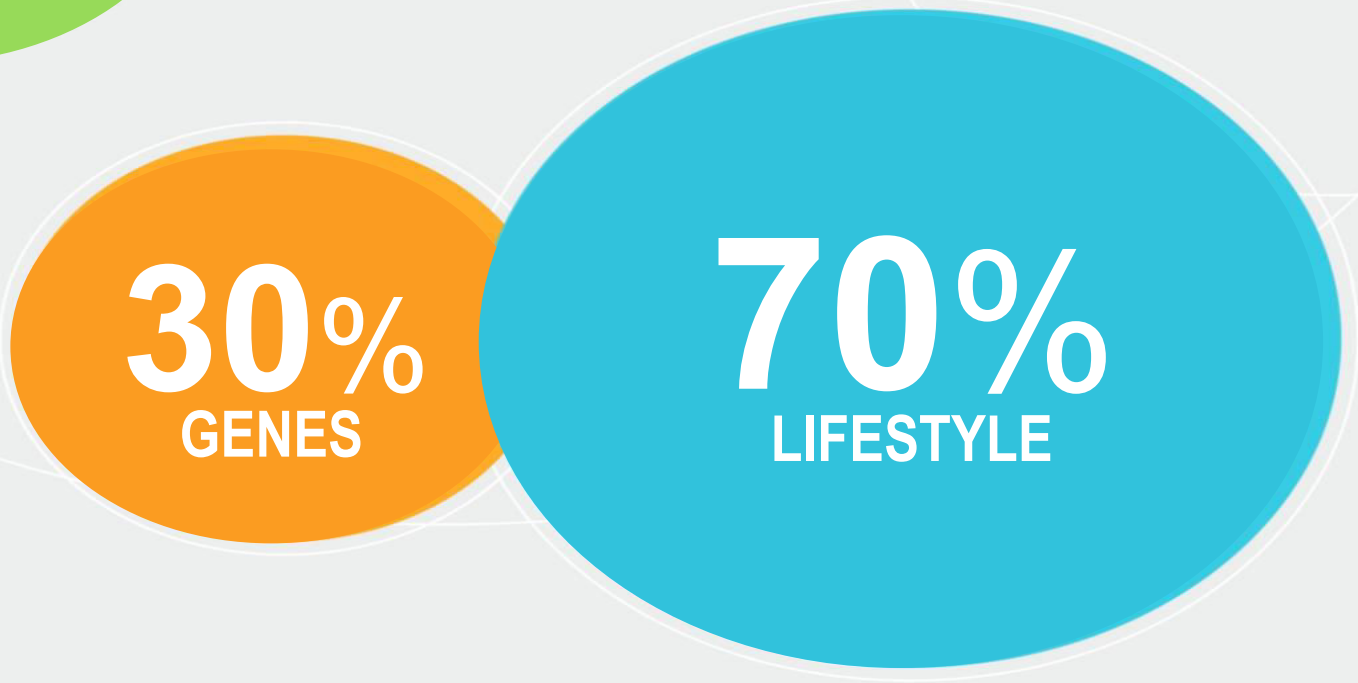
FOOD SUPPLEMENT/ NUTRACEUTICAL REGULATORY FRAMEWORK

Rini Sanyal 23 March, 2017

SETTING UP THE CONTEXT

- According to UNICEF, one-in-three children living in India are mal nourished, about 46% of them under the age of three are too small for their age while 47% are underweight and 16% have “wasted away,” meaning low weight for their height
- World Health Organization (WHO) recognised the growing burden of non-communicable diseases (NCDs) in India
- According to Wall street Journal - Obesity is an increasingly prevalent problem among India’s affluent middle and upper classes
- India now faces double burden of Malnutrition and Obesity
- Lack of Physical activity, proper diet contributes to the overall lifestyle – results in Obesity related Mal nutrition and other associated issues like NCDs
- As per study report of All India Institute of Medical Sciences - Almost 20% of India’s adult population is overweight, while approximately 20% of school-aged children are obese and the numbers are steadily growing

