



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

# Food Additives Regulations: Harmonization with CODEX

---

Sunil Bakshi  
Advisor (Codex/Regulations)  
FSSAI

# Food Safety & Standards Act, 2006

## - Objectives

1

- Consolidating multiple laws and establishment of single point reference system

2

- Establishing Food Safety and Standards Authority of India

3

- Regulating manufacture, storage, distribution, sale and import of food products

4

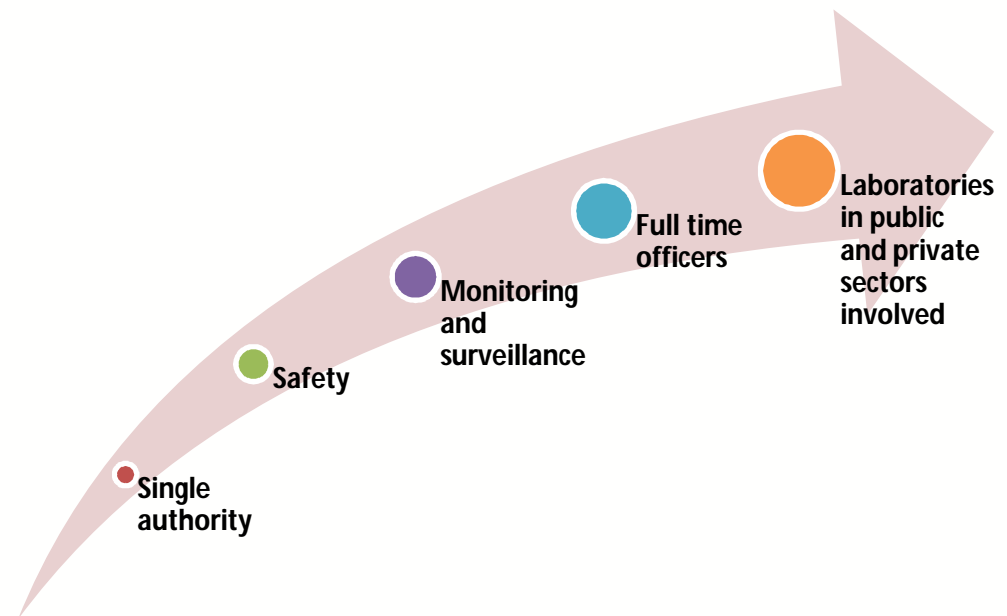
- Ensuring availability of safe and wholesome food for human consumption
- 

