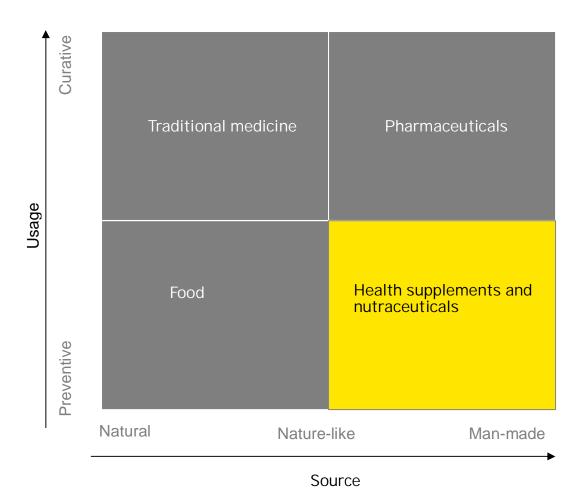
- As per the annual report 2016-17 of Nestle– The year 2016 witnessed a spate of innovations and renovations by Nestle with the launch of more than 30 new products and variants. Nestlé's focus in the milk product category has been on the value-added segment. E.g., products introduced NESTLÉ a+ GREKYO, NESCAFÉ RTDs (Ready-To-Drink), renovated its entire CERELAC range fortifying it with Iron
- PepsiCo in 2016 had widened its portfolio with the introduction of range of fruit juices drinks in flavors such as litchi and apple
- Mother dairy, which sells around 10,950 lakh liter fortified milk per annum (highest in India), is already experimenting with different value adds in the milk category and already launched the 'low calorie' doi (yogurt) and 'low calorie' ice cream (chocolate)
- , ITC launched in 2016, Aashirvaad Sugar Release Controller Atta
- GSK launched Horlicks Growth + in May 2016 as clinically proven formula for catch up growth for children between 3-9 years

<sup>&</sup>lt;sup>18</sup> EY Report- Value Added Services- Wellness and Preventive Healthcare- 2016



Ideally, intake of nutrients through food would have been sufficient to prevent curative measures such as pharmaceuticals and traditional medicines to a large extent.

However, in absence of requisite nutrition through food, an external intervention in the form of health supplements and nutraceuticals has become imperative.

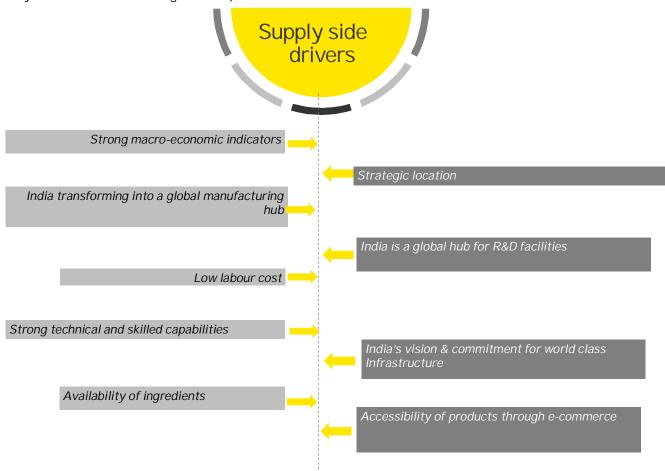






# 5 Supply drivers for health supplements and nutraceuticals in India

The demand drivers are strong and so are the supply side drivers which have ensured that India becomes a very critical market for the global players in this sector.



"India has three things to its credit – Democracy, Demography and Demand. And I am sure, you will not find all of them together at any other destination. India offers you the potential of low cost manufacturing. India has low cost and high quality manpower ... We are trying to further harness these strengths through better management and good governance." –

Prime Minister of India - Narendra Modi



#### Strong macro-economic indicators

India is the fastest growing economy in the world. According to the World Bank's Global Economic Prospects, June 2017, India is projected to grow at a strong 7.2% this year and at 7.5% and 7.7% in the next two years. The mid-year survey of the economy, released recently by the Chief Economic Adviser, reiterates optimism in the economy stemming largely from the launch of the Goods and Services Tax, besides macroeconomic and financial market stability. Signs of the Indian economy's progress is evident. It had the highest improvement in the World Economic Forum's Global Competitiveness Index moving from 55<sup>th</sup> rank in 2015-16 to 40th rank in 2017-18. India has retained its position as the top FDI destination globally, receiving FDI of US\$ 60.08 billion in FY 2016-17.