HEALTHY LIVING



Source: United Nations Department of Economic and Social Affairs, Population Division.
World Population Prospects. The 2004 Revision. New York: United Nations 2005

PREFACE…

- Specialised Foods like Food or Health supplements. FSDUs, Nutraceuticals etc. have witnessed a tremendous growth in India in recent years due to their potential in providing health benefits, which is the key driving factor for this sector and
- Addresses Reducing dietary deficiency and improves general wellbeing

❖ **Key differentiators**

- Can not be compared with conventional foods or standardised Foods
- Formats – capsule, tablets, pills, sachets, jelly or gel, liquid, powder
- To be taken in measured unit quantities / recommended serving

ADDRESSING THE NUTRITIONAL NEED

- ✓ Supplementary nutrition is focussed to provide and reduce the dietary gap of micronutrients and other nutrients in normal diet
- ✓ Key to compensate the dietary deficiencies which exist due to poor or wrong diet / type of food(veg / non veg) or existing Health conditions
- ✓ Vitamins and minerals aid in cell function, convert macronutrients into energy and help support the immune system etc.

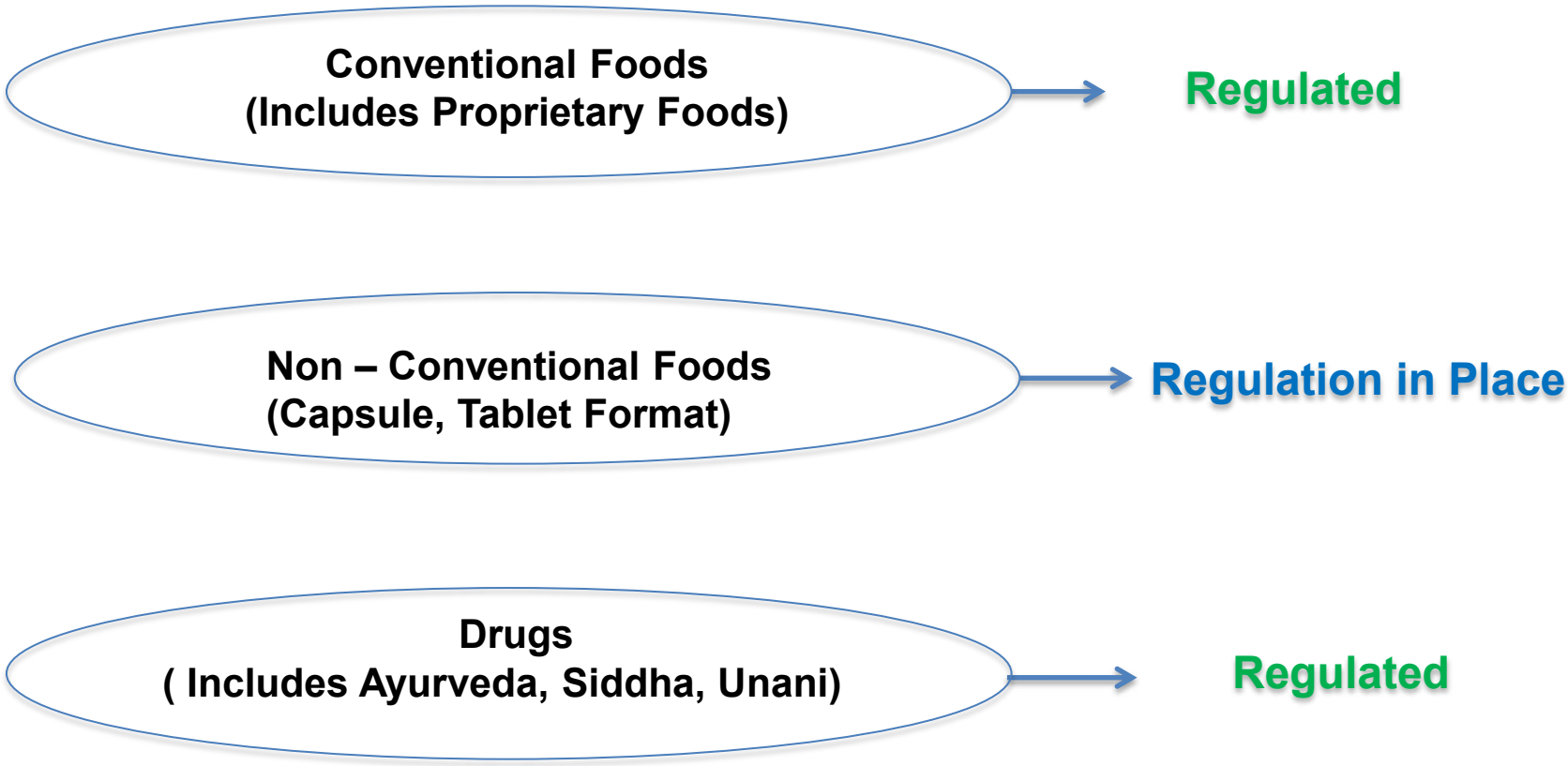
❖ Contributory Factors

1. Lifestyle
2. Lack of adequate level of Nutrition from diet

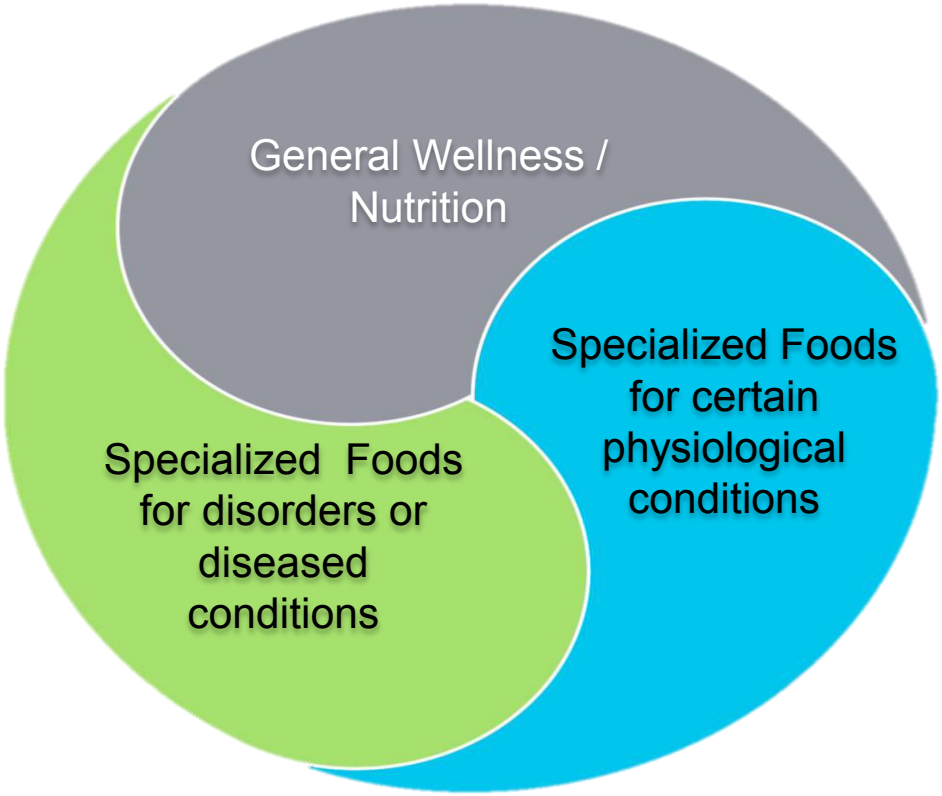
AGENDA

- Regulatory Need
- Product coverage
- Recognition under section 22 of the Food Safety & Standards Act 2006
- Regulatory Framework
- General Conditions
- Format Specific Requirements
- Certain Incongruities and
- Ask

