



WORLD TRADE CENTRE
MUMBAI

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ASSOCIATION OF
INDUSTRIES

Interactive session on

'Innovative Food Products in India - Regulators Role'

For better understanding of the Policy, Regulation, Safety Measures and recently introduced Acts

Prabodh Halde
Head –TRA MARICO Ltd.

**Food safety & standards regulations – impact to
industry and way ahead**

24th January 2015

What we will cover

- Indian Food Industry
- Transition from PFA to FSSAI
- FSSA / FSS REGULATIONS.
- Licensing and Registration
- Impact on Industry
 - Compliance and penalties
- Way Forward

- **Indian Food Industry**

An overview of Indian Agriculture

(Production side)

- Second largest arable land in the world
 - Diverse agro-climatic zones across the country,
 - Round the year sunshine
 - Potential to cultivate a vast range of agricultural products
 - Large marketable surpluses and abundant raw material for processing
 - Vast pool of skilled manpower in research and extension
- ❖ These advantages being leveraged, for India to be a leading food supplier to the world.

An overview of Indian Agriculture

	India	India's Rank in World Production
Arable Land (Million ha)	151	2
Irrigated Land (Million ha)	55	1
Wheat	72	2
Rice, Paddy	124	2
Coarse grains (including maize)	29	3
Milk	91	1
Fruits	47	2
Vegetables	82	2
Edible Oilseeds	25	3
Pulses	15	1
Sugarcane	245	2
Tea	0.85	1
Cattle (million)	186	2

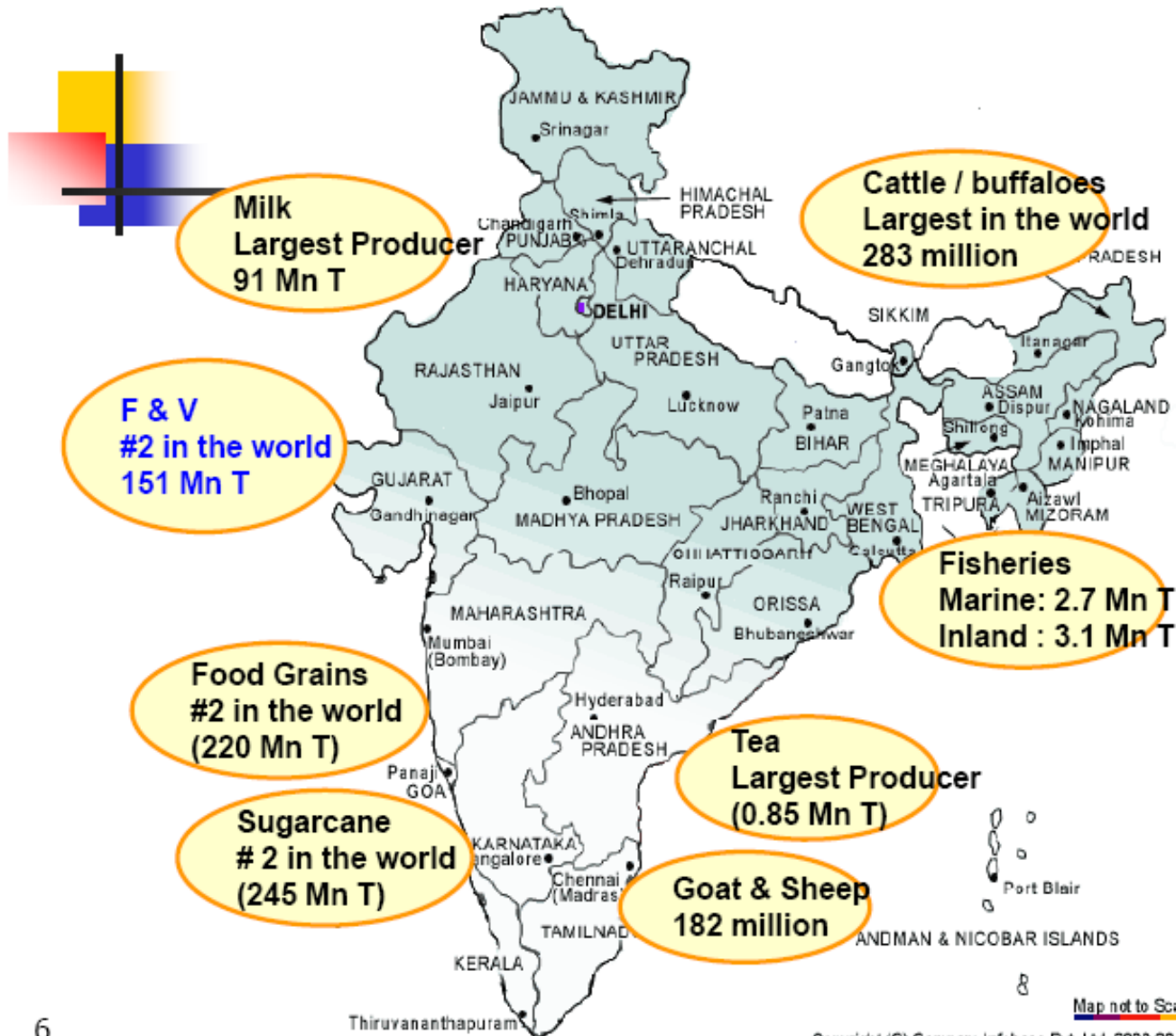
India is the front ranking producer of many perishable commodities

China : \$195 bn; USA : \$150 bn; India - \$105 bn.

India produces

- » 41% of world's mango,
- » 23% of Banana,
- » 24 % of cashew nut,
- » 10% of onion,
- » 30% of cauliflower,
- » 36% of Green Peas.

India is the front ranking producer of many perishable commodities



Food processing still at a nascent stage

Level of processing (Fruits & Vegetables)

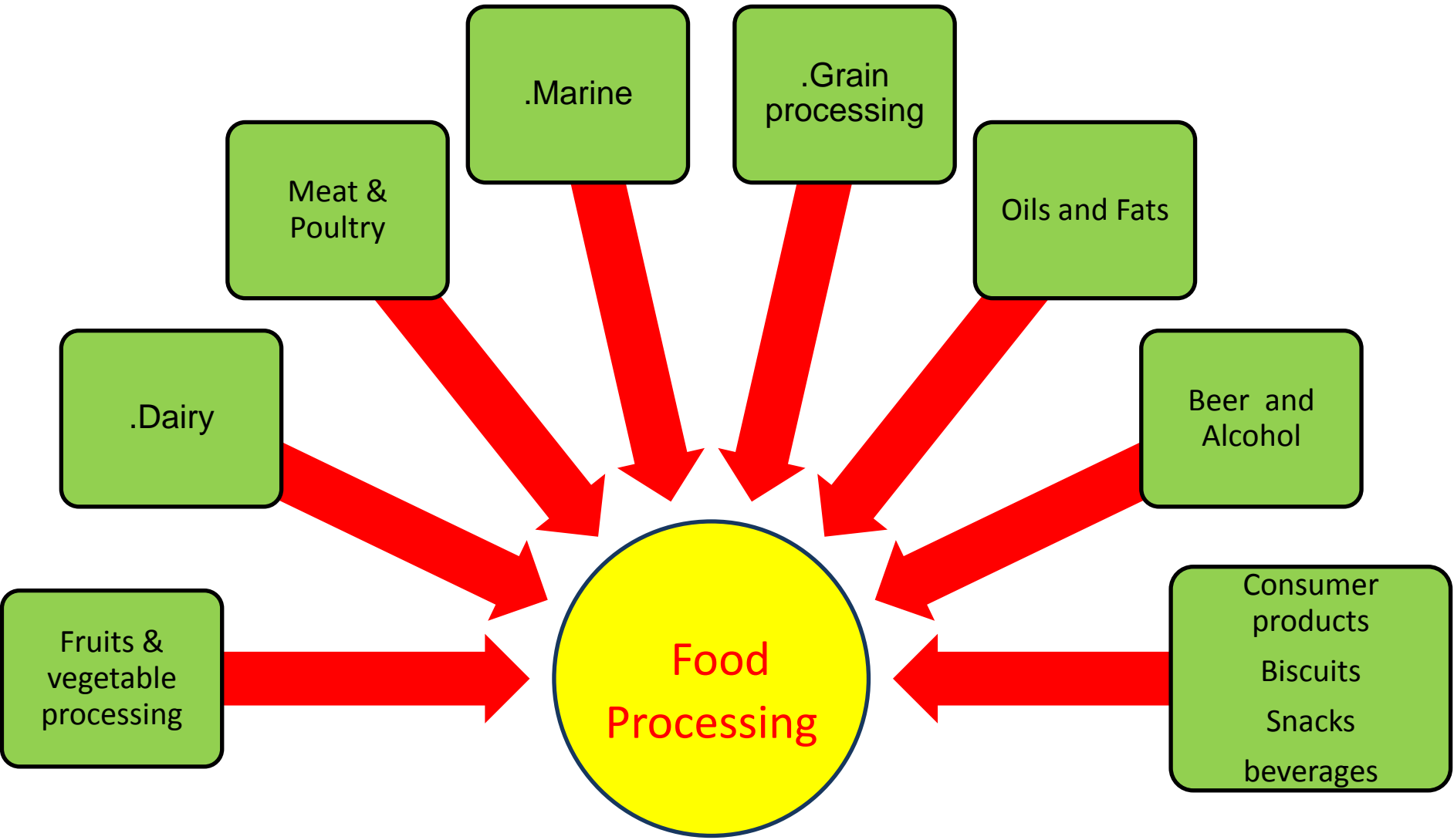
USA -	80 %
France -	70 %
Malaysia-	80 %
Thailand-	30 %
India -	3 %