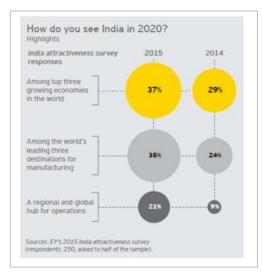
#### Strategic location

India's 7500 km coastline has 12 major ports, over 200 minor ports and is strategically located on world trade routes. Some of the emerging and established markets such as Middle-East and South East Asian

countries are closely located. India is surrounded by the Bay of Bengal, the Arabian Sea and the Indian Ocean, an arrangement that facilitates most its overseas trade in all main directions<sup>19</sup>.

#### India transforming into a global manufacturing hub

India's manufacturing sector has evolved through several phases- from the initial industrialization and the license raj to liberalization and the current phase of global competitiveness. Today, Indian manufacturing companies in several sectors are targeting global markets and are becoming formidable global competitors. Many are already amongst the most competitive in their sectors. The country is expected to rank amongst the world's top three growth economies and amongst the top three manufacturing destinations by 2020. Several heath supplements and nutraceuticals players have large scale manufacturing facilities in India. Largest number of US FDA



approved plants located outside the US are in India<sup>20</sup>, which is a testament to the high quality global standards in manufacturing practices.

Segments	Key players in India
Functional/ fortified foods	Cargill, Britannia, Kelloggs, Nestle, PepsiCo, Heinz, Baggrys, GlaxoSmithKline Consumer Healthcare, Patanjali, Mother Dairy, General Mills, Ruchi Soya
Functional beverages	Redbull, Coca-cola, PepsiCo, Goldwin Healthcare, GlaxoSmithKline, Hector Beverages
Dietary supplements	Amway, Dabur, Herbalife International, Danone, Novartis

<sup>&</sup>lt;sup>19</sup> Make in India

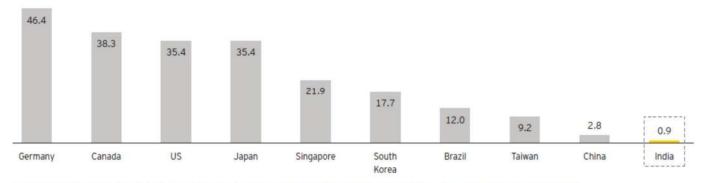
<sup>&</sup>lt;sup>20</sup> https://www.ibef.org/industry/pharmaceutical-india.aspx



#### Low labor cost

Favorable demographic dividends for the next 2-3 decades resulting in sustained availability of quality workforce. India's most lucrative feature for foreign investors is the abundance of labor. In addition, labor costs in the country remain far below those of advanced and other developing economies. India is the most competitive in terms of both average monthly wages and minimum monthly wages, compared to its Asian peers. This gives it an advantage in low-value-added, labor intensive manufacturing.

Global wage comparison (cost of labor, US\$ per hour)



Sources: EY-SIAM report: Make in India - Leveraging human capital, National Skill Development Corporation - Auto Sector Report and EY analysis

#### Knowledge

India has strong technical and engineering capabilities backed by excellent scientific and technical institutes. India is expected to be the largest supplier of university graduates in the world by 2020<sup>21</sup>. India has 712 university level institutions, 36,671 colleges along with 11,445 standalone institutions. India has demonstrable capability to reach near 100% literacy level by 2025<sup>22</sup>.

#### Availability of ingredients

India became the third largest global market for active pharmaceutical ingredients in 2016, with a 7.2% increase in market share<sup>23</sup>. Further, India is leading in terms of milk production in the world, 2nd largest producer of fruits and vegetables, 2nd in rice, wheat and production of other cereals resulting in availability of the ingredients<sup>24</sup>. India also has rich repository of various plants or botanical ingredients, for e.g., neem, makhana, tea extract, etc. With a large agricultural resource base, abundant livestock and cost competitiveness, India is fast emerging as a sourcing hub of processed foods and beverages.

<sup>&</sup>lt;sup>21</sup> Morgan Stanley Research

<sup>&</sup>lt;sup>22</sup> Educational Statistics at a Glance 2014, Ministry of Human Resources Development

<sup>&</sup>lt;sup>23</sup> Make in India

<sup>&</sup>lt;sup>24</sup> MOFPI



India is a global hub for R&D facilities

The Indian players are continuously innovating by launching new products to meet the specific nutrients requirements and taste preference of the consumers of all age levels and thereby increasing their market share.

To cater to the local dietary habits many companies have set up world class R&D facilities in India, for e.g., Nestle, Danone Nutricia Research, Heinz, Abbott, GSK, Herballife had in March 2017 launched its R&D lab in India in partnership with Syngene, etc.

The Contract Research and Manufacturing Services industry is estimated to reach US\$ 18 billion in 2018<sup>25</sup>. The market has more than 1000 players.



