

Future of Regulatory and Emerging Trends

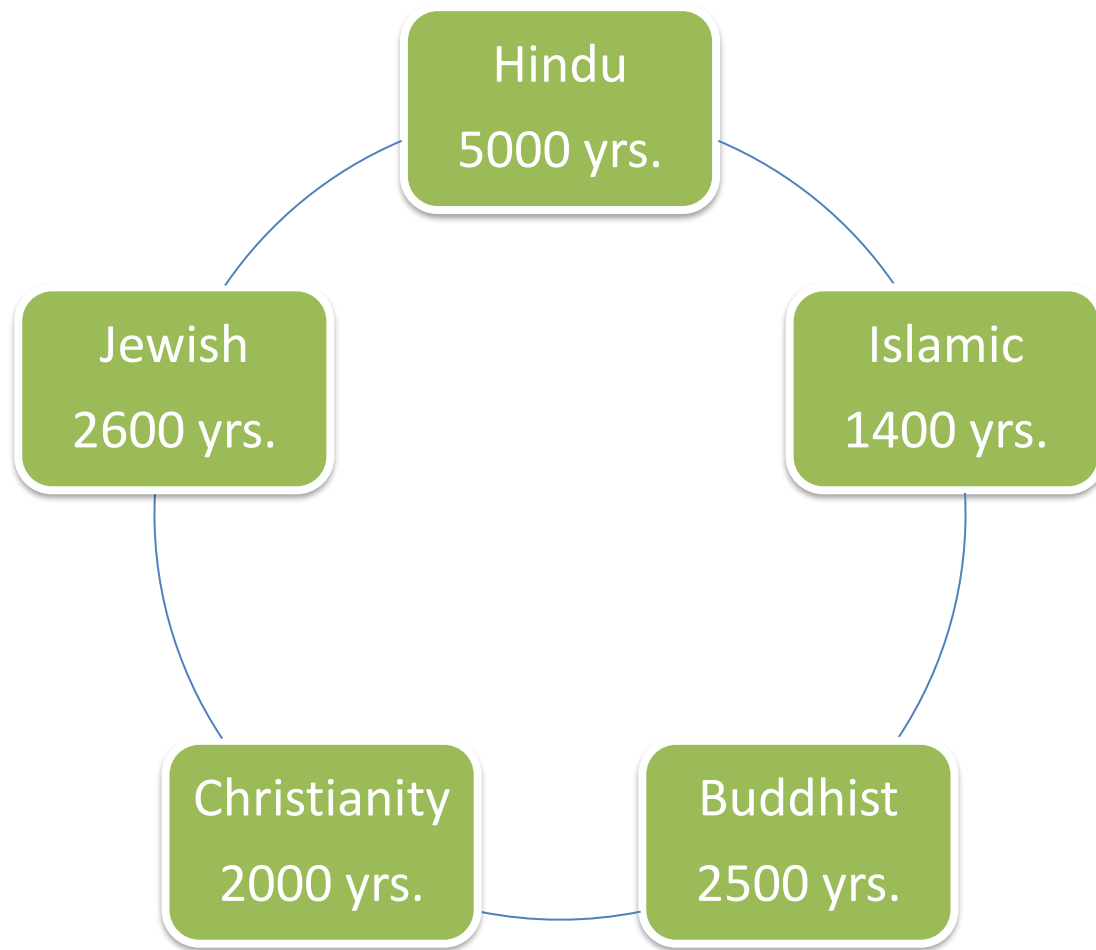
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Agenda

- **History of Ancient Regulations**
- **Risk Analysis**
- **Future Regulatory Challenges**
- **Emerging issues**
- **Solutions**

History of Ancient Regulations



History of Ancient Regulations

Chanakya Arthashastra (Highlights)

This book is 2500 year old and authored by Kautilya.