# Food Safety & Standards Act, 2006

- A leap forward

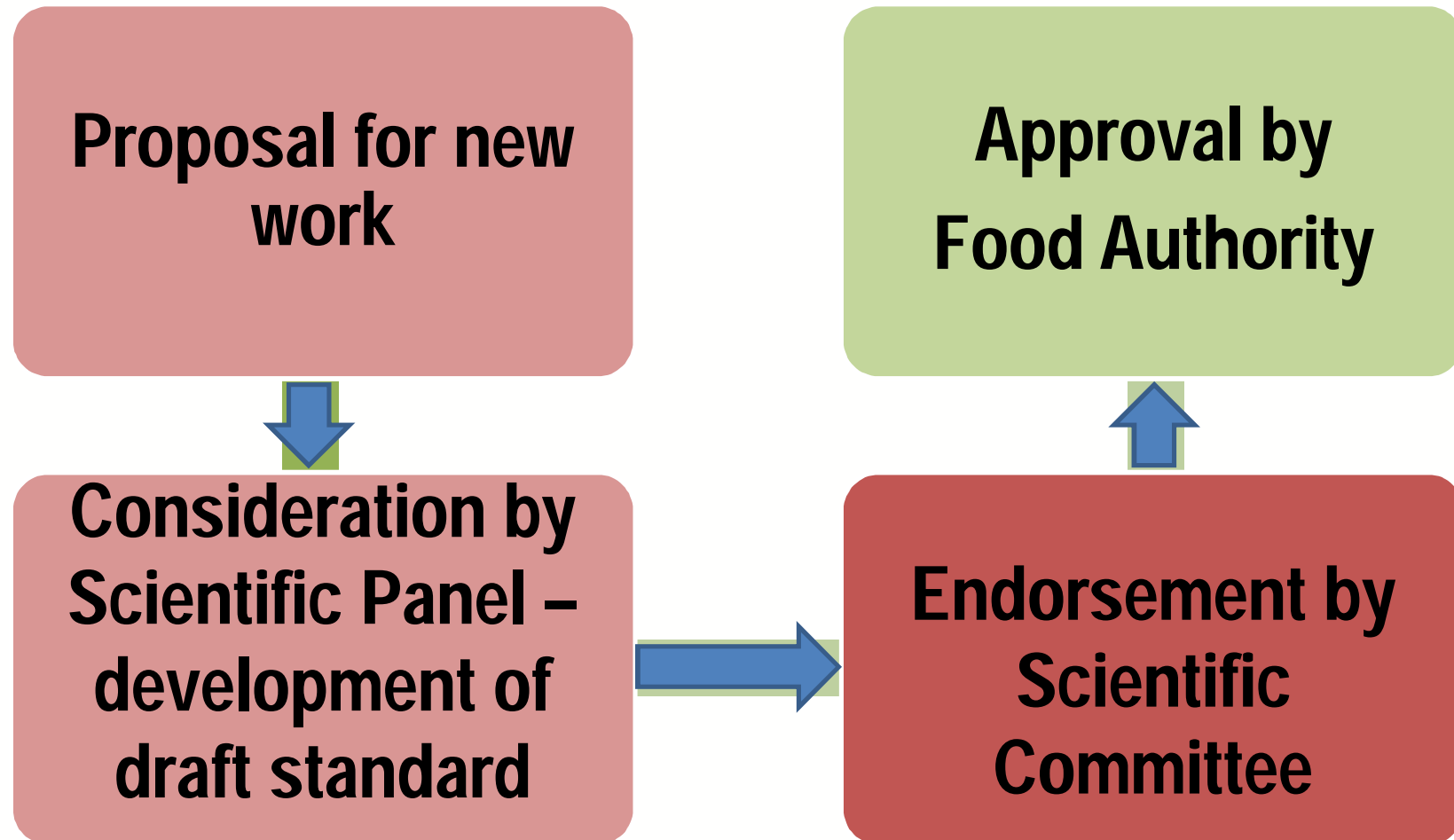


- Multilevel, multi dept. control to single line of command
- Single reference point
- Decentralization of licensing
- Transparent regulatory mechanism
- Investor friendly mechanism
- Adequate information dissemination
- Speedy disposal of cases
- Consistency between domestic and international food laws
- High degree of consumer confidence