Research and Development (R&D) in India is part of NESTLÉ S.A.'s global R&D network and supports all markets worldwide with new product development and manufacturing excellence for Noodles. It is also a Centre of expertise for local Indian cuisine within the NESTLÉ R&D network and offers assistance to Culinary, Confectionery, Nutrition and Dairy products in the South Asia Region (SAR).

Better nutrition in the region is a perpetual challenge. Its meaning changes with the stage of development, the degree of social awareness, and scientific advancement. The new NESTLÉ R&D facility in India will help develop great tasting food solutions that are relevant for consumers in the South Asia Region, creating products that take the promise of taste and health to a broader economic and social section than ever before. It will also strengthen NESTLÉ's position as the leader in Nutrition, Health and Wellness in the emerging markets.

Nestle India website - Link https://www.nestle.in/aboutus/researchanddevelopment

Accessed on 4 October 2017

India's vision and commitment to world class Infrastructure<sup>26</sup>

Maintaining a high growth trajectory requires state-of-the art infrastructure and the Government of India has articulated the infrastructure vision for India through some significant plans being announced. From advanced airports to magnificent metro and bullet train projects, from futuristic freeways to stellar solar projects: all bespeak India's aspiration to create a world-class infrastructure. The budget allocation for infrastructure upgradation has been increasing and in the Budget 2017, the GOI has allocated a record budget allocation of approximately INR 4 trillion to improve infrastructure. Some of the recent key infrastructure initiatives are highlighted as under:

- Delhi-Mumbai Industrial Corridor With a planned investment of US\$100 billion in the Delhi-Mumbai Industrial Corridor and 3,360 km of Dedicated Freight Corridors under construction, India's Infrastructure projects are unstoppable
- Ports The project includes modernization of ports, setting up of coastal economic zones, new major ports and fish harbors. At a capital outlay of US\$ 10 billion, 415 projects have been identified under the Sagarmala Initiative
- Smart Cities An ambitious "Smart Cities" initiative envisions 100 smart cities 2022
- Urban landscape: Under this initiative, with a capital outlay of US\$ 7.69 billion, the objective is to recast the urban landscape and make urban centers more livable and inclusive
- Roads & Highways: Development of about 7000 km of national highways under Bharatmala Pariyojana initiatives with a capital outlay of US\$ 12 billion
- GOI has approved a new Central Sector Scheme Pradhan Mantri Kisan SAMPADA Yojana which is implemented by MoFPI. It is a comprehensive package which will result in creation of modern infrastructure with efficient supply chain management from farm gate to retail outlet

<sup>&</sup>lt;sup>25</sup> ibef

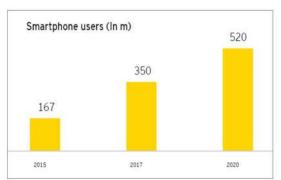
<sup>&</sup>lt;sup>26</sup> Make in India

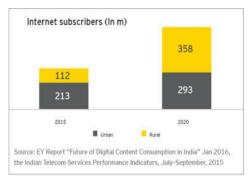


- Mega Food Parks: For providing a mechanism to link agricultural production to the market by bringing together farmers, processors and retailers so as to ensure maximizing value addition, minimizing wastage, increasing farmers' income and creating employment opportunities particularly in rural sector. Mega food park typically consist of supply chain infrastructure including collection centers, primary processing centers, central processing centers, cold chain and around 30-35 fully developed plots for entrepreneurs to set up food processing units. 42 MFP are being setup with an investment of US\$ 2.38 billion. So far 9 Mega Food Parks are already functional.
- Cold chain projects: 134 cold chain projects are being setup to develop supply chain infrastructure. As on 22 July 2016, out of 134 Cold Chain Projects 87 projects have been completed.

#### Accessibility of products through e-commerce

In India, the e-commerce revolution has become a reality. With billions in daily sales and staggering discounts, online shopping is making headlines and attracting both consumers and retailers. In contrast to a decade ago, when the prevalent opinion was that too many challenges like low Internet penetration, limited payment infrastructure (i.e., restricted use of credit cards), consumer psychology and behavior, logistics and warehousing issues would prevent online shopping's emergence. Online retail, or "e-tail," has grown at a breakneck speed of 50%–55% CAGR over the five years period from 2009 to 2013 to reach around US\$ 4.5 billion in 2014 and is expected to see similar growth going forward<sup>27</sup>. The sector is expected to see similar growth going forward driven by favorable demographics. The online health supplements and nutraceuticals market in India also gets a boost as 60% of India's population is between 15 to 60 years of age who would have higher access to internet. Given that health supplements and nutraceuticals require tremendous amount of awareness and content, smartphones will play a large role in growing this category online.