Level of Processing (Perishable products)

	<u>Organized</u>	<u>Unorganized</u>	<u>Total</u>
Fruits / Vegetables	1.3%	0.8%	2.2%
Milk /milk products	13%	22%	35%
Buffalo Meat	21%	-	21%
Poultry	6%	-	6%
Marine Products	8%	15%	21%

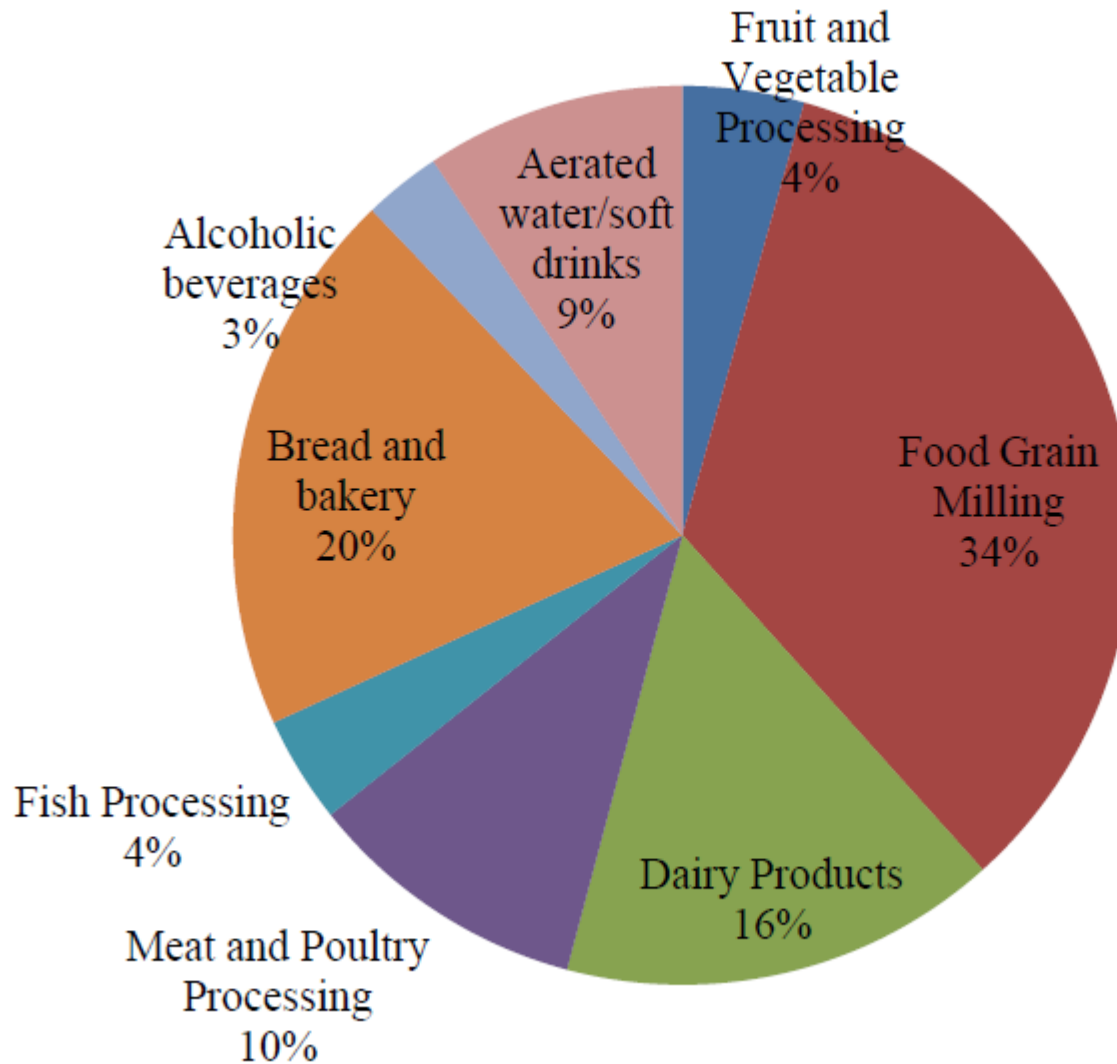
Good scope for food processing

Food processing sector



PRESENT VALUE 4 LACS CRORE

Major Segments in Food Processing Industry



PFA to FSSA

Food Legislation – Milestones in India

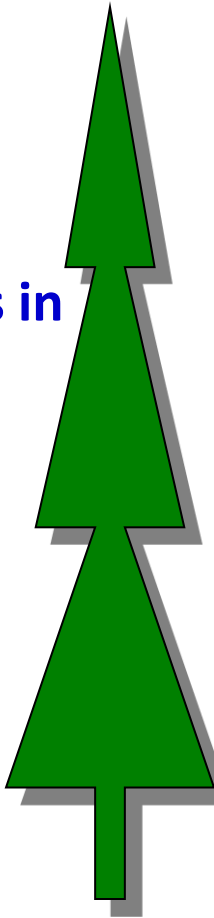
1899 : States' / Provinces' own food laws with difference in standards for the same commodity --
Conflicts in inter provincial trade.

1943 : Central Advisory Board for Central Legislation that brings in uniformity throughout the country.

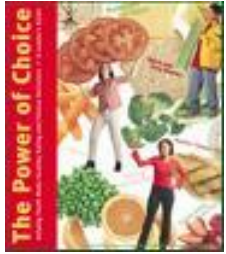
1954 : Central Legislation –
Prevention of Food Adulteration Act, 1954.
Rules and Standards framed under the Act 1955.

2006: FOOD SAFETY & STANDARDS ACT – 2006.

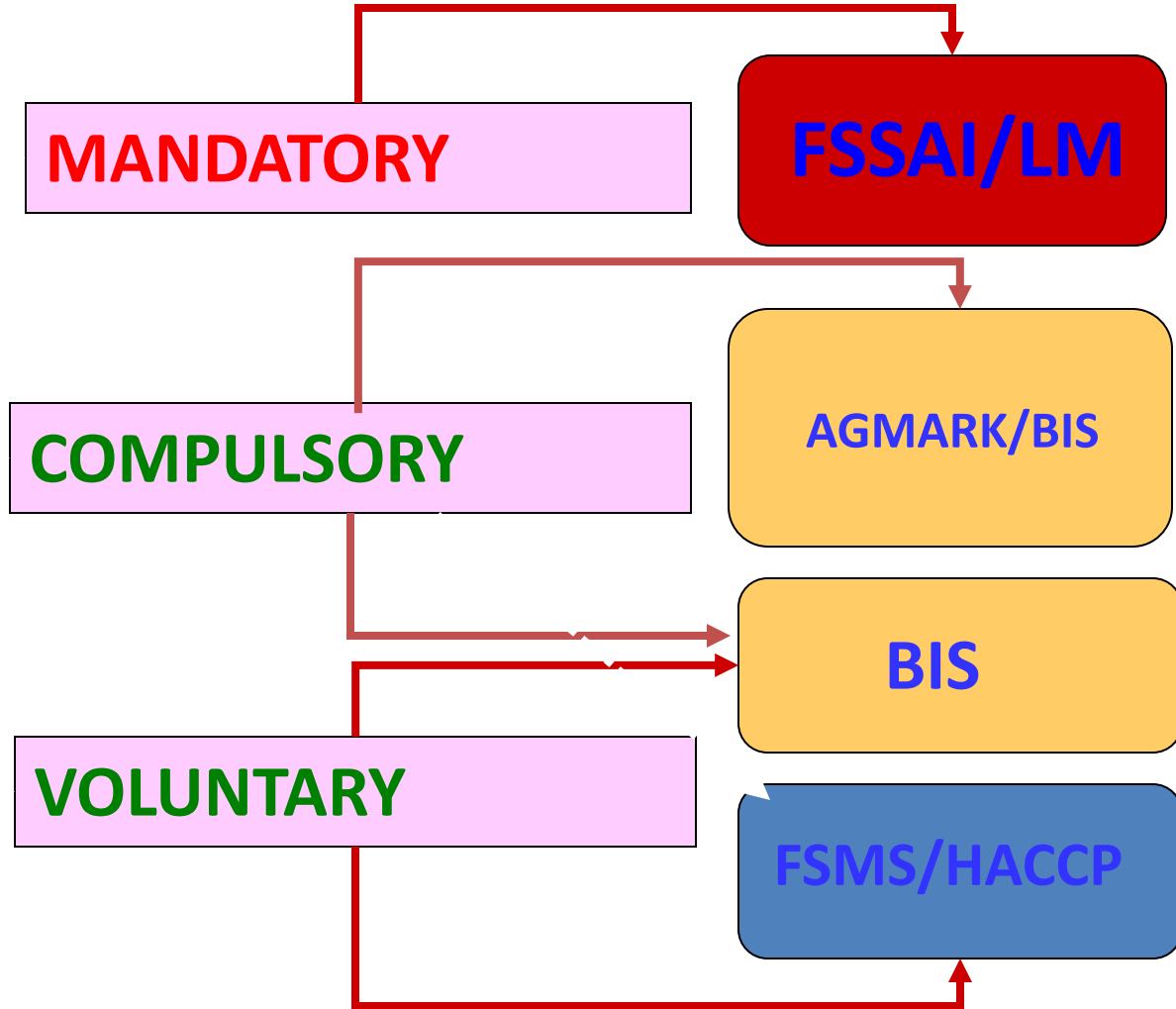
2011 : FSSR



Present Food Regulatory/Certification System



**FOOD LAWS
(INDIA)**





1955

PFA



2006

FSSAI

MODI Mantra -

Minimum Government, Maximum Governance

I believe government has no business to do business. The focus should be on **Minimum Government but Maximum Governance.**

