Nutraceutical Regulation: Innovation Challenges

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Regulatory Compliance

Consumer Safety

Products should not create any "**HARM**" to the users!

Environmental Safety

Should not "**UNDULY**" harm the environment "**Directly**" or "**Indirectly**"!

Ethics & Values

In accordance with the "**Principles**" & "**Values**" set by the society!

Right Quality

Users should not be "**Cheated**" (Counterfeits, Spurious etc.)!

Economy

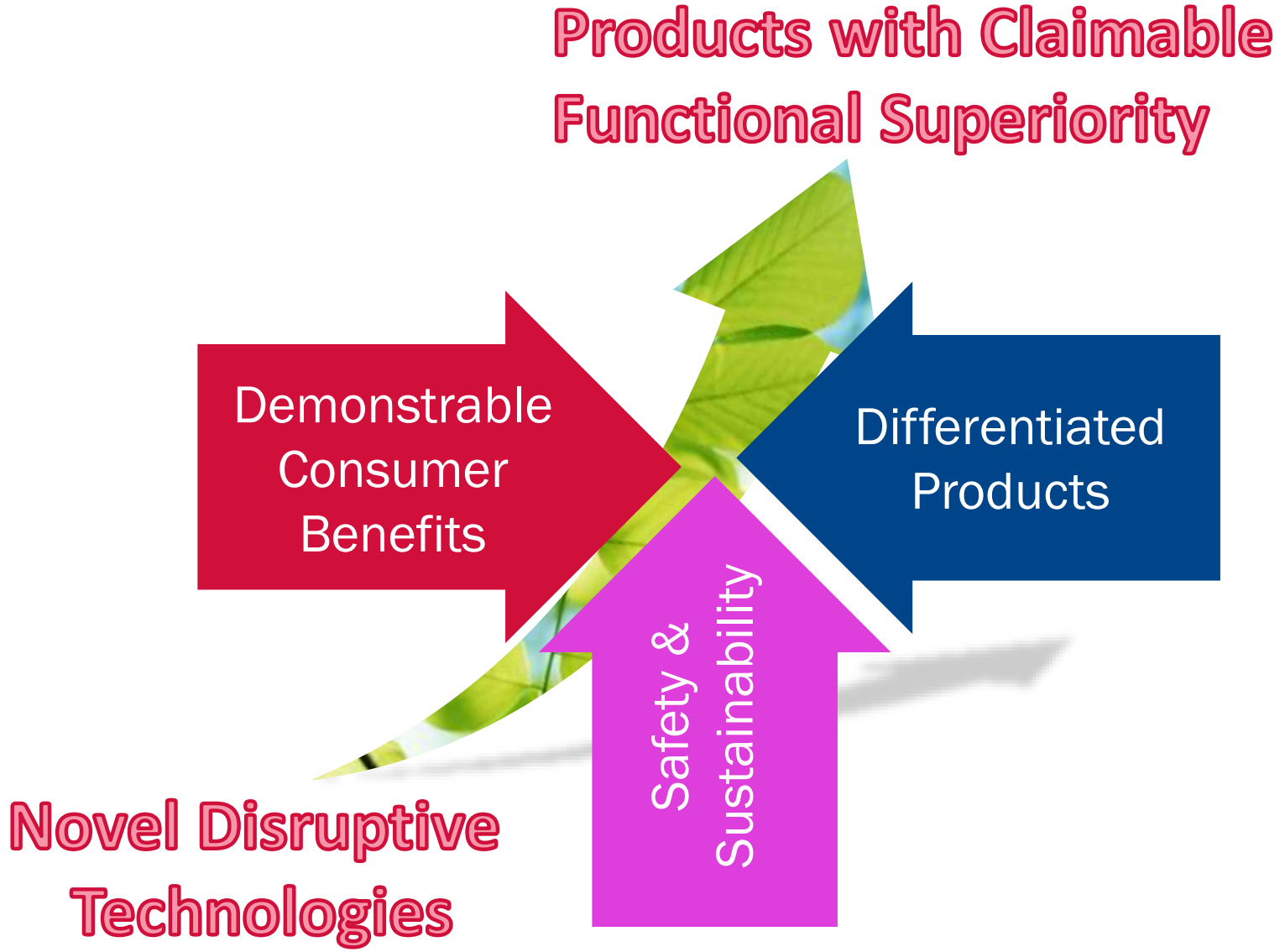
Promote/enhance healthy "**TRADE**"!