Book provides an ancient Indian treatise on statecraft, economic policy and military strategy written in Sanskrit

Some references to Modern FMCG Segments

- Punishment for adulteration for milk , salt and oil
- Domestic duty at 5 % and import duty at 10% to safe guard local trade
- Common tax concept like GST
- Weights and Measure control by having separate department of weights and measure
- Stamping the weights and measures
- Selling commodity on standard weights only
- Selling commodities for higher profits
- Illegal import control

Birth of Modern Regulations

Tort of Negligence -1932

- *Donoghue v Stevenson* - 1923
- A fight of brave lady for 9 yrs against present system to evolve new regulations
- **Mother of all Control Orders & Consumer Protection Law**



Snail in Ginger Beer

Safety Evaluation

Involvement / Commitment

High

Low

Hazard Base approach

Risk Base approach

1940 -1990

Yr 2000 on wards

Control

Trust

Product Specifications
Inspections

Procedures
Monitoring
Feedback
System

Supplier/
Customer
C.O.P.Q

Problem solving
continuous
Improvement

Food Safety
Management
Systems
culture change
Enterprise Wide

Q.C

Q.A

T.Q.A

T.Q.M

Control Driven

Culture / Behavior Driven

Modern Food Regulations

- Codex Alimentarius Commission
Adopted by 173 countries -1963
- USFDA – Food & Drugs
- European Union – EFSA
- Food Safety Australia and New Zealand
- Japan Food Safety Commission
- South Africa Food safety and Quality Assurance
- Gulf Standards –GSO Standards
- National Agency of Drug & Food control Malaysia

Basis of Modern Regulations

Risk base approach.

Risk analysis

- Risk analysis is powerful tool for carrying out **science based** analysis and for reaching sound, consistent solution for food safety problem
- Risk is basically combination of two concepts
 - *Probability – How likely to happen -*
 - *Severity – How bad would it be if this did happen -*

Risk Analysis Framework



Risk = Hazard X Exposure

Risk Analysis Process

- Risk analysis should be based on all available scientific evidence, information on perception, cost, environment, culture factors etc
- Which needs to gathered and analyzed according to scientific principles to the extend possible

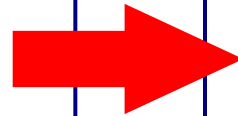


Risk Based Approach:

Use scientific evidence-based risk assessment methodologies to ensure that the risk of adverse health and/or environmental effects from exposure to chemicals used in our products is acceptably low.

Hazard-based

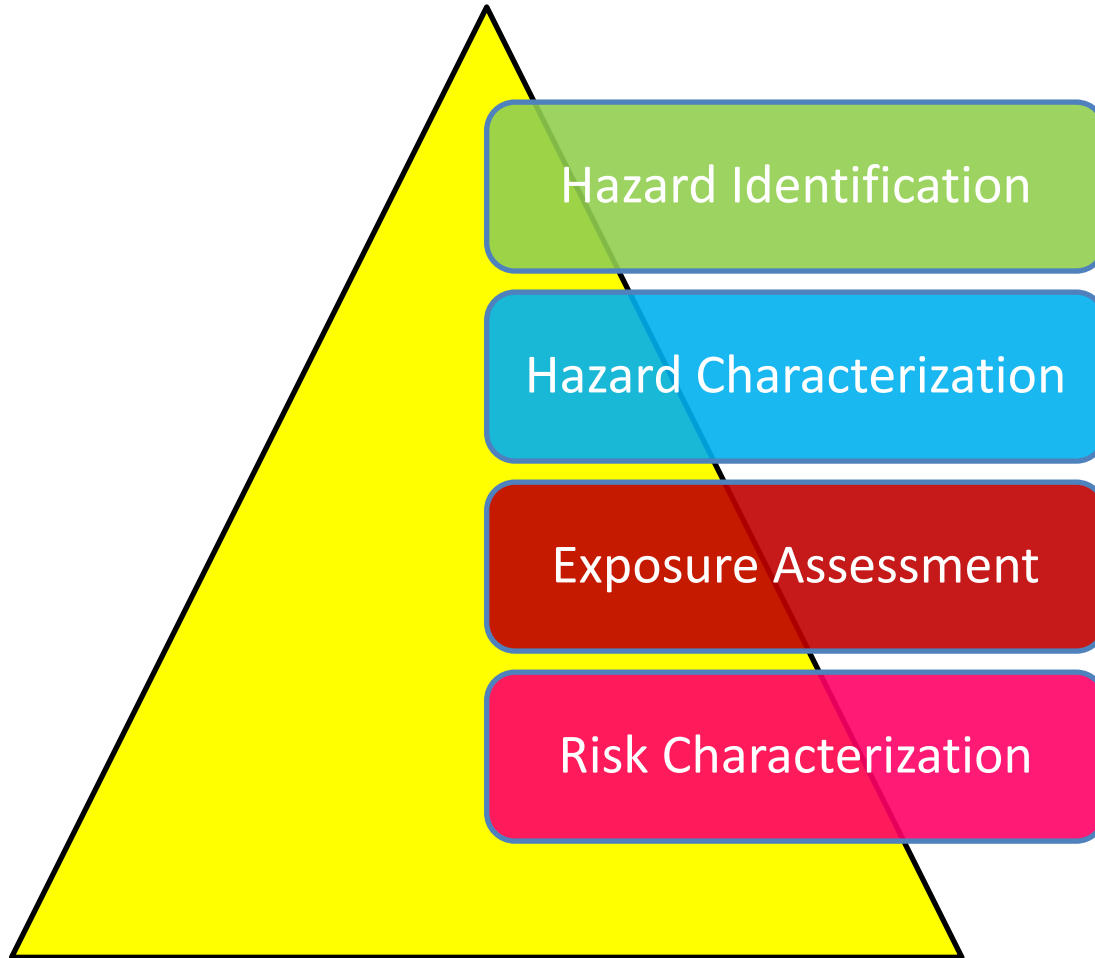
- Check-list compliance
- Unnecessary testing
- Doesn't consider how product is used
- Yes / no decisions
- Overly conservative