- There is need to review the role of **central regulatory commissions and authorities** to ensure that they serve the nation's interests

Ease of doing business in India is a prime concern for you and us. **I assure you that we are working very seriously on these issues**

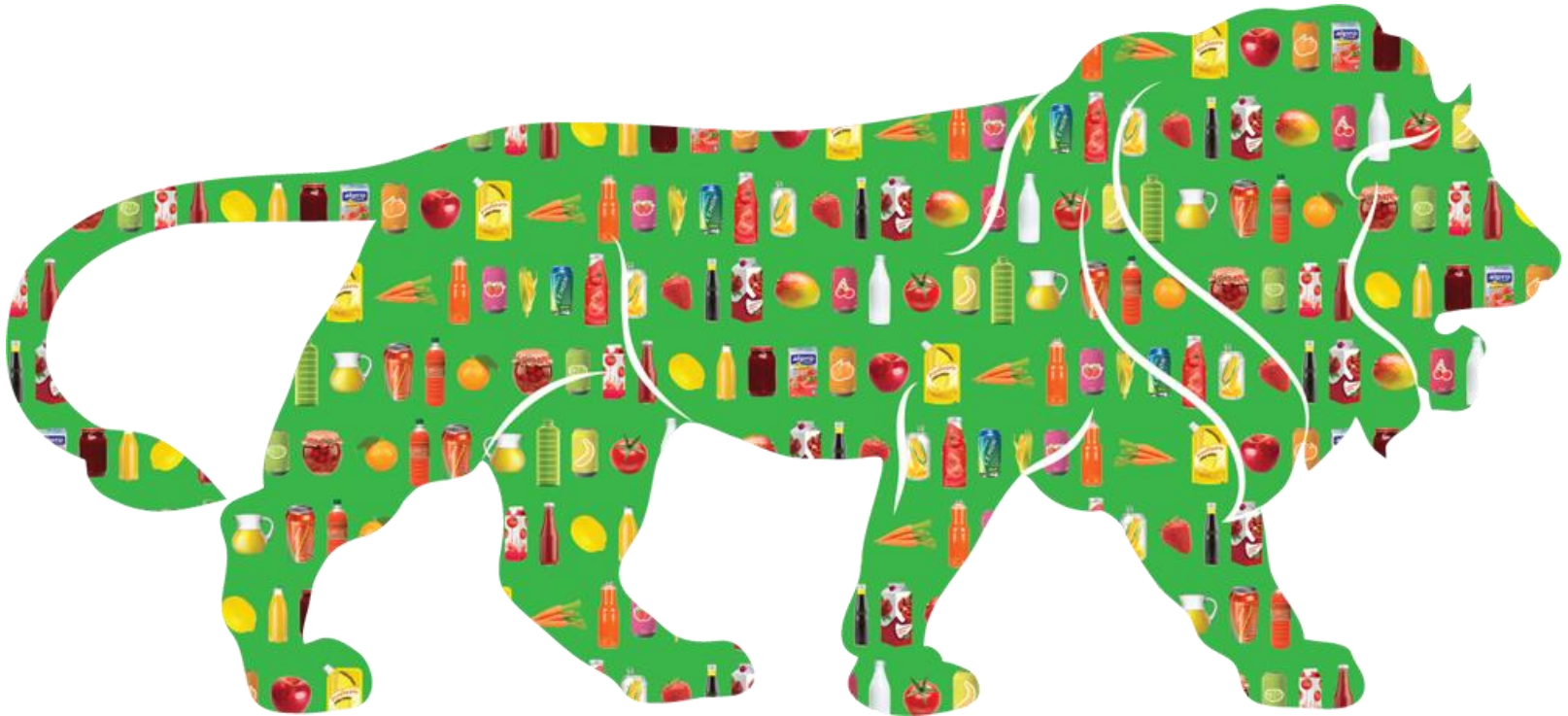
Government of India is working towards **single window clearance** at the Federal and State levels

I tell the world, 'Make in India'. Sell anywhere **but manufacture here.** We have the skill and talent for it,

There is no need to leave the nation. **We want our companies to shine as multinational companies,**"



MAKE IN INDIA – Regulatory Role





Food Safety and Standards Authority of India

भारतीय खाद्य संरक्षा एवं मानक प्राधिकरण



Search in FSSAI



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E-office



Contact us

About FSSAI

Legislation

Outreach

Media Center

RTI

States Food Safety

FSSAI Helpline

Designated Officer - Central Licensing

What's New

Announcements

Meetings

Advisories

Notifications

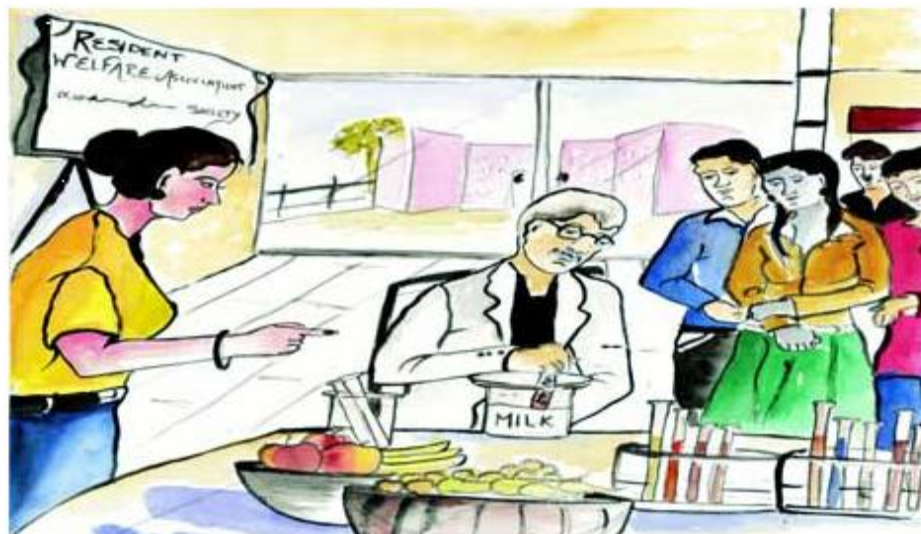
Draft For Consultations

Science in FSSAI

Imported Food

Int. Co-operation

Codex



The Food Safety and Standards Authority of India has been established under the Food Safety and Standards Act, 2006 as a statutory body for laying down science based standards for articles of food and regulating manufacturing, processing, distribution, sale and import of food so as to ensure safe and wholesome food for human consumption.....

Update

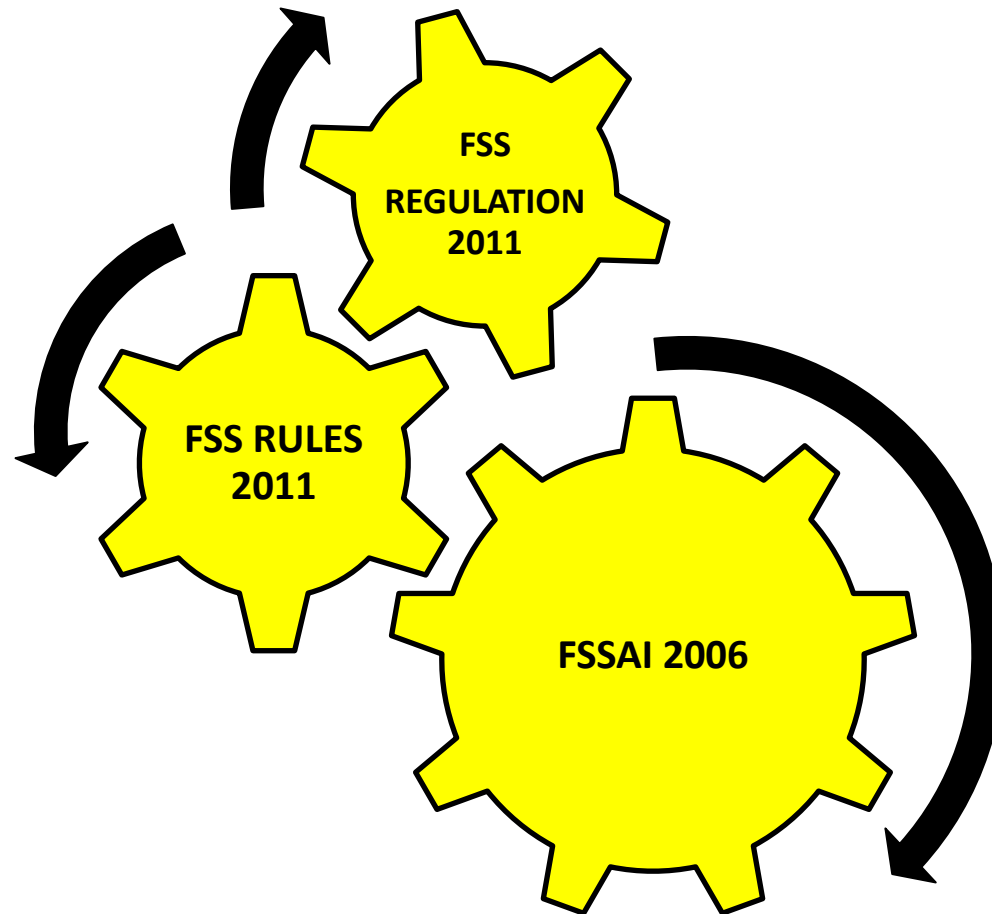
Preparation of Demand Draft against Payment for the testing of Samples of Imported Food Articles by Laboratories notified by FSSAI - Reg (17-11-2011) .