For e.g., Healthkart.com a venture of the Bright Lifecare formed in March 2011 had within a span of less than 4 years transacted with over 500,000 customers and is expecting to grow at 2-3 times on a year on year basis<sup>28</sup>.

Zota Healtcare, in June 2016, launched Nutravedic, an e-commerce portal through which the company clocks 30 orders per day with an average ticket size of Rs. 500. It plans to have 10 lakh customers and clock around 500 orders a day<sup>29</sup>.

BigBasket processes over 50,000 orders per day and has crossed 5 million customer milestone in  $2017^{30}$ . Further, as per the press release issued by Godrej, its nature's basket, India's pioneering and premium food destination is targeting to achieving 3x growth by FY 2020 and targeting a revenue of INR 10 billion by  $2020^{31}$ .

 $<sup>^{27}</sup>$  EY Report - Now that India shops online, how do you turn growth into profit?

<sup>&</sup>lt;sup>28</sup>http://www.nuffoodsspectrum.in/inner\_view\_single\_details\_print.php?page=3&content\_type=panel&vrtcl\_panel\_nm=&ele\_id=NOR\_54afa19e0f8292.63349998

<sup>&</sup>lt;sup>29</sup>https://yourstory.com/2016/11/zota-healthcare-nutravedic/

<sup>&</sup>lt;sup>30</sup>http://www.business-standard.com/article/companies/bigbasket-crosses-5-mn-customer-milestone-117051901055 1.html

<sup>&</sup>lt;sup>31</sup>Press release dated 14 December 2016 issued by Godrej Nature's Basket





## 6 India's regulatory framework– A quick overview

#### Foreign exchange laws in India

Indian exchange-control regulations with respect to cross-border and foreign currency transactions are governed under FEMA (along with the regulations and guidelines prescribed thereunder). FDI in India is permitted either under the Automatic Route or the Approval Route, as explained below:

#### Foreign Exchange laws in India

Automatic route: No prior approval is required to be sought by the investor

The only requirement would be to intimate the RBI (through an Authorized Dealer Bank), within 30 days of the inflow of funds and issuance of shares respectively

Approval route: Prior approval of the Government is required to be obtained by the investor. Up to 2017, the FIPB was entrusted with the authority to provide such approval.

In 2017, in order to further enable ease of doing business in India, the Finance Minister,

#### Manufacturing sector

Subject to the provisions of FDI policy, 100% FDI is permitted for the manufacturing sector under the automatic route. A manufacturer is also permitted to sell its products manufactured in India through wholesale, retail or e-commerce activities.

For pharmaceuticals,

Greenfield project- 100% is allowed under automatic route.

Brownfield projects approval is required for beyond 74%. Department of Pharmaceuticals is the competent authority for grant of approval.

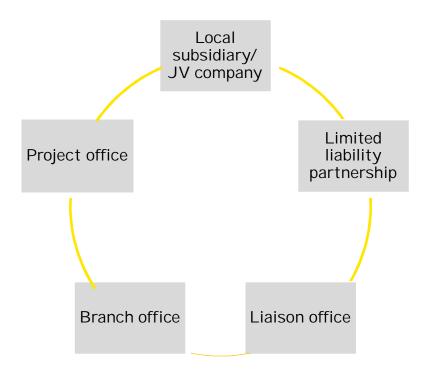
inter alia, announced phasing out of the FIPB, as a part of his Union Budget speech. Pursuant to the same, in June 2017, the DIPP issued a notification whereby the FIPB was replaced by the online FIFP for processing of FDI proposals that require Government approval. FIFP is an online single point interface of the GOI for investors to facilitate FDI





## Forms of business presence in India

While incorporation of a company (private company, listed public company, joint venture company, etc.) is one of the most common form of establishing presence in India, other common forms of business presence include limited liability partnerships, project offices, branch offices and liaison offices.



- Local Subsidiary/ JV Company: Subject to FDI regulations; funding can be via debt/equity/internal accruals; no restrictions on repatriation of dividend
- Limited Liability Partnership: Liability of partners restricted to their agreed contribution; foreign investment permitted in sectors where 100% FDI allowed under the automatic route (with no sector-specific conditions for receiving FDI)
- Liaison office: Such offices are initially opened in India by certain foreign corporates, to act as a communication channel, spread awareness of their products and explore new opportunities
- Branch office: Such offices are opened in India to undertake specific business activities (as may be permitted by RBI), such as trading, consultancy services, research work, technical support services, etc.
- Project office: A foreign corporation having secured a contract from an Indian company may set-up a project office provided that the same is funded by inward remittances from abroad



## Regulations framed by FSSAI

Up to 2006, various laws existed to handle food related issues, such as Prevention of Food Adulteration Act, 1954; Fruit Products Order, 1955; Meat Food Products Order, 1973; Vegetable Oil Products (Control) Order, 1947; Edible Oils Packaging (Regulation) Order 1988; Milk and Milk Products Order, 1992. However, in 2006, such laws were consolidated to form the Food Safety & Standards Act, 2006 (FSS Act).