REGULATORY NEED



PRODUCT COVERAGE



As per the international Regulations and Codex Guidelines such products are marketed as **Food**

Recognition under Food through Food Safety & Standards Act 2006

SECTION 22 AND THE SCOPE

- Covers foods which are specifically processed or formulated to satisfy particular dietary requirements due to particular physical or physiological condition or specific diseases and disorders"… thus covers food that may be used even in certain diseased conditions

- Basic differentiating factor - prevent, cure, treat and such other related claims are prohibited

REGULATORY FRAMEWORK

FSSAI has gazette notified

The Food Safety and Standards (Health Supplements, Nutraceuticals, Foods for Special Dietary Uses, Foods for Special Medical Purposes, Functional Foods and Novel Food) Regulations, 2016 on 23rd December 2016

Compliance of existing as well as new products latest by 1st January, 2018

Additional Declaration on securing business during this transition

FBOs may continue manufacturing, importing, storing, packing, distributing and selling products / ingredients following any of the below listed criteria:

The product was

- in the market prior to the 2011 (FSS Act implementation)
- either approved or granted NOC during the PA regime
- already Licensed

CATEGORIES IDENTIFIED

- Food or Health or Dietary Supplements / Nutraceuticals - Physical
- Food for Special Dietary Uses – Physiological
- Food for Special Medical Purposes – Disease / Disorder

However, the FSS Act and the new regulation have clubbed all the above under the same definition

It's a Category specific Regulation

All such products to comply with the General requirements as well as Specific labelling and claim conditions as specified under the category

COMPLIANCES

Criteria	Description
Format	Capsule, gel, tablet and such other forms including powders and liquids
Ingredients	Either standardised, allowed/ approved or listed as per category
Additives	Listed as per category and also Additives limited by GMP
Nutrients	As per the specified schedules
Plants & Botanical extracts	As per the specified schedule
Label Declarations	Specifically Provided (over and above general labelling regulation)
Claim(Nutrient or Health)	Specifically provided (over and above the Claim regulation in the pipeline)

GENERAL CONDITIONS

- Capsule format(hard, soft or vegetarian) - comply with general monograph & quality criteria as per Indian Pharmacopoeia
- For making claims on Food Supplements - Individual nutrient content shall not be less than 15% of RDA
- For Higher Nutrient Content claim – nutrient content not less than 30% of RDA
- Quantity of nutrients added shall not exceed the RDA specified by ICMR(only in case where such limits are not provided, limits laid down by international Food Standards body like Codex shall apply
- Purity Criteria for the ingredients used in the categories shall be as determined and notified in the official gazette by the Food Authority from time to time
- Tolerance limit for variation of nutrients(during sample analysis of finished products) shall not be more than –(10)% from the declared value
- Formulation of such foods shall be based on the principles of medicine / nutrition and supported by valid scientific data
- Manufacturing of both ingredients and products shall be carried out in compliance with established Good Manufacturing Practices.

GENERAL - DECLARATIONS

Over and above the mandatory labelling requirements laid down under FSS Packaging & Labelling Regulations 2011 and also specific labelling requirements for each formats

- Label shall also specify purpose, the target consumer group and the physiological or diseased conditions depending on the usage
- Recommended duration of use
- Label, accompanying leaflet, advertisement to provide sufficient information on
  - nature
  - purpose
  - instructions & precautions(if any)

GENERAL - CLAIMS

FBOs allowed to make ‘Nutritional’ or ‘Health’ claims provided there is direct / implied relationship between the nutrients / ingredients used and there is documented Scientific basis

- Claims can be made on basis of
  - Nutrient or ingredients and
  - health benefits
- Types of Health claims
  - Nutrient Function claim
  - Health Maintenance claim
  - Enhanced Function claim
  - Immunity Claims
  - Anti ageing claim
  - DRR Claim