Clarification regarding standard of Infant Formula for Authority's Website (16-11-2011).

Limited Tender Enquiry for printing of FSSAI Diary 2012. Dated:(15-11-2011)

Training Programme of Designated Officers from 15-11-2011 to 18-11-2011 at Gujrat - Reg. Dated:(15-11-2011)

Legislative Frame



Objectives of FSSAI

W

- To consolidate the laws relating to food
- To establish food safety and standards authority of India for laying down science based standards for articles of food

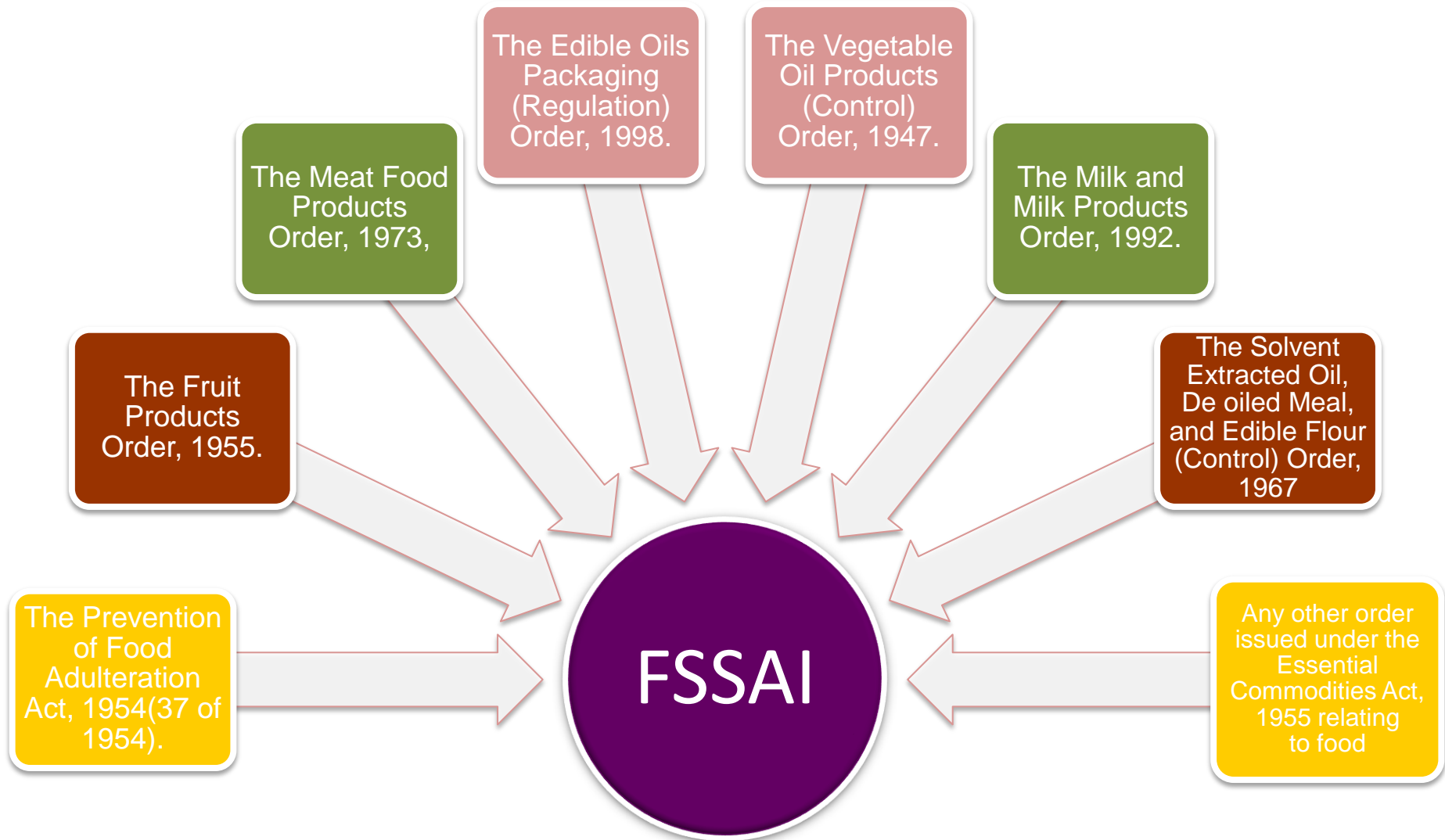
H

- To regulate the manufacture, storage, distribution, sale and import of food products