The FSS Act has been formulated with an aim to establish a single reference point for all matters relating to regulation and supervision of food safety and standards.

To this effect, the FSS Act has established an independent statutory authority– The Food Safety and Standards Authority of India (FSSAI), for laying down scientific standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.

The administrative authority for FSSAI is the Ministry of Health and Welfare, Government of India which administers it through the central government appointment of the Chairperson and Chief Executive Officer (CEO) along with a 22 member team. The members comprise a cross section of various sectors from agriculture, commerce, consumer affairs, food processing, health, legislative affairs, farmers, scientists & technologists, small scale industries and retail organizations. The FSSAI, along with the State Food Safety Authorities are presently responsible for enforcing various provisions of the FSS Act.

FSSAI is also the National Codex Contact Point of India (NCCP), and functions as an interface between Codex Alimentarius Commission (CAC) and India as a member country. The FSSAI has adopted some of the Codex Alimentarius international food standards which contribute to the safety, quality and fairness of this international food trade.

Some of the key functions of the FSSAI under the FSS Act include:

- Framing of regulations to lay down food standards and guidelines
- Laying down procedure and guidelines for accreditation of laboratories for food testing
- Provide scientific advice and technical support to the government in areas which have a direct or indirect bearing of food safety and nutrition
- Collation of data regarding food consumption, contamination, identification of emerging risks, introduction of a rapid alert system, etc.
- " Disseminating information and promoting awareness about food safety and nutrition in India
- Provide training programs to food businesses
- " Contribute to the development of international technical standards for food, sanitary and phytosanitary standards

The FSSAI had notified Food Safety and Standards (food or health supplements, nutraceuticals, foods for special dietary uses, foods for special medical purpose, functional foods and novel food) Regulations, 2016 on 23 December 2016. The said regulations contain:

- Detailed definitions of each category of food based on their contents and use
- Schedules detailing various ingredients which can be used for making the 8 categories of food as given in the regulations
- It also contains provisions relating to quality requirements, labelling and packaging of products, making of claims by a food business operator relating to its product nutrition and health benefits

FSSAI has given a one year window to comply with the regulations by the Food Business Operator by making the said regulation effective from 1 January 2018.

FSSAI has also released the Food Safety and Standards (Fortification of Foods) Regulations, 2017 which are operational, w.e.f 17 April 2017 and contains:



- Schedule detailing the micronutrient content for fortification along with the minimum level of micronutrient
- " Obligations relating to quality, packaging and labeling of the products.

FSSAI approval process for non-specified food and food ingredients

FSSAI notified the Food Safety and Standards (approval of non-specified food and food ingredients) Regulations, 2017.

"Non-specified food" means any food other than proprietary food or food ingredients, including additives, processing aids and enzymes for which standards have not been specified in any regulation made under the FSS Act.

All the food business operators have to now submit applications for prior approval of non-specified food and food ingredients.

Further information on FSSAI can be found at http://www.fssai.gov.in

## Regulations for plant quarantine and animal quarantine

### Plant quarantine

The regulatory measures for plant quarantine are operative through the Destructive Insects & Pests Act.

The purpose and intent of this Act is to prevent the introduction of any insect, fungus or other pest, which is or may be destructive to crops.

Further, the import of agricultural commodities is presently regulated through the Plant Quarantine (Regulation of Import into India) Order, 2003 and the provisions under New Policy on Seed Development, 1988.

Further information can be found at http://www.ppqs.gov.in

### Animal quarantine

GOI had initiated a central sector scheme namely "Animal Quarantine & Certification Services" to prevent the ingress of any exotic and dangerous diseases into India through importation of livestock and livestock products which is governed by the provisions of Livestock and Livestock Products Importation Act.

Further information can be found at http://www.aqcsindia.gov.in



## Key mercantile laws in India

India has a robust set of economic and commercial laws that have been enacted, and which enable domestic and multinational companies to smoothly operate their business in the country. Some of the key mercantile laws in India are as under.

## Indian Contract Act, 1872

This is the Indian law that encapsulates provisions governing the entire life of a contract from its formation to its implementation and conclusion.

### Companies Act, 2013

It is the main legislation that provides for the law relating to the functioning of the corporates in India.