GENERAL - PROHIBITIONS

- No hormones, steroids or psychotropic ingredients shall be added
- No Plants and botanicals ingredients specified in Schedule IV (in normal or naturally occurring forms) shall not constitute to be a Food supplement Nutraceutical, FSDU or a FSMP
- Minimally processed Cereals, legumes, fruits, vegetables, spices (cleaned, dried, powdered etc.) as juice or cocked form shall not constitute any of the above food formats.
- No treating, curing, preventive and even mitigating claims allowed

Format Specific Compliances

HEALTH SUPPLEMENTS

TO SUPPLEMENT NORMAL DIET **ABOVE THE AGE OF 5 YEARS**

Description	**May be a concentrated source of one or more nutrients, amino acids, enzymes, minerals, proteins, other dietary substances, plants or botanicals, prebiotics, probiotics and substances from animal origin or other similar substances having established nutritional or beneficial effects, which are presented as such, may offered alone or in combination but are not drugs as defined in clause (b) of section 3 of Drugs & Cosmetics Act, 1940'**
Ingredients	**Shall contain ingredients / nutrients specified in Schedule I, Schedule II, Schedule IV, Schedule VII, Schedule VIII , Schedule VI(only Enzymes). Already standardized and approved ingredients are also allowed**
Additives	**Scheduled VA, VE, VF**
Nutrients	**Schedule I, II, VI (only enzymes), VII, VIII**
Plants & Botanicals	**Schedule IV**
Label Declarations	**- HEALTH SUPPLEMENT** **- common name or description of the nature of product** **- Declaration relating to amount of nutrients / substances with nutritional / physiological effect** **- Not to be used as a substitute for a varied food** **- Warning: NOT FOR MEDICINAL USE** **-Statement : stored out of reach of children**

NUTRACEUTICALS

Description	**Nutraceuticals shall provide a physiological benefit and help maintain good health**
Ingredients	**Shall contain any of the ingredients as specified in Schedule I, Schedule II, Schedule IV, Schedule VI, Schedule VII, Schedule VIII**
Additives	**Scheduled VA, VE, VF**
Nutrients	**Schedule I, II, V*I,* VII, VIII**
Plants & Botanicals	**Schedule IV**
Label Declarations	**- Nutraceutical along with common name** **- amount of each nutraceutical ingredients in the product that has a nutritional or physiological function** **-advisory warning : "recommended usage"** **- 'Not For Medicinal' Use prominently written / to be stored away from children** **- warning : on any other precautions to be taken, any side effects, contraindications, product –drug interaction, as applicable**

COMPARATIVE

SL.	Health Supplements	Nutraceuticals
1	Supplement normal diet	Physiological benefits, maintain good health
2	Category 13.6	Category 13.6
3	Nutrient usage limited by RDA	Nutrient usage limited by RDA
4	Schedule I, II, IV, VI(only enzymes), VII, VIII	Schedule I, II, IV, VI, VII, VIII
5	Product led claims shall be based on human studies with evidence based data	Product led claims shall be based on human studies with evidence based data `
6	Not allowed to use any nutraceutical ingredient (schedule VI)	Can use vitamins/ minerals (schedule I & II)

ADDRESSING INCONGRUITIES

Section 22 of the Act defines supplements,Nutraceuticals,FSDUs etc. as one

the Regulation echoes the same understanding, then how to address

- Similar categories in different names not readily recognised globally
- Inconsistency in use of ingredients / nutrients across formats
- Conflict in use of RDA limit

Besides,

Ingredients under Schedule IV needs careful revision as plant and botanical extracts are highly complex active ingredients and not merely plants / fruits or vegetables. Reference to Pharmacopoeia for purity criteria

Certain ingredients which are in use in the country are missing in the list of ingredients – need priority inclusion provided they are safe

Already approved spices, essential oils etc. needs to be incorporated in the regulation for ease of reference

There are few repetitions and conflicts in General and Specific conditions which needs to be streamlined

Labelling and Claim part needs to be further simplified and most of the declaratory requirements to be covered under Labelling & Claim Regulations

Use of “Warnings” needs to be evaluated further and should be applicable only where it is necessary

ASK: a clear unambiguous and implementable legislation

Thank You