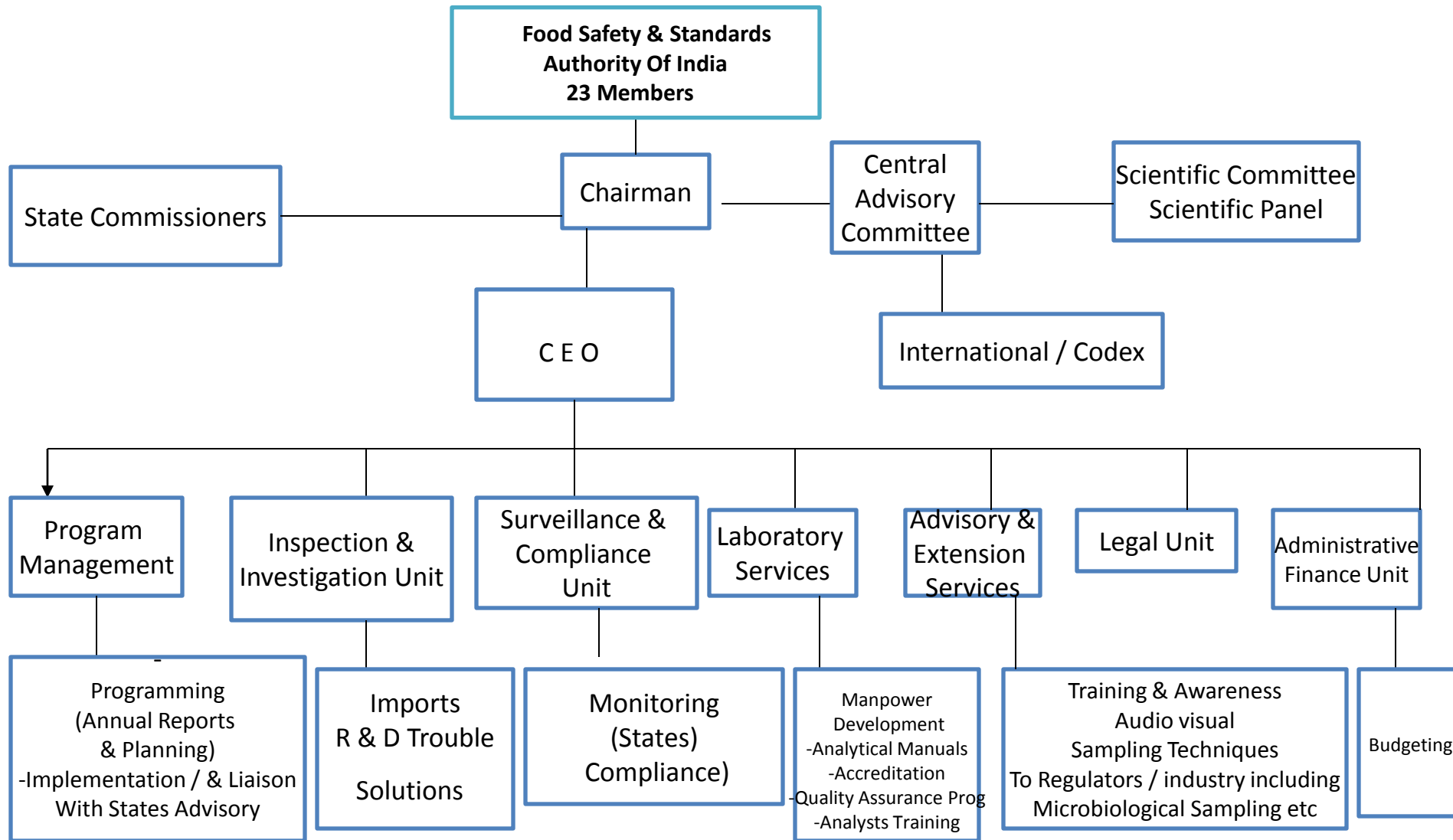
Y

- To ensure availability of safe and wholesome food for human consumption

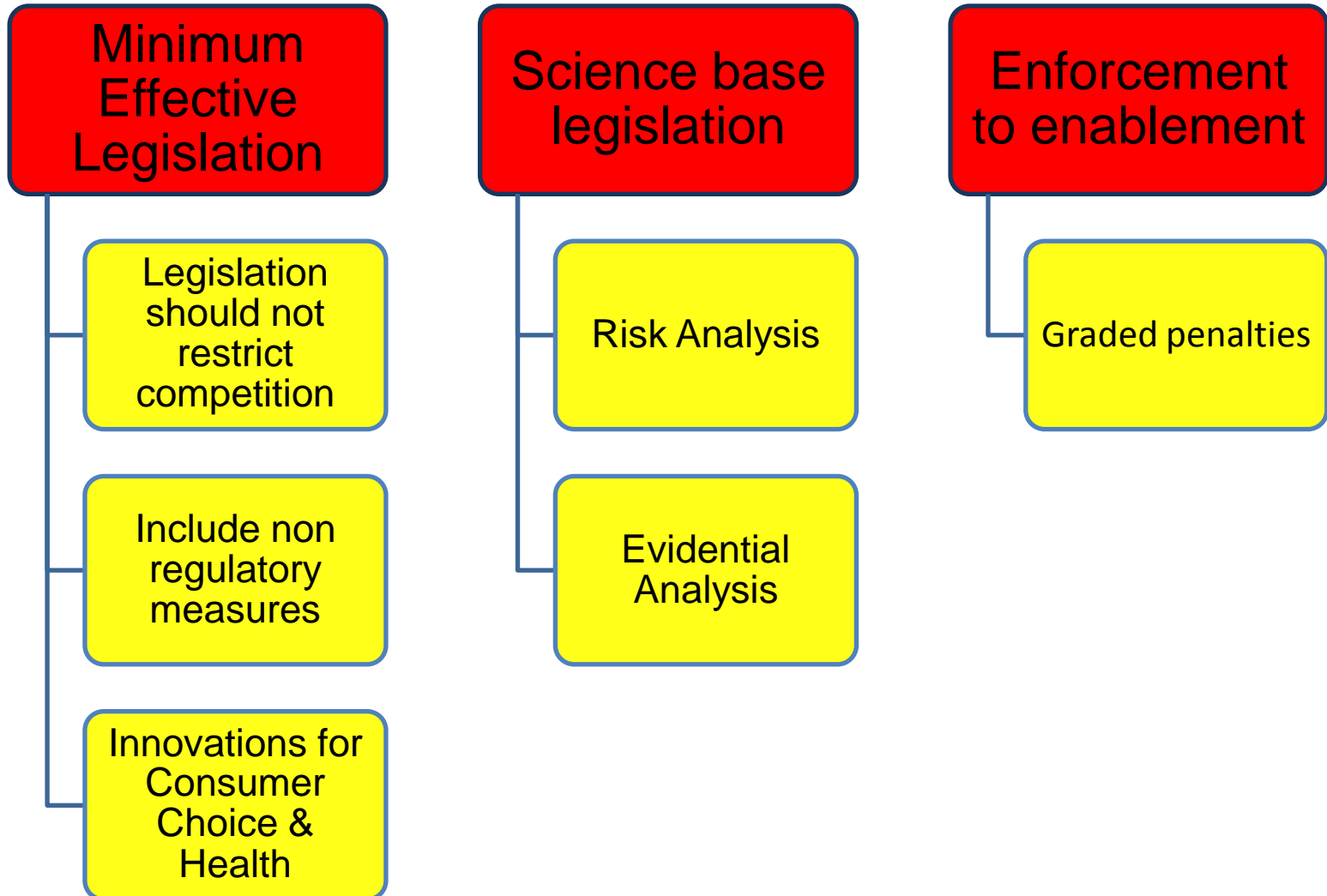
FSSAI replaces the following acts :



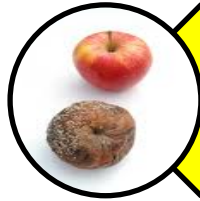
FSSAI STRUCTURE



Where is the emphasis :



Salient features



Defines the concept of “**substandard**” and “**unsafe food**”;



emphasizes on the need on risk assessment; not trade restrictive



Provisions relating to **functional and novel food**



Prescribes graded penalties for offenses/violations



Improvement notices

Risk Characterization

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$

- **Hazard (including sensitive populations)**
- **Exposure:**
 - Which Foods
 - Quantitative

Regulatory Mechanism



Central Advisory Committee



Scientific Panels



Scientific Committees



Food Authority and the State
Foods Safety Authority

Food Safety and Standards Rules, 2011

1. General

1.1 Title and commencement

1.2 Definitions

2. Enforcement structure and procedures

2.1 Qualifications and duties

2.2 procedure of taking extracts of documents and matter connected therewith

2.3 seizure of articles of food by the food safety officer and matter connected therewith

2.4 Sampling and Analysis

2.5 Nomination by company in the prescribed Performa

3. Adjudication and appeal to tribunal

3.1 Adjudication proceedings

3.2 Appellate Tribunal

3.3 Procedure for Appeal to Appellate Tribunal

FSS Regulations – Chapters



1. General-- Mainly Definitions
2. Licensing and Registration of food business
3. Packaging and Labeling regulations
4. Food Safety and Standards (Food Product and Food Additives)
5. Substances added to food
6. Prohibition and Restriction on sales
7. Contaminants, Toxins and Residues
8. Laboratory and Sample Analysis

Packaging



Packaging Requirements

General Requirements

- Following materials/metals shall not be used for packaging of food-
 - containers which are rusty
 - enameled containers which have become chipped and rusty
 - copper or brass containers which are not properly tinned
 - containers made of aluminium not conforming in chemical composition to IS:20 specification for Cast Aluminium & Aluminium Alloy for utensils or IS:21 specification for Wrought Aluminium and Aluminium Alloy for utensils

Packaging Requirements

Containers made of plastic materials should conform to-

- IS : 10146 Specification for Polyethylene in contact with foodstuffs)
- IS : 10142 Specification for Styrene Polymers in contact with foodstuffs)
- IS : 10151 Specification for Polyvinyl Chloride (PVC), in contact with foodstuffs)
- IS : 10910 Specification for Polypropylene in contact with foodstuffs)
- IS : 11434 Specification for Ionomer Resins in contact with foodstuffs)
- IS: 11704 Specification for Ethylene Acrylic Acid (EAA) copolymer
- IS: 12252 Specification for Poly alkylene terephthalates (PET)
- IS: 12247 Specification for Nylon 6 Polymer
- IS: 13601 Ethylene Vinyl Acetate (EVA)
- IS: 13576 Ethylene Metha Acrylic Acid (EMAA)

Label

- 'Label' means any tag ,brand, mark, pictorial or other descriptive matter written, printed, stenciled, marked, embossed, graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package and includes a product insert

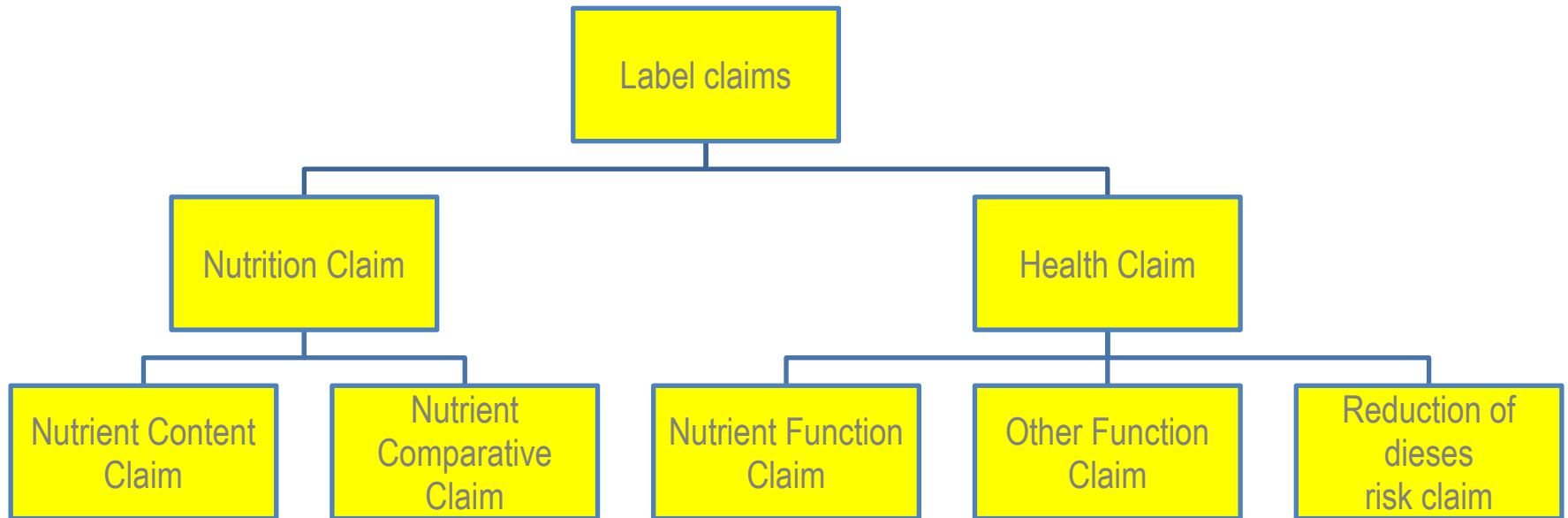
Label Must Carry...