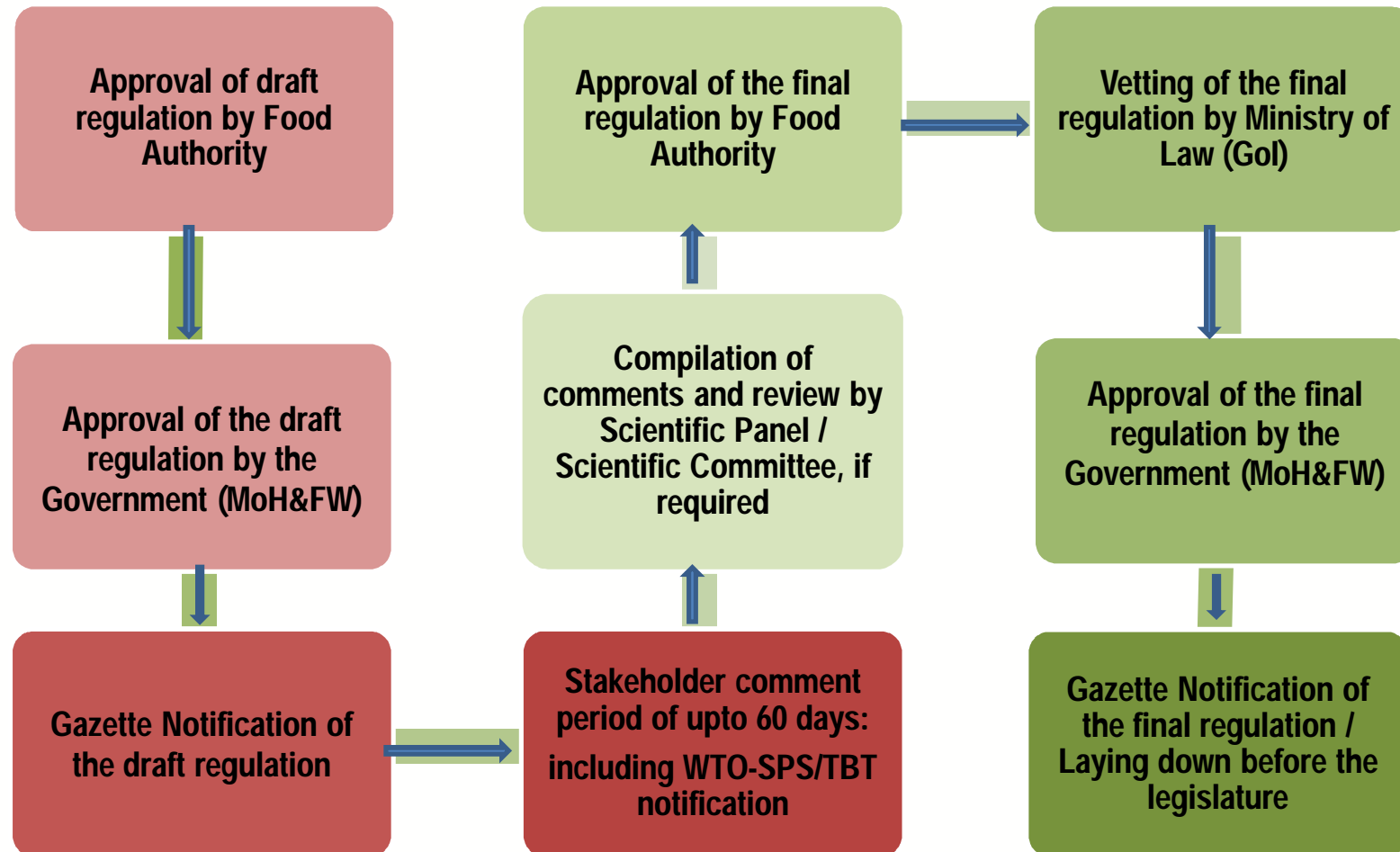
# Food Safety and Standards Authority of India

## - Standards development process



# Food Safety and Standards Authority of India

## - Procedure for framing regulations



# Food Safety and Standards Authority of India

## - Scientific Panels



Currently 17 scientific panels under the Food Authority exist on various subject matters consisting of independent scientific experts

- Functional foods, nutraceuticals, dietetic products and other similar products
- Method of sampling and analysis
- **Food additives, flavourings, processing aids and materials in contact with food**
- Contaminants in the food chain  
Biological hazards
- Pesticides and antibiotic residues
- Labelling and claims / advertisements
- Genetically modified organisms and foods
- Fortified foods

- Milk & milk products
- Meat & meat products, including poultry
- Cereals, pulses & legume and their products (including bakery)
- Fruits & vegetables and their products (including dried fruits and nuts salt, spices and condiments)
- Oils & fats
- Sweets, confectionery, sweeteners sugar & honey
- Water (including flavoured water) & beverages (alcoholic non-alcoholic)
- Fortified and enriched food
- Fish and fisheries products

## Food Safety and Standards Authority of India - Scientific Panels

### Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food - Mandate

Provide scientific advice on:

- ❖ use of food additives, flavourings, processing aids, and materials in contact with food;
- ❖ associated subjects concerning the safety of other deliberately added substances to food and
- ❖ questions related to the safety of the processes.