Risk-based

- Expertise- & evidence-driven
- Essential testing only
- Product use / exposure determines outcome
- Options to manage risks
- Uncertainties explicit

Risk Assessment

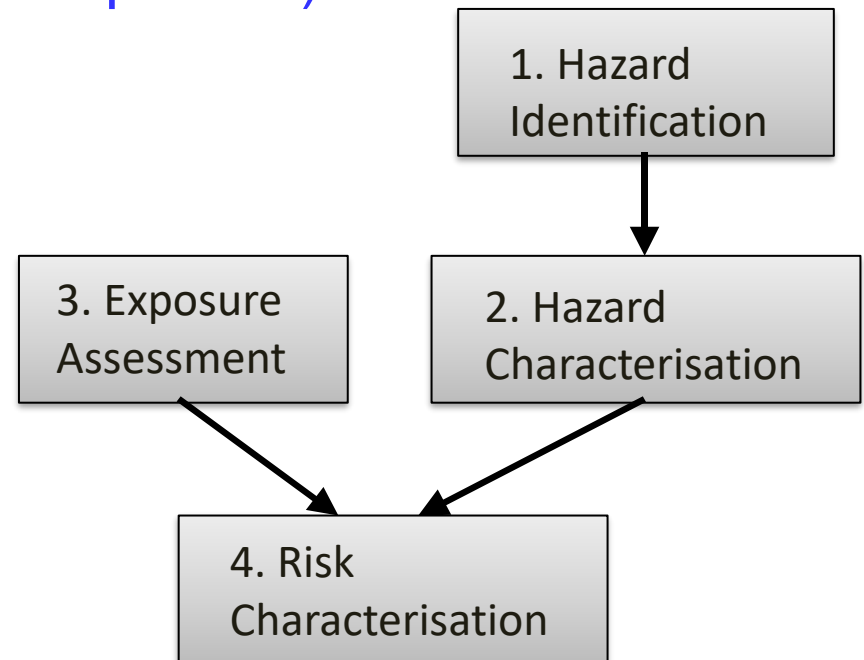


Risk Assessment :

- Take example of Chemicals in Food
- 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



Chemicals in Food

- **Naturally occurring**

- Food constituents – carbohydrates, fats, protein, vitamins, minerals
- Natural toxins e.g. aflatoxin
- Other ingredients in food e.g. isoflavones, caffeine, cyanogenic glycosides, methyl eugenol

- **Intentionally added to food**

- New ingredients e.g. GM, novel foods
- Additives e.g. flavors, sweeteners, colours
- Nutrients e.g. Omega-3 oils, fructose
- Vitamins and minerals
- Functional ingredients e.g. Ayurveda

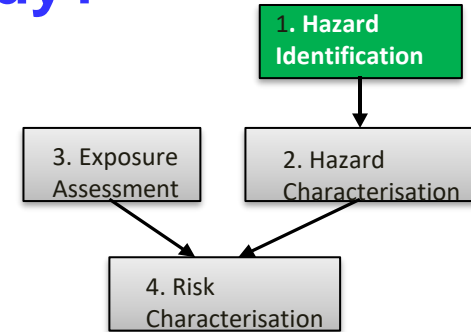
- **Unintentionally added to food (Contaminants)**