- Name of the food
- List of ingredients in descending order
- Nutritional information
- Name and complete address of manufacturer
- Net content by weight or Volume
- Lot no/Batch identification
- Date of Manufacturing /Packing
- Best Before Date
- Veg logo of appropriate dimensions

Nutritional Labeling

Nutrition Information	
Amount per 100g of product	
Energy	# kcal
Protein	# g
Carbohydrates Sugars	# g
Fat	# g
Saturated fatty acids	# g
Polyunsaturated fatty acids	# g
Monounsaturated fatty acids	# g
Trans fatty acids	# g
Cholesterol	# mg

Claim Classification



•Licensing/Registration of Food Business

Licensing and Registration of Food Business

Registering Authority

Food Safety Officer or any official in Panchayats, Municipal Corporation or any other local body in an area, notified as such by the State Food Safety Commissioner for the purpose of registration

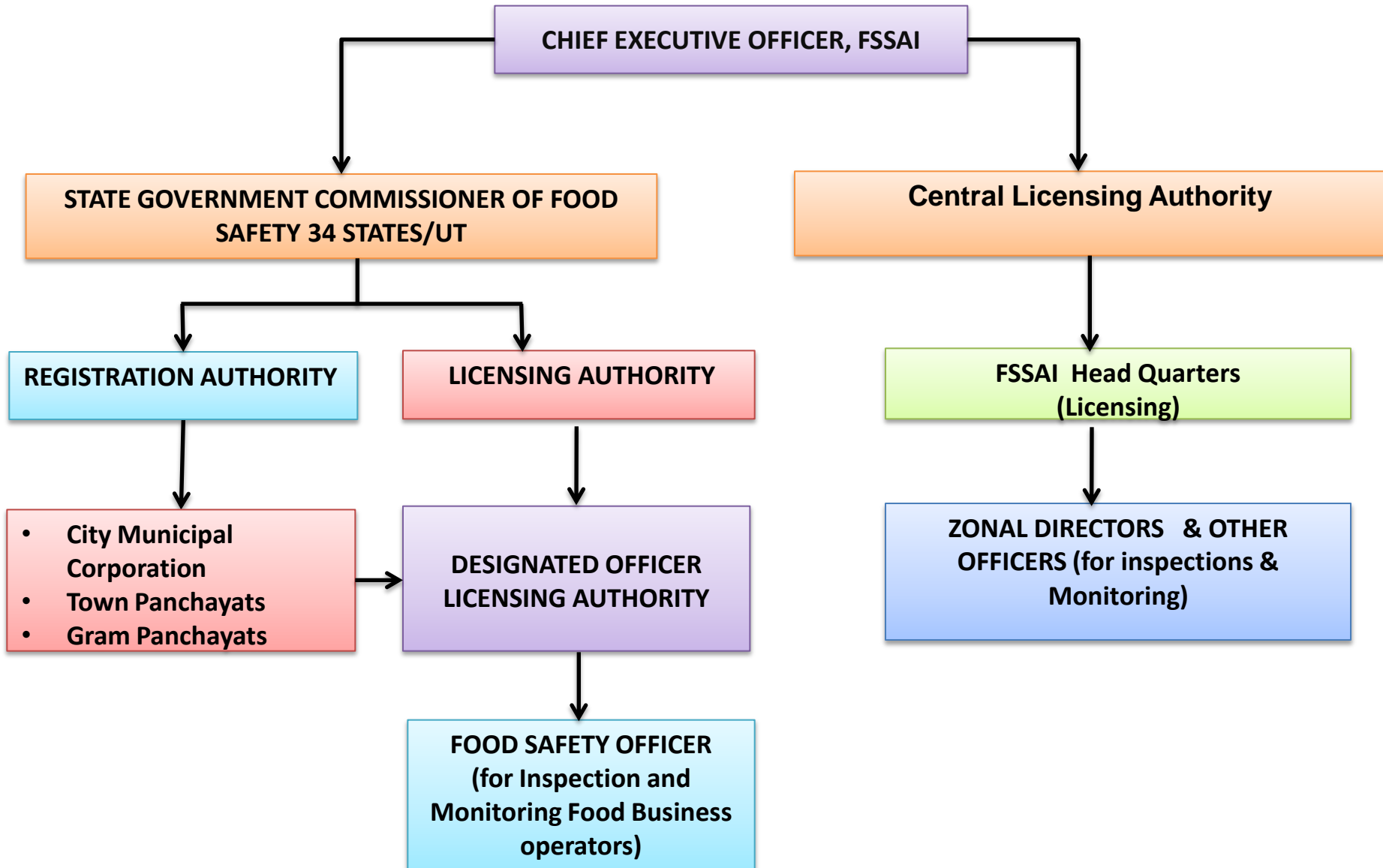
State Licensing Authority

Designated Officers appointed under Section 36(1) of the Act by the Food Safety Commissioner of a State or UT for the purpose of licensing and monitoring.

Central Licensing Authority

Designated Officer appointed by the Chief Executive Officer of the Food Authority of India in his capacity of Food Safety Commissioner

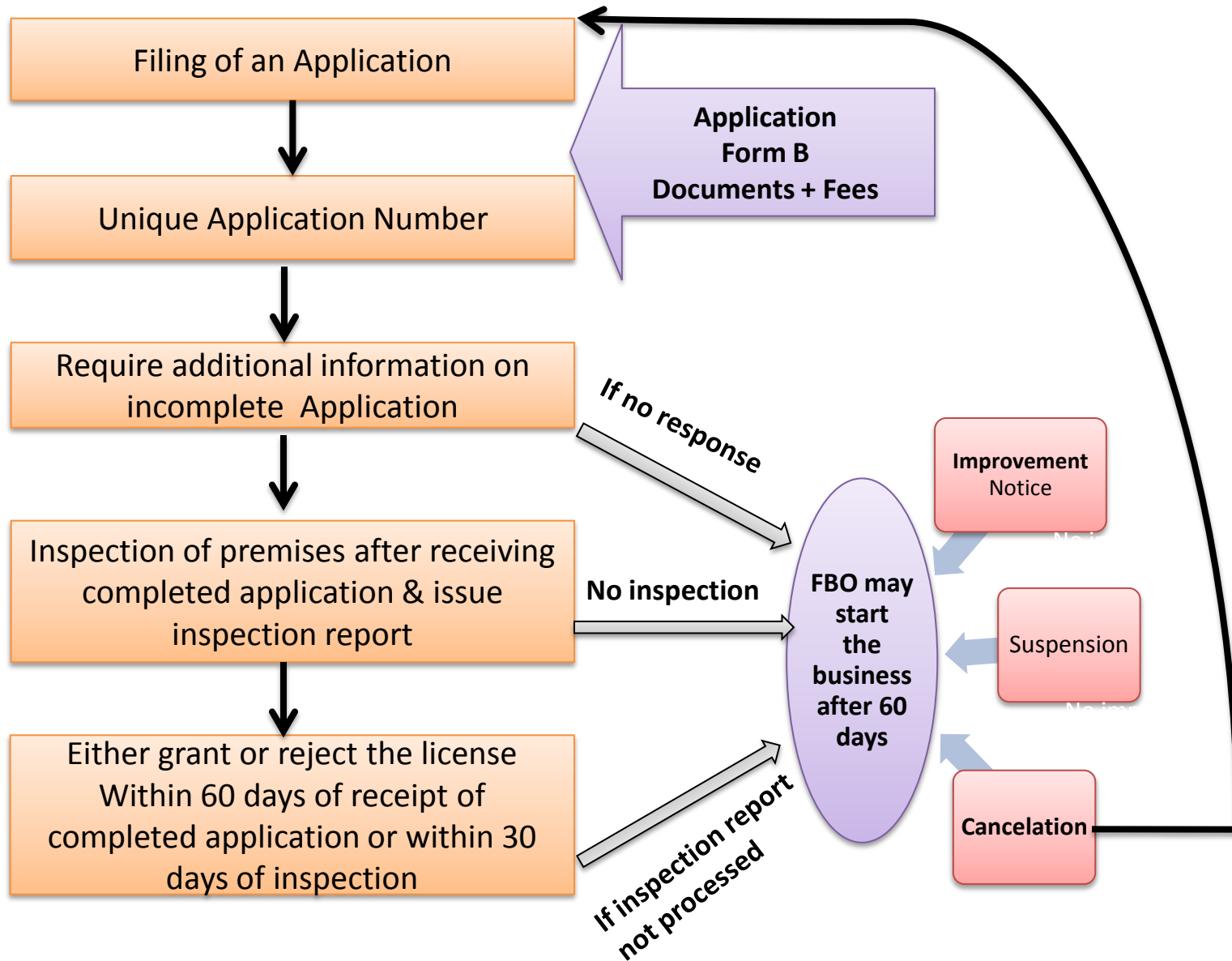
Framework For Registration/ Licensing/Monitoring Of Food Business Establishments



Schedule 1

- i. **Dairy units** : >50 thousand liters of liquid milk/day or 2500 MT of milk solid per annum.
 - ii. **Vegetable oil processing units and refineries: installed capacity >2 MT per day.**
 - iii. **Slaughter houses** : >50 large animals, 150 or more small animals, 1000 or more poultry birds per day.
 - iv. **Meat processing:** >more than 500 kg of meat/day or 150 MT per annum.
 - v. **All other food processing:** > 2 MT/day except grains, cereals and pulses milling units.
- i. 100 % Export Oriented Units
 - ii. All Importers importing food items
 - iii. Any article of Food which does not fall under any of the food categories or deviates from the prescribed specification for additives.
 - iv. Retail chains operating in three or more states
 - v. Food catering services in establishments and units under Central government Agencies like Railways, Airlines and airport, Seaport, Defense etc.