Ensure smooth, fair and honest operations within the market

Regulations – Enabling Innovations

“While Ensuring Compliance of Existing Portfolio, Leverage Scientific Expertise to Identify and Support Innovation for New Products”

Why Innovation



Nutraceutical Regulations

Nutraceutical Regulation

New Opportunities - Defined Eight Categories of Food

Health Supplements	Nutraceuticals	Foods for Special Dietary Use	Food for Special Medical Purpose	Specialty Food containing plants or botanicals	Foods containing Probiotics	Foods containing Prebiotics	Novel Foods
▪ Supplement the normal diet through concentrated source of nutrients (plants etc.) for a person above 5 years	▪ Botanical extracts to provide physiological benefits and help maintain good health	▪ For a particular dietary requirements viz. ▪ Weight mgmt. (low weight, obesity) ▪ Conditions like Diabetes, high BP etc. ▪ Higher than RDA	▪ Special diet for meal replacement ▪ Higher than RDA	▪ Over 400 botanical ingredients including Indian traditional herbs (Ayurvedic)	▪ Over 28 strains have been. Approved. ▪ Viable no. of organisms ≥10^8 CFU/g.	▪ Over 11 Prebiotic compounds have been approved.	▪ Food having no history of human consumption, obtained through a new technology etc. ▪ Prior Approval from the Food Regulator

General requirements related to the categories, use of ingredients and Claims detailed in the regulation
Ingredients / Additives have been mentioned for each of the categories in Schedules I to VIII in the Regulation

Opened up new opportunities
Differentiated offering to consumers
Created a Market equivalent to global
Goodness of Traditional Knowledge

Nutraceutical Regulation 2022

New Nutraceutical Regulation

Redefined – 5 Categories of Food

Health Supplements

- For supplementing the normal diet of a person with Vitamins/minerals/proteins/amino acids/botanicals

Nutraceuticals

- Botanical extracts /Molecules/Isolates defined in specific schedule to provide physiological benefits and help maintain good health

Foods for Special Dietary Use

- For special dietary needs - Weight mgmt. obesity, Diabetes, high BP, sleep mgmt., food for Sportspersons etc.
- Specific requirements for Weight mgmt. and Food for Sportspersons

Food for Special Medical Purpose

- Food specially meant for dietary mgmt. of persons with specific medical conditions, diseases or disorders
- Specific requirements for Weight reduction. and Food intended special diagnostic purposes

Prebiotic Food & Probiotic Food

- List of prebiotic compounds for providing health benefits to gut microflora / 31strains probiotics for health benefits
- Usage levels defined / format restrictions

>RDA of micronutrients allowed – Format restrictions and only by prior approval

General requirements related to the categories, use of ingredients and Claims detailed in the regulation
Ingredients defined for categories in Schedules I to IV/ Additives mentioned for categories / formats in Annexures

As the regulation evolved - more challenges

- Additives Restrictions
- Format restrictions
- Complexity in schedules/labeling not simplified

New Innovations & Consumer Needs Propelling Demand for Supplements

Innovative solutions and rise of the health-conscious consumer has opened up Benefit areas

- **Personalized Nutrition (Science Based Solution)**
- **Mental Health & Stress**
- **Immune Health**
- **Bone Health**
- **Gut Health**
- **Weight Management**

Higher Level of Nutrients / Better Delivery Systems being evaluated

New Innovations & Consumer Needs Propelling Demand for Supplements

- Tablet / Capsules – preferred formats
- Convenient format to innovate products and deliver consumer needs
- Higher levels of vitamins/minerals for delivering key benefits

Nutraceutical Regulation Challenges

Additives Issues:

- Restrictions of use of additives for categories
- Restrictions for formats
- Should have been allowed across categories and have been safety based
    - Toxicological risk assessments would have allowed safe use of additives across categories and would have helped compliance and innovation

Nutraceutical Regulation Challenges

Format/RDA Challenges:

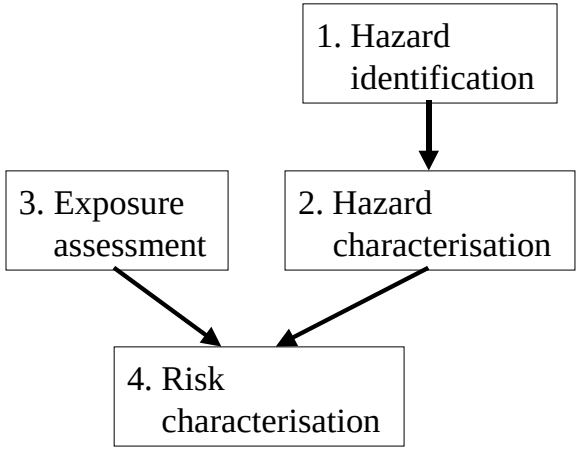
- >RDA of vitamins and minerals allowed in FSDU and FSMP for specific physiological needs with prior approval
- Restrictions for formats
- Should have been allowed across formats and have been safety based
    - Toxicological risk assessments would have allowed safe use of additives across categories and would have helped compliance and innovation

Safety Assessment

- Ensure foods placed commercially on the market are safe for the consumer and do not present undue risk

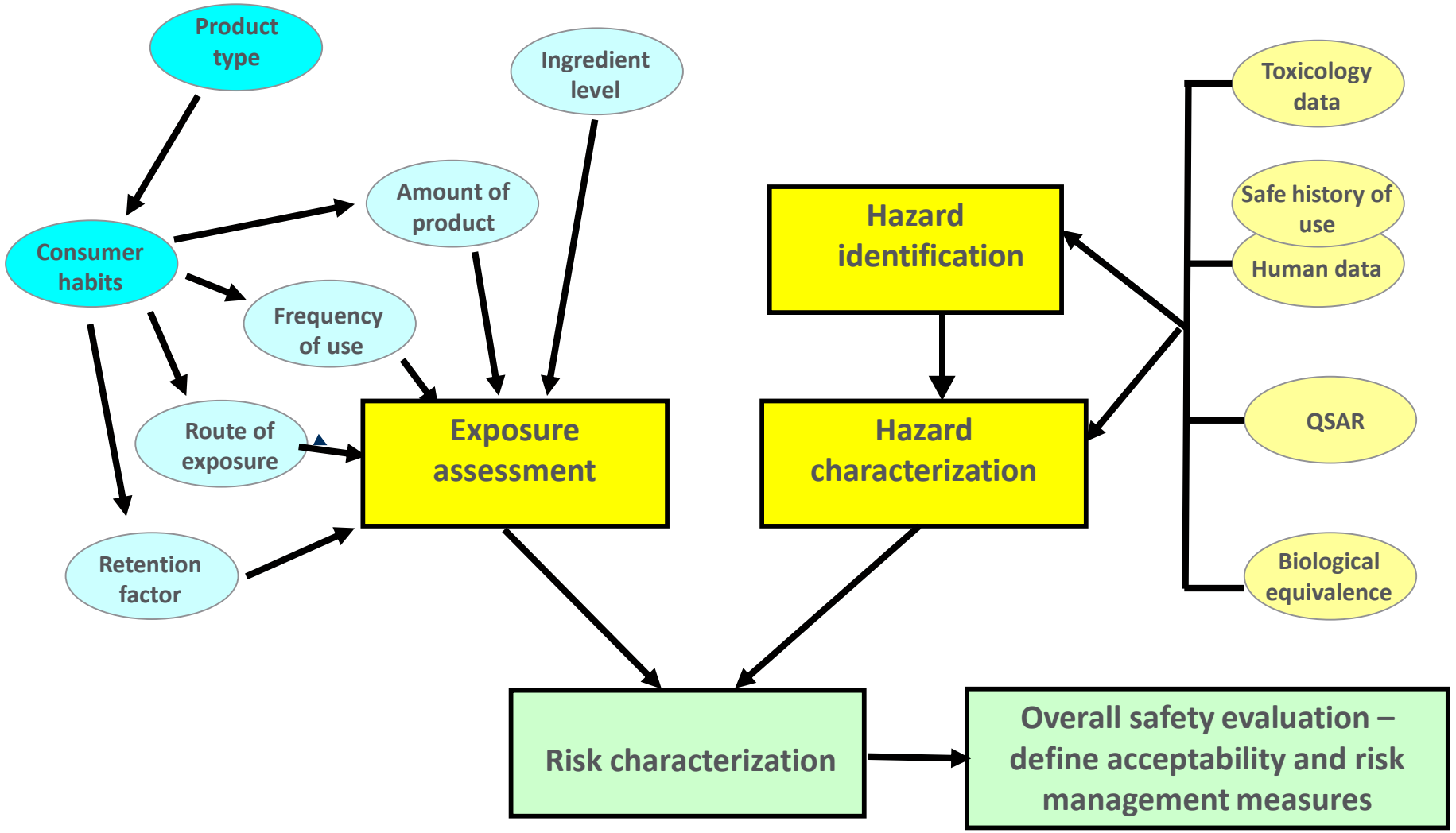
$$\text{Risk} = f\,(\text{Hazard} \times \text{Exposure})$$

