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FOOD SAFETY AND STANDARDS  
AUTHORITY OF INDIA

*Inspiring Trust, Assuring Safe & Nutritious Food*  
Ministry of Health and Family Welfare, Government of India



# FSSAI –CHIFSS Orientation Workshop

## “Risk Assessment Framework Structure – Novel Foods and Additives”

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# NOVEL FOOD DEFINITION – EU\*

➤ 10 types of novel food; Cut-off date: 15 May 1997

1. New or intentionally modified molecular structure

Consisting of, isolated from or produced from:

2. Micro-organisms, fungi or algae

3. Material of mineral origin

4. Plants or their parts

5. Animals or their parts

6. Cell culture or tissue culture derived from animals, plants, microorganisms, fungi or algae

7. Food production process - significant changes in the composition/ structure, affecting its nutritional value, metabolism or level of undesirable substances

8. Engineered nanomaterials

9. Vitamins mineral and other substances produced using a new process

10. Food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements

# NOVEL FOOD DEFINITION – CANADA\*

A novel food:

- No history of safe use as a food; or
- Process that has not been previously applied to food and causes the food to undergo a major change; or
- Food derived from a genetically modified plant, animal or microorganism.

# NOVEL FOOD DEFINITION – FSSAI\*

- May not have a history of human consumption; or
- May have any ingredient used in it which, or the source from which it is derived, may not have a history of human consumption; or
- A food or ingredient obtained by new technology with innovative engineering process, where the process may give rise to significant change in the composition or structure or size of the food or food ingredients which may alter the nutritional value, metabolism or level of undesirable substances.

# EXAMPLES OF NOVEL FOODS

- New foods: e.g. phytosterols/phytostanols used in cholesterol reducing spreads
- Traditional foods eaten elsewhere in the world: e.g. chia seeds, baobab, noni juice
- Foods produced from new process: e.g. bread treated with UV light to increase level of vitamin D
- Vitamins produced using a new process: e.g. vit K from Antarctic Krill oil rich in phospholipids



# SUBSTANTIAL EQUIVALENCE

- Concept used to determine whether a new food shares similar health and nutritional characteristics with an existing, familiar food with an established history of safe use
- Is the starting point in the safety evaluation rather than the end-point
- Allows the safety evaluation to focus on where there are differences
- Recognises that existing foods often contain anti-nutrients that can be consumed safely e.g. potatoes (solanine) and tomatoes ( $\alpha$ -tomatine alkaloids)

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# HISTORY OF SAFE USE - DEFINITION

“significant human consumption of food (over several generations and in a large diverse population) for which there exists adequate toxicological and allergenicity data to provide reasonable certainty that no harm will result from the consumption of the food”

- Health Canada, 2003

# HISTORY OF SAFE USE

## - APPLIED TO THE SAFETY ASSESSMENT OF NOVEL FOODS

### Characterisation

- Biology (origin, genetic diversity)
- Geographic distribution
- Composition
  - Proximate analysis
  - Nutritional profile
  - Chemical hazards (toxicants, allergens, contaminants)
  - Bioactives

### Details of use

- Preparation & processing (fermentation, soaking, peeling, cooking)
- Purpose (food, supplement, pharmaceutical)
- Pattern of consumption
- Intake (ranges, populations)
- Known limitations of use (cultural practice, specific uses)