- Environmental e.g. Dioxins/PCB
- Process e.g. acrylamide
- Food contact materials e.g. bisphenol A

Hazard Identification

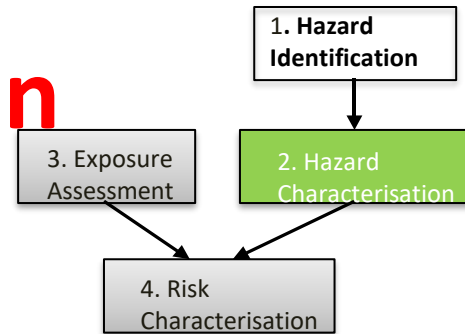
What is known about the chemical(s) already?

- Information from the supplier
- Regulatory approvals
- Literature search on the chemical
 - Standard toxicology studies
 - Investigative / research publications
 - Media stories
- Uses of the chemical other than food



Build up a picture to determine what the safety issues are and what package of safety support might be needed.

Hazard Characterization



Types of Toxicology Studies

Relevant hazard endpoints are considered, which are dependent on the potential route of exposure: Food – oral!

- Acute toxicity
- Allergy (type I)
- Systemic toxicity
 - sub-chronic
 - chronic
- Reproductive toxicology including teratogenicity
- Genotoxicity
- Carcinogenicity
- Absorption, Distribution, Metabolism & Excretion (ADME)

Hazard



Adverse Health Effect

Hazard Characterisation

What is the safe dose/intake of a chemical?

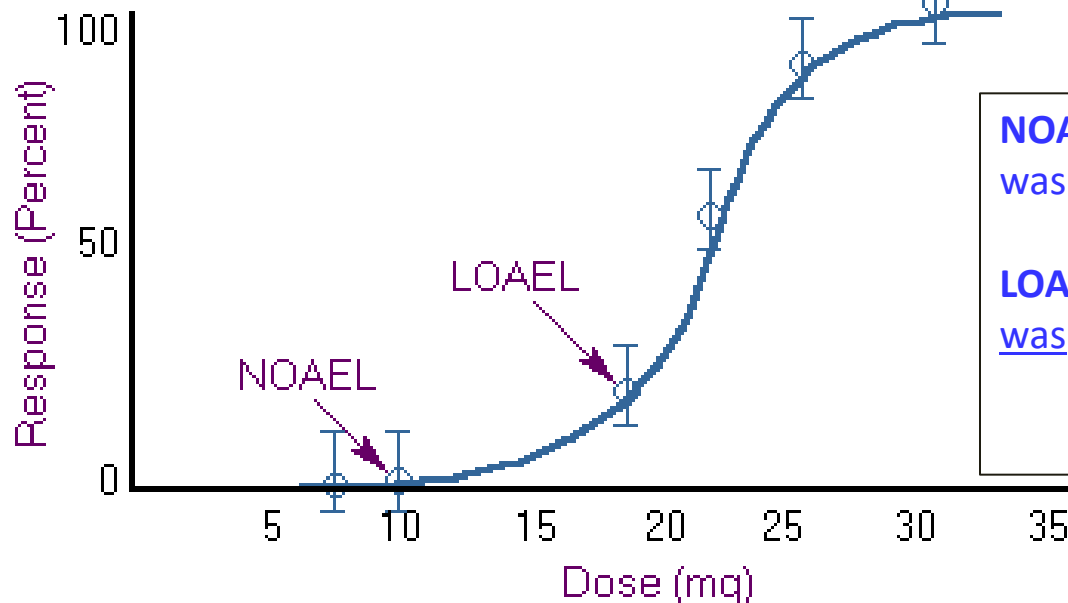
- Need to identify the critical effect in the safety data
 - Effect should be relevant for man
- No Observed Adverse Effects Level (NOAEL)
 - Dose that produced no adverse effects in the study.
 - Identifying the critical effect in the most sensitive species