Under the Companies Act, the National Company Law Appellate Tribunal ('NCLAT') was constituted w.e.f. 1 June 2016. NCLAT is a quasi-judicial body adjudicating matters related to corporate law.

The NCLAT has 11 branches, 2 at New Delhi (one being the principal bench) and one each at Ahmedabad, Allahabad, Bengaluru, Chandigarh, Chennai, Guwahati, Hyderabad, Kolkata and Mumbai

## LLP Act, 2008

The Limited Liability Partnership Act, 2008 was enacted by the Parliament of India to introduce and legally sanction the concept of LLP in India.

## The Competition Act, 2002

The Competition Act provides for the establishment of the Competition Commission of India (CCI) and Competition Appellate Tribunals to hear and settle appeals against the orders of the CCI and also to adjudicate on the claims of compensation that may arise from the findings of the CCI or the orders of the Appellate Tribunal

## Protection of IP Rights

Copyrights: India's copyright law, laid down in the Indian Copyright Act, 1957 and amended by the Copyright (Amendment) Act, 2012, fully reflects the Berne Convention on copyrights to which India is a party.

Trademarks: The Trade Marks Act, 1999 (TM Act) and the Trade Marks Rules, 2002 governs the law relating to trademarks in India.

Patents: The Indian Patents Act, 1970 provides for the grant, revocation, registration, license, assignment and infringement of patents in India. Any infringement of a patent is punishable under the terms of this Act.



### Labor Laws

Industrial Disputes Act, 1947: It is the main legislation in India that provides for the investigation and settlement of industrial disputes.

Trade Unions Act, 1926: It provides for the registration of trade unions of employers and workers and is administered by state governments. It confers legal and corporate status on registered trade unions.

Factories Act: 1948: It is the principal legislation that governs the health, safety and welfare of factory workers.

Employees Provident Fund and Miscellaneous Provisions Act, 1952: It seeks to ensure the financial security of employees in an establishment by providing a system of compulsory savings.

# Securities & Exchange Board of India Act, 1992

The Securities & Exchange Board of India Act (commonly known as the SEBI Act) is an Act of Parliament, enacted for the regulation and development of the Indian securities market.

The Act has been regularly amended to meet the changing requirements of the securities market in India

## Negotiable Instruments Act, 1881

The law related to promissory notes, bills of exchange, cheques and other negotiable instruments is codified in India under the Negotiable Instruments Act, 1881.

## Information Technology Act, 2000

The Information Technology Act, 2000 is an Act of the Indian Parliament, notified on 17 October 2000.

It is the primary law in India dealing with cybercrime and electronic commerce, and is based on the United Nations Model Law on Electronic Commerce 1996 (UNCITRAL Model) recommended by the General Assembly of United Nations by a resolution dated 30 January 1997.



## Direct tax laws in India

The administration, supervision and control in the area of direct taxes lie with the Central Board of Direct Taxes (CBDT), which works under the Ministry of Finance.

## Corporate income-tax

A corporation's income consists of:

- Income from house property
- Income from business
- Capital gains on disposition of capital assets
- Residual income arising from non-business activities

Tax treaty: If there is a tax treaty entered into between India and the country of residence of the taxpayers, then provisions of the domestic tax law, or the tax treaty, whichever is more beneficial would apply.

India has an extensive network of tax treaties, including comprehensive agreements, tax information exchange agreements, limited agreements, etc.

## Individual income-tax

Liability of income tax: Liability for income tax is governed by the tax residential status of individuals during the tax year.

Types of income subject to tax in India:

- Employment income
- " Income from house property
- Self-employment/ business income
- Capital gains
- Residual income arising from other activities

## Transfer Pricing in India

Objective: Comprehensive transfer pricing regulations were introduced in India, effective from 1 April 2001, with the objective of preventing associated enterprises from manipulating prices in intra-group transactions, for example, by transferring their profits outside India.

While there are some differences, Indian transfer pricing provisions are generally in line with transfer pricing guidelines issued by the Organisation for Economic Co-operation and Development (OECD Guidelines).