Procedure of Licensing



Return

FBO shall submit a return in Form 'D' on or before 31st May of each year, in respect of each class of food products handled by him during the previous financial year

Any delay in filing return beyond 31st May of each year shall attract a penalty of Rs 100 per day of delay.

Registration/ License Fee Per Annum In Rupees

Sr. No.	Particulars	Amount
1.	Fees for Registration	Rs 100
2.	Fees for License issued by Central Licensing Authority	Rs 7500
3.	Fees for License issued by State Licensing Authority: 1. Manufacturer/ Miller (i) Above 1 MT per day Production (ii) Below 1 MT of Production	Rs 5000 Rs 3000
4.	Any other Food Business Operator	Rs. 2000

- The payment shall be made by the Food business operator through Bank draft or online transfers or treasury chalan or any other suitable means as specified by the Licensing Authority

Online Licensing Facilitation



Food Safety and Standards Authority of India

(Ministry of Health & Family Welfare, Govt. of India)

Central Licensing System^{Beta}



The software is currently under Beta testing by FSSAI Regional Offices.

User Name:

Password:

Sign In

[Forgot Password?](#)

[Sign Up](#)

[Up](#)

Guidelines

- ➔ [About Central Licensing](#)
- ➔ [How to Apply](#)
- ➔ [Fee Structure](#)
- ➔ [Eligibility Criteria](#)
- ➔ [Document Checklist](#)
- ➔ [Rules of Submission](#)
- ➔ [Central Licensing \(Flow Chart\)](#)



Track Your Application Status

Enter Application Reference No.

Submit

Enter your " Application Reference No. " to get to know the latest Application Status.

Latest Announcements

- ▶ [The Food Safety and standards Rules, 2011](#)

Send Your Feedback



Download User Reference Manual



Note : Food Business Operators (FBOs) are also invited to participate in Beta testing of the software. FBOs need to Sign Up to get a username and password.

About Online System

- ➔ FSSAI provides an opportunity for Food Business Operators (FBOs) to apply for Central Licensing through online. It also provides an option to track the status of application online that are submitted to FSSAI through a Application Reference No. provided by the system during the submission of application online.
- ➔ The FBOs should take a print out of the Online Application Form generated through the system and submit the application to FSSAI with all supportive documents within fifteen days from the date of submission of application online.
- ➔ To apply for Central License, the FBOs need to Sign Up to get a user name and password.

Nomination

- FBO shall inform Licensing authority, the particulars relating to the person in-charge of food safety for all establishments/branches
- Appropriate certification that the concerned person has been so nominated shall also be furnished
- Nominations shall be filed in Form IX
- Any change in the nominations shall be conveyed to Licensing Authority

FORM NO. IX
(Form of Nomination - Refer rule 2.5.1)

NOMINATION OF PERSONS BY A COMPANY

Being the proprietor or a signatory authorized by the board of directors of the company in terms of Rule 2.5.1 (2), I do hereby give notice that the following person(s) is/are nominated as the person(s) in charge of establishment, branch or the unit mentioned against the name of the person(s) and shall be responsible and liable for food safety or any contravention of the Act and rules/regulations or directions issued thereunder in respect of the concerned establishment/branch/unit. The person(s) shall take all such steps as may be necessary to prevent the commission by the Company of any offence under and comply with the provisions of Food Safety and Standards Act, 2006 and the Rules and Regulations made thereunder.

Branch wise/office wise nomination .

Establishment/branch/unit name	Name and Sign of Person i/c
1.	1.
2.	2.
3.	3.

A certified copy of the resolution of the board regarding the authorized signatory, dated _____ is enclosed.

Place: _____ For _____ Ltd./Private Ltd.