1. Hazard Identification

3. Exposure Assessment

2. Hazard Characterisation

4. Risk Characterisation

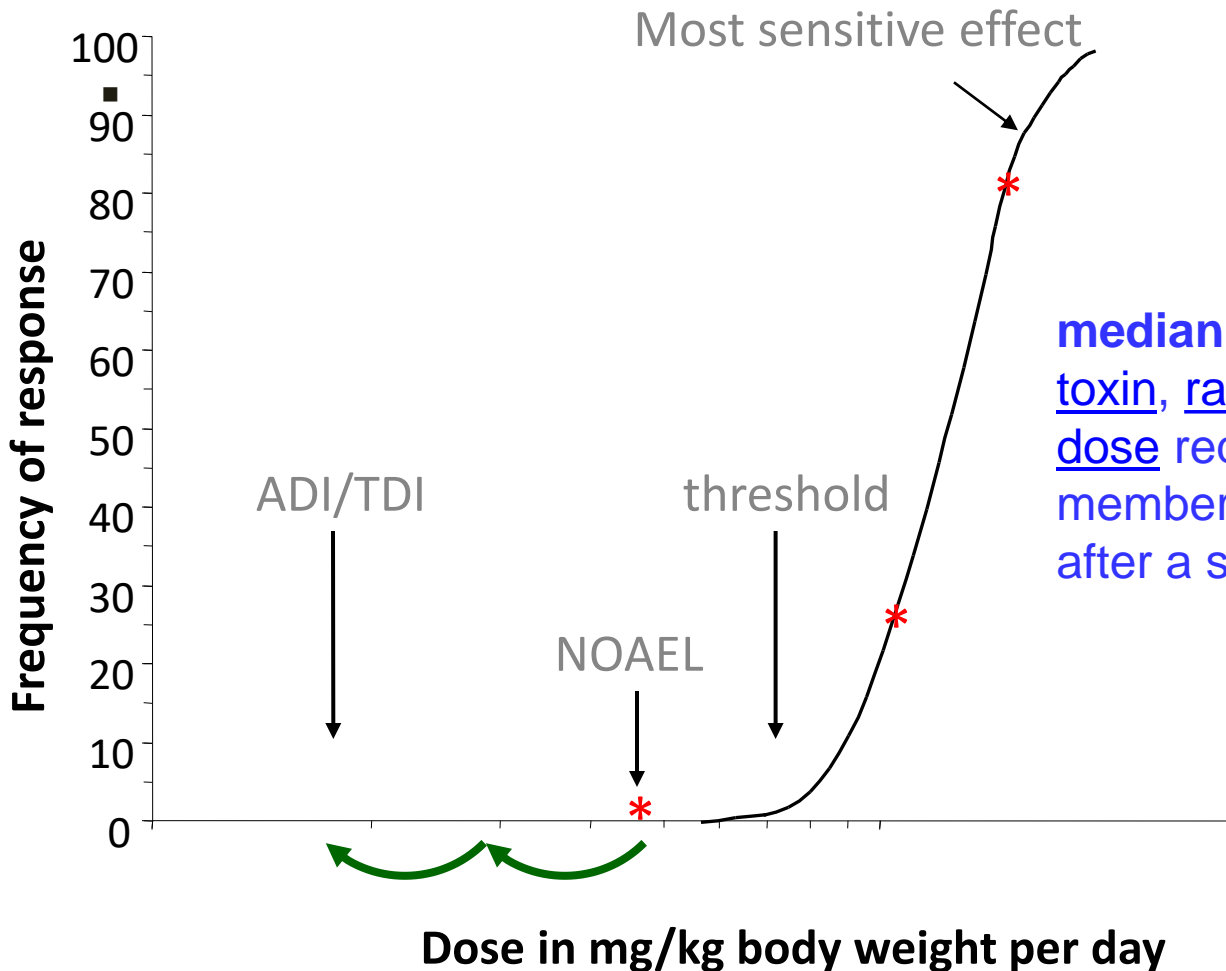


NOAEL: Highest data point at which there was not an observed adverse effect.

LOAEL: Lowest data point at which there was an observed toxic or adverse effect.