## Important tax rates applicable to corporates (as per Income-tax Act, 1961)

Particulars	Base tax rate* (%)
Domestic company: Where total turnover for FY 2014-15 does not exceed INR 50m	29
Domestic company: Any other case	30
Non-resident company	40
Non-residents & foreign companies: Royalty and FTS	10
Long term capital gains	20
Long term capital gains: On transfer of listed shares	Exempt
Short-term capital gains: On transfer of listed shares	15
Dividend distribution tax (subject to grossing-up)	15
Interest on foreign currency borrowings made prior to 1 July 2017	5
Interest on foreign currency borrowings made after 1 July 2017	20
Interest on rupee denominated bonds made prior to 1 July 2020	5
Minimum Alternate Tax (on book profits, adjusted for limited additions & deletions that are prescribed): Payable only if the same exceeds tax payable under normal provisions	18.5

<sup>\*</sup>The base tax rate mentioned above is exclusive of education cess and higher secondary education-cess, aggregating to 3% on the total tax liability, and also excluding applicable surcharge (if any)

## Applicable surcharge rates on income-tax (as per domestic tax law):

Particulars	Surcharge rate (%)
Domestic company: Taxable income between INR 10m & 100m	7
Domestic company: Taxable income in excess of INR 100m	12
Foreign company: Taxable income between INR 10m & 100m	2
Foreign company: Taxable income in excess of INR 100m	5
Individuals: Taxable total taxable income exceeds INR 10m	15



## Historic launch of GST

At the stroke of midnight on 30 June 2017, the Goods & Service Tax (GST) was implemented in India, thereby becoming India's largest tax and fiscal reform since independence.

GST has replaced central level indirect-taxes, including excise, service tax, customs duty and state taxes like VAT, CST, octroi duty, entry tax, entertainment tax, etc., to become a single comprehensive tax levied on the manufacture, sale and consumption of goods and services at a national level. Under the GST regime, only the final consumer is required to bear the tax on value addition at every stage, from producer/service provider to the retailer.

The government's main objective of implementing GST was to streamline the existing indirect tax structure, mitigate cascading and double taxation issues, and eliminate inefficiencies in the current tax system.

Implementation of GST is aimed at creating a common national market-

"One Nation One Market" as proclaimed by Hon'ble Prime Minister Narendra Modi, by eliminating state boundaries, and also to support and boost other Government flagship projects such as "Make in India", "Ease of Doing business in India", and so on.

In India, the government's GST rate fitment exercise, has tried to align GST rates with the existing indirect tax effective rates.

"GST will not only ease the process of doing business, but will also improve the way of doing business. GST will play an important role in achieving the goal of New India"

Narendra Modi, Hon'ble Prime Minister of India





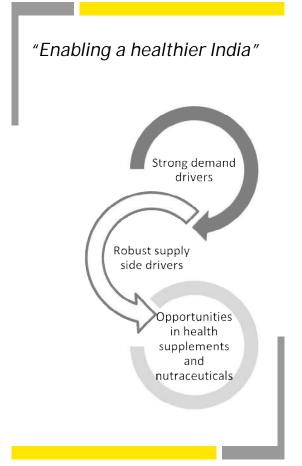
## 7 Outlook

The outlook for the health supplements and nutraceuticals industry in India is very positive.

The popularity and growth of this industry can be attributed to consumers increased inclination and awareness towards health and nutrition. Consumer focus is shifting from medical treatment for sickness to a positive approach for prevention of diseases.

The industry is now not only about usage of dietary supplements but also the consumers increasingly accepting the fortified/ functional packaged food and beverages as part of their daily diet. All the three segments, i.e., dietary supplements, functional foods and functional beverages are growing at a double digit rate. The Indian consumer base is only set to increase and there are tremendous opportunities for the existing as well as new entrants. With India set to become the most populated country in the world, there exists a huge potential in this market.

The Indian government is implementing several path breaking reforms to make India a better place for doing business. The strong and favorable demand, supply drivers along with India's regulatory framework builds a very strong case for doing business in India. This is perhaps the best time to enter the Indian market.





## **EY offices**

### Ahmedabad

2<sup>nd</sup> floor, Shivalik Ishaan Near C.N. Vidhyalaya Ambawadi Ahmedabad - 380 015

Tel: +91 79 6608 3800 Fax: +91 79 6608 3900

### Bengaluru

No.24 Vittal Mallya Road Bengaluru - 560 001

Tel: +91 80 4027 5000

+ 91 80 6727 5000

+918022240696

Fax: +91 80 2210 6000

Ground Floor, 'A' wing Divyasree Chambers # 11, O'Shaughnessy Road Langford Gardens Bengaluru - 560 025 Tel: +91 80 6727 5000 Fax: +91 80 2222 9914

### Chandigarh

1<sup>st</sup> Floor, SCO: 166-167 Sector 9-C, Madhya Marg Chandigarh - 160 009 Tel: +91 172 331 7800 Fax: +91 172 331 7888

#### Chennai

Tidel Park, 6<sup>th</sup> & 7<sup>th</sup> Floor A Block (Module 601,701-702) No.4, Rajiv Gandhi Salai Taramani, Chennai - 600 113 Tel: +91 44 6654 8100 Fax: +91 44 2254 0120