- 4 step risk assessment paradigm
  - Hazard identification
  - Hazard characterisation
  - Exposure assessment
  - Risk characterisation



- Food safety testing is ‘case by case’

Safety Assessment



Toxicology Endpoints

- Acute
- Sub-chronic
- Chronic
- Carcinogenicity
- Genotoxicity
- Teratogenicity
- Reproductive toxicology
- Absorption, distribution, metabolism & excretion

Safety Assessment

Toxicology Endpoints

- Acute
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- No observed adverse effects level (NOAEL)
  Dose that produced no adverse effects in the study.
  Identifying the critical effect in the most sensitive species

- For chemicals deliberately added to food
  - Acceptable Daily Intake (ADI) established

  ADI is “amount of chemical, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk”

  ADI = NOAEL ÷ Safety Factor

  Typical safety factor used is 100 (10×10)

  SF of x10 to account for inter-species variation

  SF of x10 to account for human variation

  Consumption greater than ADI still likely to have no effect because of conservative nature of safety factors.

Nutraceutical Regulation Challenges

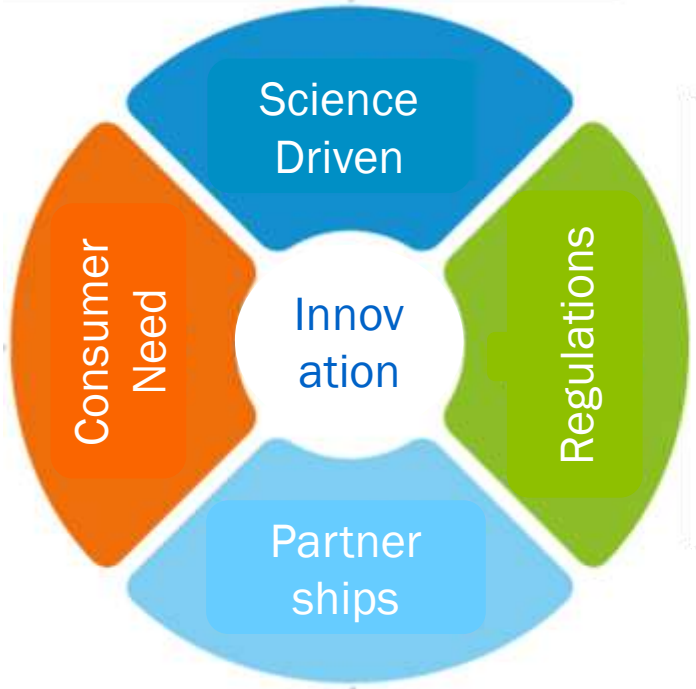
Other challenges:

- Regulations if mapped to international guidelines would allow us to develop products at global parity
- Allowing TULs/>RDA levels of micronutrients across formats to meet the need of specific target population/specific physiological needs
- Schedules Complexity – Use of particular ingredients define the product category

Innovation: Driving Value for Business, People and Consumers

Catering to consumer needs for creating products to support health benefits

Backed with scientific support /ensuring compliance Delivering demonstrable benefits



Scientific collaboration between Industry/ academia / regulators

Conducive regulatory environment to support innovation and new product development


THANK
YOU!