### Previous human exposure

- Which populations – diversity?
- Genetic background, age groups

### Health effects

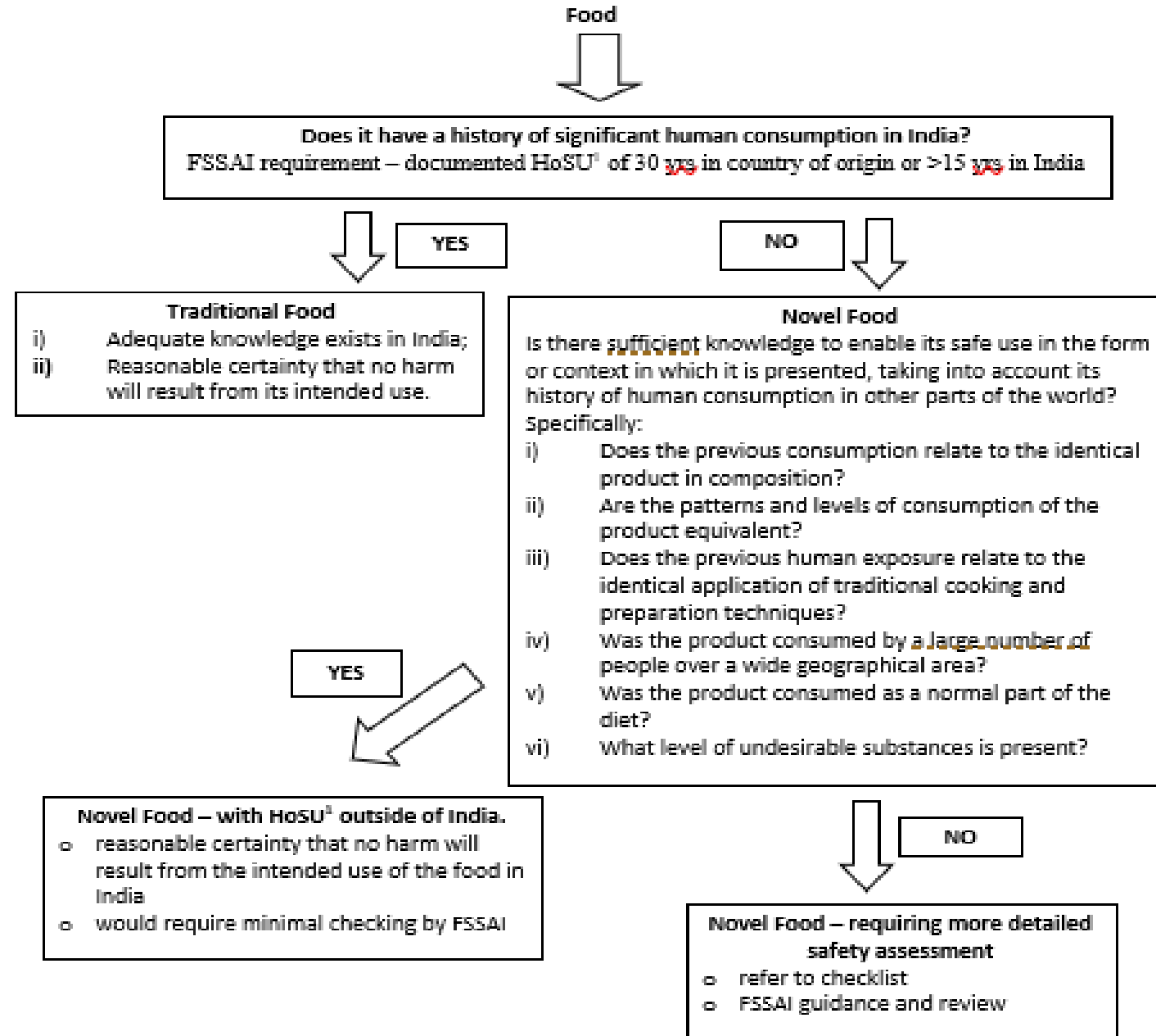
- Evidence from human exposure
  - Known adverse effects
  - Case reports
  - Known precautions
  - Over-consumption
  - Mis-use
  - Specific sub-populations

- **Potential hazards**

- Toxicology data
- Nutritional data
- Allergens
- Known contaminants
- Bioactives e.g. phytoestrogens



## NOVEL FOOD DECISION TREE FOR INDIA



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# CHECKLIST – GO TO DOCUMENT

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# CASE STUDIES – GO TO DOCUMENT

Thanks