# Food Safety and Standards Act, 2006



## - Provisions for food additives

- 3 (1)(j) **“Food”** means **any substance**, whether processed, partially processed or unprocessed, which **is intended for human consumption** and includes primary food to the extent defined in clause (zk), genetically modified or engineered food or food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum, and any substance, including water used into the food during its manufacture, preparation or treatment .....
- (y) **“ingredient”** means **any substance, including a food additive** used in the manufacture or preparation of food and present in the final product, possibly in a modified form;
- (k) **“food additive”** means any substance not **normally consumed as a food by itself or used as a typical ingredient of the food**, ..... **the intentional addition of which to food for a technological (including organoleptic) purpose** in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food but does not include “contaminants” or substances added to food for maintaining or improving nutritional qualities;




# Food Safety and Standards Act, 2006

## - Provisions for food additives

### 19. Use of food additive or processing aid

No article of food shall contain any food additive or processing aid unless it is in accordance with the provisions of this Act and regulations made thereunder.

***Explanation.***— For the purposes of this section, “**processing aid**” means any substance or material, not including apparatus or utensils, and **not consumed as a food ingredient by itself, used in the processing of raw materials, foods or its ingredients to fulfil a certain technological purpose** during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.



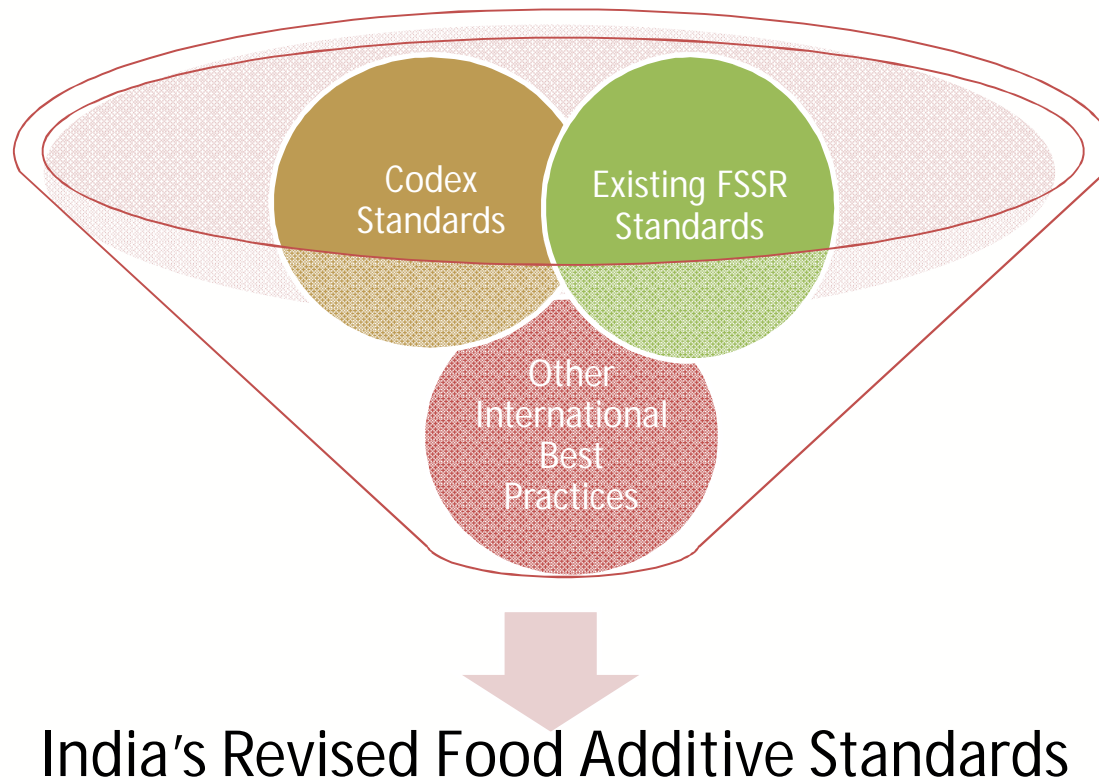
# Food Safety and Standards Regulations - Provisions for food additives



## Food Safety and Standards (Food Products Standards and Food Additives) Regulations 2011

- ✓ Sub-regulation 3.1 of the above regulations outlines:  
*“the provisions and requirements for the use of additives, flavourings, processing aids and materials in contact with food”*
  
- ❖ Initially additive provisions adopted from the erstwhile Prevention of Food Adulteration (PFA) Rules 1955.
  