#### Delhi NCR

Golf View Corporate Tower B Sector 42, Sector Road Gurugram - 122 002 Tel: +91 124 464 4000 Fax: +91 124 464 4050

3<sup>rd</sup> & 6<sup>th</sup> Floor, Worldmark-1 IGI Airport Hospitality District Aerocity, New Delhi - 110 037 Tel: + 91 11 6671 8000 Fax + 91 11 6671 9999

4<sup>th</sup> & 5<sup>th</sup> Floor, Plot No 2B Tower 2, Sector 126 Noida - 201 304 Gautam Budh Nagar, U.P. Tel: +91 120 671 7000 Fax: +91 120 671 7171

### Hyderabad

Oval Office, 18, iLabs Centre Hitech City, Madhapur Hyderabad - 500 081 Tel: +91 40 6736 2000 Fax: +91 40 6736 2200

#### Jamshedpur

1st Floor, Shantiniketan Building Holding No. 1, SB Shop Area Bistupur, Jamshedpur - 831 001 Tel: +91 657 663 1000

BSNL: +91 657 223 0441

### Kochi

9<sup>th</sup> Floor, ABAD Nucleus NH-49, Maradu PO Kochi - 682 304 Tel: +91 484 304 4000

Tel: +91 484 304 4000 Fax: +91 484 270 5393

#### Kolkata

22 Camac Street 3<sup>rd</sup> Floor, Block 'C' Kolkata - 700 016 Tel: +91 33 6615 3400 Fax: +91 33 2281 7750

#### Mumbai

14<sup>th</sup> Floor, The Ruby 29 Senapati Bapat Marg Dadar (W), Mumbai - 400 028 Tel: +91 22 6192 0000 Fax: +91 22 6192 1000

5<sup>th</sup> Floor, Block B-2 Nirlon Knowledge Park Off. Western Express Highway Goregaon (E), Mumbai - 400 063 Tel: +91 22 6192 0000

Tel: +91 22 6192 0000 Fax: +91 22 6192 3000

### Pune

C-401, 4<sup>th</sup> floor Panchshil Tech Park Yerwada (Near Don Bosco School) Pune - 411 006 Tel: +91 20 6603 6000

Fax: + 91 20 6603 6000

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### Dr. Bijaya Kumar Behera

Economic Adviser Ministry of Food Processing Industries Panchsheel Bhawan, August Kranti Marg Khelgaon, New Delhi-110049

Tel: 011-26491810 Fax: 011-26493228 Email: behera.bk@nic.in Website: http://mofpi.nic.in/

### Aashish Kasad

India region tax leader for the Consumer Products and Retail sector Ernst & Young LLP

16th Floor, The Ruby, 29 Senapati Bapat Marg, Dadar (West), Mumbai - 400 028, Maharashtra, India

Tel: +91 22 6192 0000 Fax: +912261921000

E-mail: Aashish.Kasad@in.ey.com

Website: www.ey.com

### Manish Whorra

Director

Confederation of Indian Industry The Mantosh Sondhi Centre 23, Institutional Area, Lodi Road, New Delhi - 110 003 (India)

Tel: 91 11 45771000 / 24629994-7

Fax: 91 11 24626149 E-mail: manish.whorra@cii.in

Website: www.cii.in

Notes	



### **Ministry of Food Processing Industries**

Government of India

The Ministry of Food Processing Industries is concerned with formulation and implementation of the policies for the food processing industries within the overall national priorities and objectives.

The Ministry acts as a catalyst for bringing in greater investment into this sector, guiding and helping the industry and creating a conducive environment for healthy growth of the food processing industry. The Ministry aims at:

- Creating the critical infrastructure to fill the gaps in the supply chain from farm to consumer;
- Value addition of agricultural produce;
- Minimizing wastage at all stages in the food processing chain by the development of infrastructure for storage, transportation and processing of agro produce;
- Induction of modern technology in the food processing industries;
- Encouraging R&D in food processing for product and process development;
- Providing policy support, promotional initiative and facilities to promote value added produce for domestic consumption and also exports.



## **Ernst & Young LLP**

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#### **Confederation of Indian Industry**

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the development of India, partnering industry, Government, and civil society, through advisory and consultative processes.

As a developmental institution working towards India's overall growth with a special focus on India@75 in 2022, the CII theme for 2017-18, India@75: Inclusive. Ahead. Responsible emphasizes Industry's role in partnering Government to accelerate India's growth and development.

Founded in 1895, India's premier business association has over 8500 members, from the private as well as public sectors, and an indirect membership of over 200,000 enterprises from around 250 national and regional sectoral industry bodies. With 67 offices in India and 11 overseas offices, CII serves as a reference point for Indian industry and the international business community.