Exposure Assessment

Threshold Effects



median lethal dose, LD₅₀ of a toxin, radiation, or pathogen is the dose required to kill half the members of a tested population after a specified test duration

Salt LD-50 – 180 gm/day
Salt ADI – 6 gm/day

Risk Characterization

Risk = Hazard X Exposure

- Hazard – Severity
- Exposure: Probability

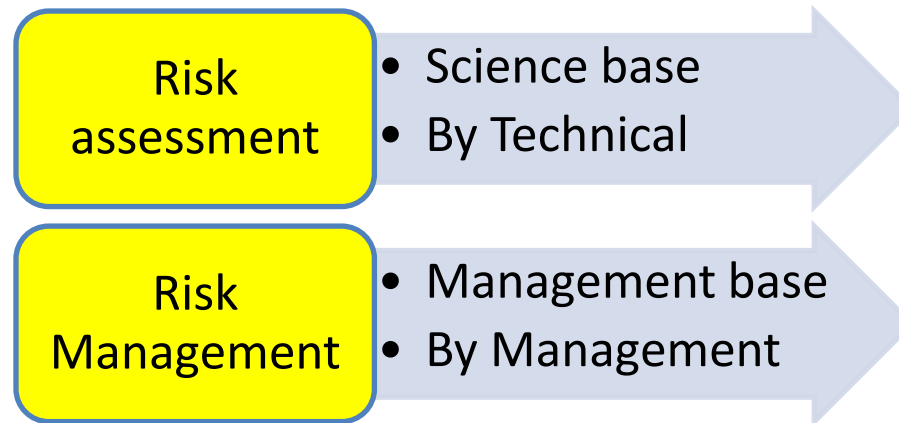
Risk Management

Risk
assessment

Risk
Management

Risk
Communication

- ❑ Risk Management is the process of choosing and implementing the appropriate prevention and monitoring measures.
- ❑ **Based on scientific risk evaluation to management solution**



Which are recent food safety issues?

- Carbonated beverage Pesticide
- Heavy metal in Chocolates
- Honey Purity
- ETO in Spices
- Export rejection of Indian sweets

Food Regulatory Challenges

- Cost of compliance
- Increased documentation
- HFSS food /Ultra Processed food : Image Vs Reality
- Claim substantiation : High cost in clinical
- Pesticide testing : Clarity
- Nutraceuticals as Pharmaceuticals
- Clean label pressure
- Allergen management across value chain

Food Regulatory Challenges

- GMO Vs Non GMO
- Active Regulators : Digital Monitoring
- Brand image Protection : Media Trials
- EU/CODEX copy for India
- Empowered consumers/NGO : Social Media
- Plastic regulation /EPR

Emerging Risks

Acrylamide	3 MCPD / GE	AMR	MOAH
Biogenic Amines	Pesticide Residues	PFAS /Microplastics	Mycobacterium paratuberculosis

VUCA world

- Volatile, Uncertain, Complex, Ambiguous
- Challenges are permanent today

Food Safety – Prepare for the Unexpected

- **Volatility**

- Frequent and unpredictable changes affecting the food industry (e.g., price fluctuations, supply chain disruptions).

- **Impact on Food Safety:** Challenges in maintaining consistent food safety standards during volatile periods.

- **Uncertainty**

- Lack of predictability and difficulty in forecasting future events

- (e.g., emerging foodborne pathogens, regulatory changes).

- **Impact on Food Safety:** Difficulty in planning and implementing long-term food safety strategies.

Food Safety – Prepare for the Unexpected

•Complexity

•Interconnected and multifaceted issues within the food supply chain (e.g., Import,, multi-tiered suppliers).

•**Impact on Food Safety:** Challenges in managing and monitoring the entire food supply chain effectively.

•Ambiguity

•Ambiguous and unclear situations that lack clarity (e.g., conflicting regulations, diverse consumer expectations).

•**Impact on Food Safety:** Difficulty in decision-making and policy implementation.

What is the Solution?

- Compliance is Hygiene
- Culture shift -
- Basics and Homework
- Strong Technical/Regulatory team
- Work with Association for long term agenda

**Way
Forward**





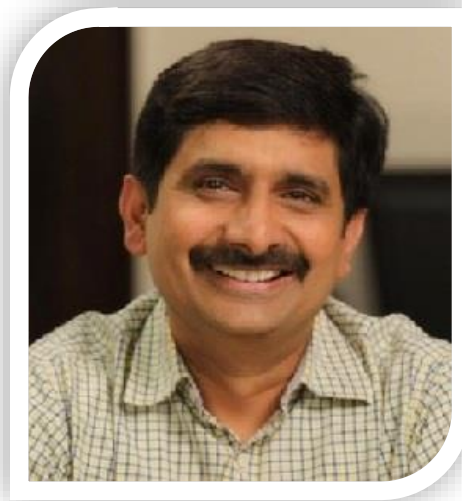
Positive participation



**Stay
United**

HOPES OF GOOD TOMORROW





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