- ❖ Additives provisions / standards rigid, Insufficient and not comprehensive, non-responsive to scientific advancements and modernization, .
  
- ❖ Additives provisions scattered / fragmented in identity standards as well as the compilation in Appendix –A of the FSS (FPS&FA) Regulations, 2011
  
- ❖ A comprehensive revision – imminent need

**Additives regulations were set on a course of revision, in harmonization with the Codex standards, given the archaic situation of the additives provisions and global advancements in this area**



# Food Safety and Standards Regulations

## - Provisions for food additives

Approach to harmonization: Basic criteria

- JECFA assessments
  - Our own assessment e.g. colours
- Additives historically used by the Indian industry.
- Codex provisions (Additives and their limits)
  - Exceptions: certain commodities
- OIV standards for alcoholic beverages
- Standards of identity and purity—JECFAS/BIS etc.

# Food Safety and Standards Regulations

## - Provisions for food additives

### Structure of the revised additives regulations (Regulation 3.1)

- **Food Additives**
  - **Definitions and explanations:** Food additive, ADI, Maximum use levels, justification for the use of food additives, GMP, specification for the identify and purity of food additives, carry over principle.
  - **Appendix-A**
    - I- Food Category system
    - II-Food Category Descriptions
    - III- functional classes, definitions and technological purposes
    - IV- use of food additives in food products (1-15 tables)
  - **Annexure-1**
    - 1. Group of additives
    - 2. notes to food additives
    - 3. GMP provisions for all categories
    - 4. annex to GMP table
  - **Other substances for use in food products:**

# Food Safety and Standards Regulations

## - Provisions for food additives

### Highlights of the revised FSS Additives Regulations

- ✓ The revised regulations, implemented in 2016, include:
  - ❖ 16 food categories covering all major food descriptions
  - ❖ Examples of Indian foods with more than 370 food additives allowed for use across different foods / food categories
  - ❖ Defines food additive, acceptable daily intake, maximum use level
  - ❖ Specifies that additives are added to serve the technological functions as provided under the regulations
  - ❖ Quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish the desired effect
  - ❖ Food additive shall be of food grade quality and should at all times conform to the applicable specifications of Identity and Purity recommended
  - ❖ Provision for carry-over of additive
  - ❖ Food additive Tables
  - ❖ Functional Classes of Additives
  - ❖ Restricted provisions

# Food Safety and Standards Regulations - Provisions for food additives



## Highlights of the revised FSS Additives Regulations:

### Food categories specified, further divided into sub-categories

1.0 Dairy products and analogues, excluding products of food category 2.0

2.0 Fats and oils, and fat emulsions

3.0 Edible ices, including sherbet and sorbet

4.0 Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds

5.0 Confectionery

6.0 Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares of food category 7.0

7.0 Bakery wares

8.0 Meat and meat products including poultry

9.0 Fish and fish products, including molluscs, crustaceans, and echinoderms

10.0 Eggs and egg products

11.0 Sweeteners, including honey

12.0 Salts, spices, soups, sauces, salads and protein products

13.0 Foodstuffs intended for particular nutritional uses (No additives for this category)

14.0 Beverages, excluding dairy products

15.0 Ready-to-eat savouries

16.0 Prepared foods

# Food Safety and Standards Regulations

## - Provisions for food additives

**Highlights of the revised FSS Additives Regulations:  
27 functional classes of additives specified**

Acidity Regulator	Flour treatment agent
Anticaking agent	Foaming agent
Antifoaming agent	Gelling agent
Antioxidant	Glazing agent
Bleaching agent	Humectant
Bulking agent	Packaging gas
Carbonating agent	Preservative
Carrier	Propellant
Colour	Raising agent
Colour retention agent	Sequestrant
Emulsifier	Stabilizer
Emulsifying salt	Sweetener
Firming agent	Thickener
Flavour enhancer	



# Food Safety and Standards Regulations *fssai*

## - Provisions for food additives

### Highlights of the revised FSS Additives Regulations:

#### Food additives Tables

- Table for food additives provisions in different food categories
  - ❖ Individual additives provisions
  - ❖ Group additives provision - Detail of additives covered under that groups also provided.
- GMP table lists out additives permitted across all food categories at GMP (exceptions listed in annexure to GMP table)
- Notes - listed numerically highlighting special conditions

# Food Safety and Standards Regulations - Provisions for food additives



## Highlights of the revised FSS Additives Regulations:

### The food category system - Hierarchical approach

- ❖ when an additive is specified for use in the main category, it is recognised for use in all its sub-categories, unless otherwise stated
- ❖ when an additive is recognised for use in a sub-category, its use is recognised in any further subcategories or individual foodstuffs mentioned in a sub-category

\*These regulations also provides

- ❖ indicative examples for each food category
- ❖ recommended maximum use level of additive in different categories

# Food Safety and Standards Regulations - Provisions for food additives



## Highlights of the revised FSS Additives Regulations:

### Provision for carry-over of additive

*“A **carry over additive** is the one present in a food, other than by direct addition, as a result of carry-over from a raw material or ingredient used to produce that food”*

The Additives regulations allows carry-over additives with certain conditions:

- ❖ the additive is acceptable for use in the raw material or other ingredients (including additives) in accordance with the provisions of these Regulations;
- ❖ the amount of the additive in these does not exceed its specified maximum use level;
- ❖ the food itself does not contain the carry over additive in a quantity greater than that shall be introduced by the use of raw material, or ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of these regulations

Exception: Food categories namely *Infant formulae, follow-up formulae, and formulae for special medical purposes for infants, and Complementary foods for infants and young children* unless a food additive provision is specifically mentioned.

# Food Safety and Standards Regulations

## - Provisions for food additives

### Highlights of the revised FSS Additives Regulations:

#### Restricted provisions

Prohibited list of flavours from use in any article of food (Regulation 3.3.1(4)):

- ❖ Coumarin and dihydrocoumarin;
- ❖ Tonkabean (Dipteryl adorat);
- ❖  $\beta$ -asarone and cinamyl anthracilate
- ❖ Estragole
- ❖ Ethyl methyl ketone
- ❖ Ethyl-3-phenylglycidate
- ❖ Eugenyl methyl ether
- ❖ Methyl  $\beta$  naphthyl ketone
- ❖ p-Propylanisole
- ❖ Saffrole and isosaffrole
- ❖ Thujone and isothujone ( $\alpha$  &  $\beta$  thujone)




# Food Safety and Standards Regulations

## - Provisions for food additives

### **Highlights of the revised FSS Additives Regulations:** Other substances for use in food products

The regulations also cover standards for other substances for use in food products, namely


- ❖ Flavouring agents and related substances
  - ❖ Lactulose syrup
  - ❖ Oligofructose
  - ❖ Trehalose
  - ❖ Phyto or Plant Stanol
  - ❖ Phyto or Plant Sterol
- 



# Food Safety and Standards Regulations

## - Provisions for food additives

### Current and future work:

- ✓ **Four other amendments** are at various stages of notification and several are operationalized on 30.06.2017 and 20.12.2017 till final notification
  - ✓ **Specification of these food additives** is equally important, quality standards of approximately 46 food additives were adopted from BIS. The standards for all the remaining food additives may also be taken in due course of time
  - ✓ FSSAI is in the process of **developing separate regulations on processing aids** including enzymes and other categories of processing aids as outlined in Codex inventory for processing aids
  - ✓ Currently, FSSAI is also reviewing the **regulations related to sweeteners, food colours and flavours**
- 



# Food Safety and Standards Regulations

## - Provisions for food additives

### **Benefits of Harmonisation**

Harmonisation of FSS food additives regulations with the Codex standards and other relevant international standards/practices has paved way for:-

- Flexibility for innovation by food processing industry;
- reduced burden on the food regulator in terms of approving new food additives/food additive provisions;
- removal of technical barriers to international trade as regards the use of food additives.



**THANK YOU**