Date: _____

1. Authorized signatory of the company

Place: _____

Date: _____

Schedule 4 Requirements

1. Location and Surrounding

2. Layout and Design of Food Establishment Premises

3. Equipment

4. Facilities

5. Food Operations and Control

6. Management and Supervision

7. Food testing Facilities

8. Audit, documentation and Records

9. Sanitation and Maintenance of Establishment Premises

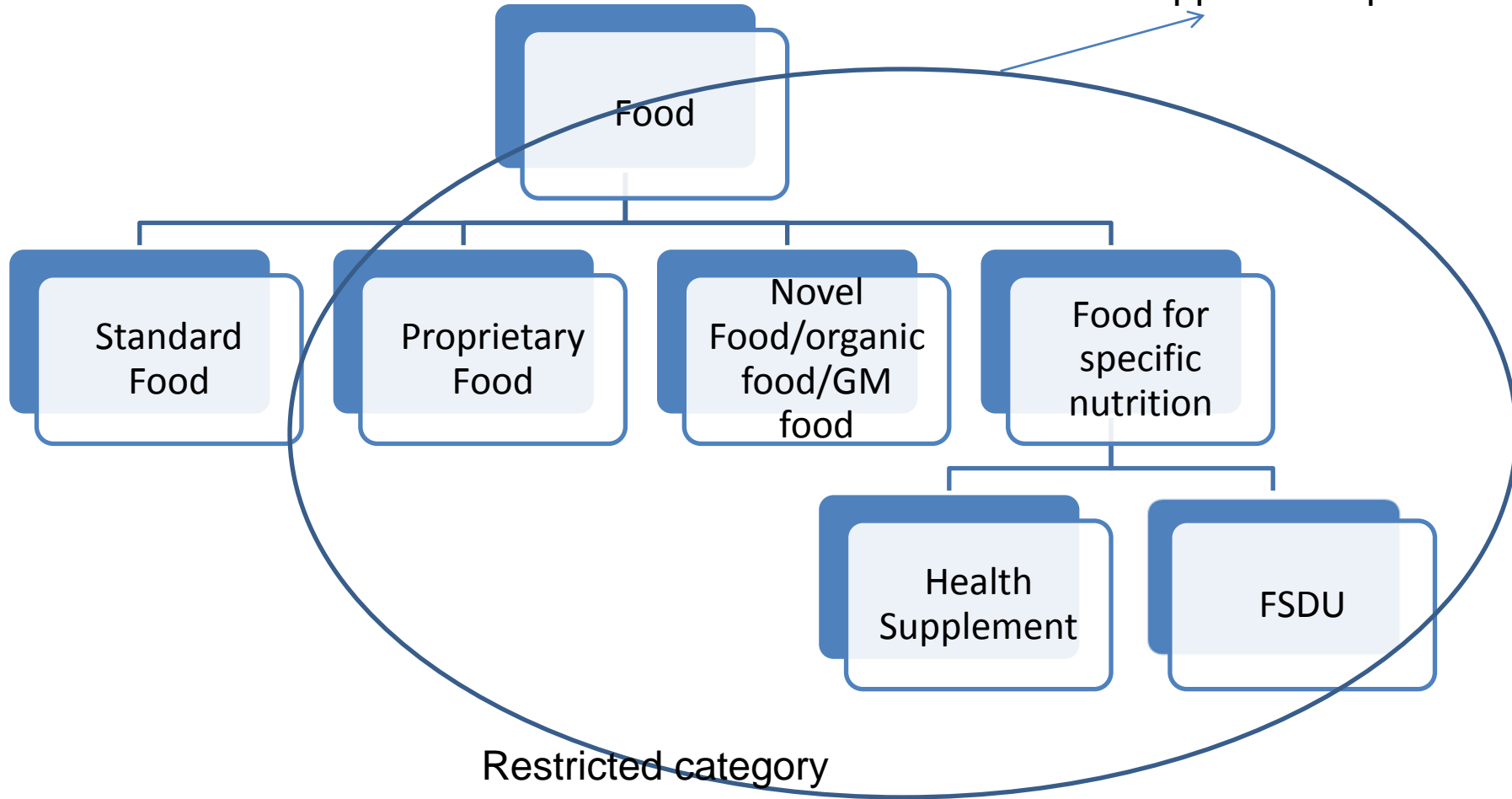
10. Personal Hygiene

11. Product Information and Consumer Awareness

12. Training

Food categorization

Pre Market Approval required



Food Vs Drug

Taste

FOODS

No Claims

Nutrition

FUNCTIONAL FOODS

**Nutritional Claims
Nutritional Comparison
Claims**

Function

NUTRACEUTICALS

Nutrient Content claims

**Risk
reduction**

HEALTH SUPPLIEMENTS

Other Functional claims

Risk Reduction Claim

CURE

**OTS/
AYU. RUGS**

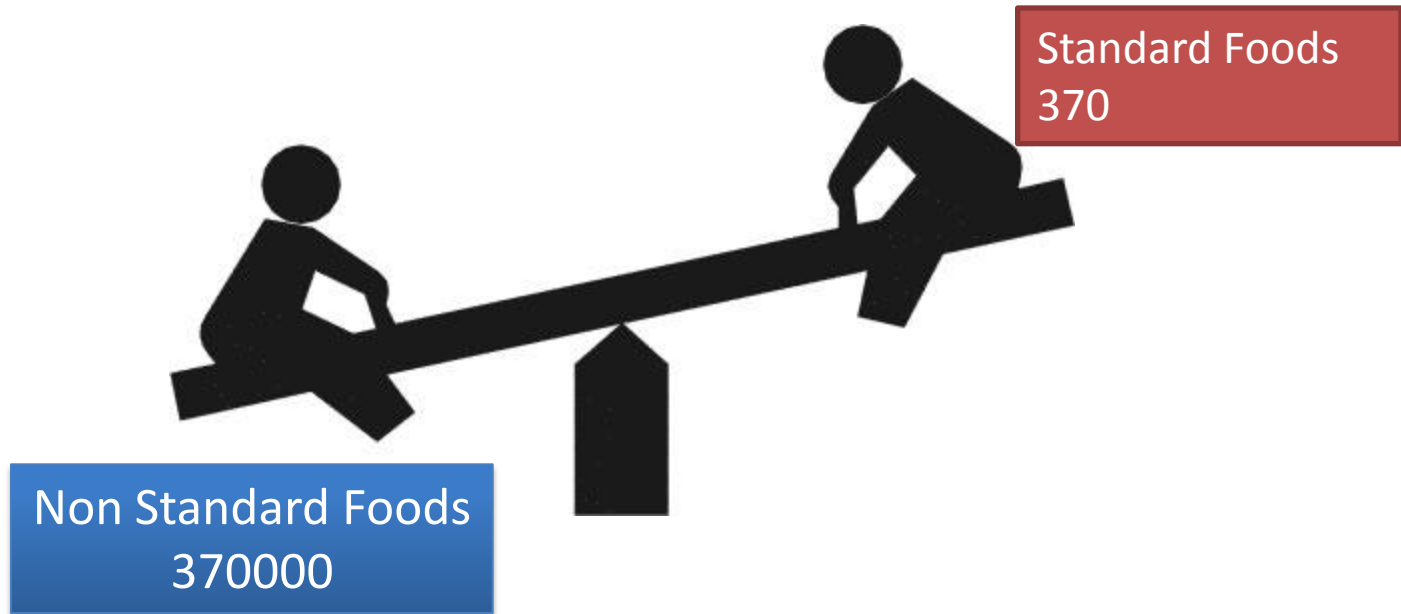
**Curative/preventive
/Confirmative claims**

Mitigate

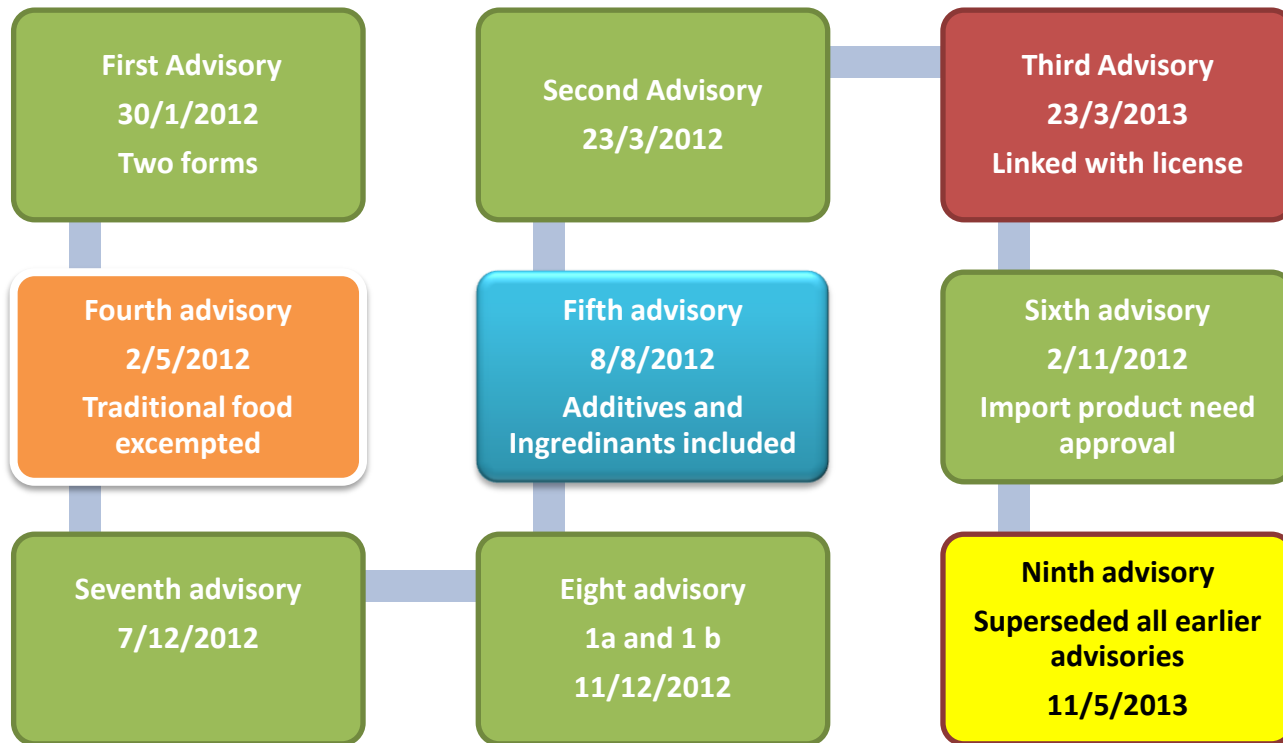
DRUGS

Prevent

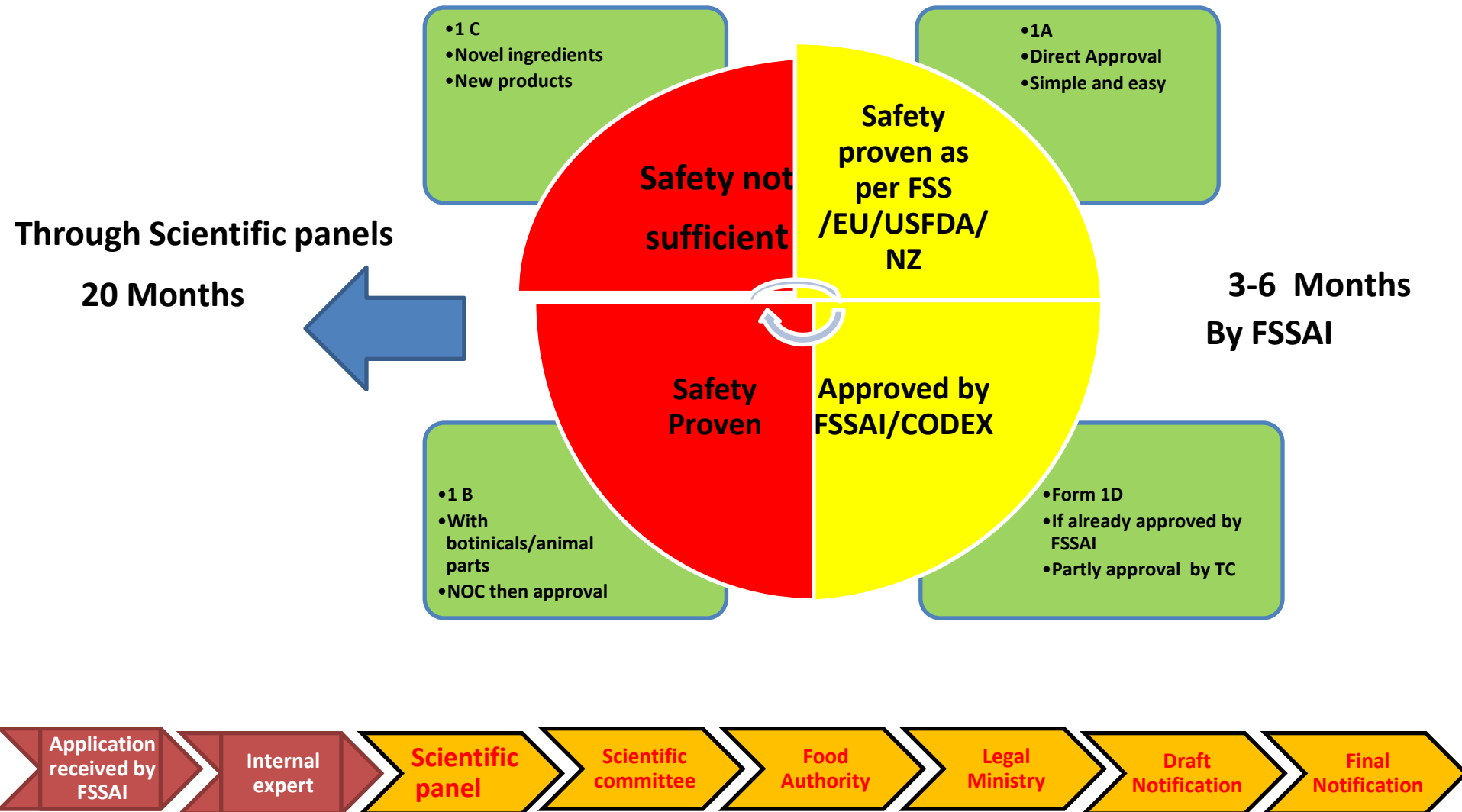
Product approval Problems



Advisories so far...



Proprietary Food Product Approval System



Liability for Compliance (section 27)

✓ **Manufacturer shall be liable for meeting all requirements under this Act**

• **Wholesaler/distributor shall be liable only for**

- Sale after expiry
- stored or supplied in violation of the safety instruction
- Unsafe or misbranded
- Manufacturer unidentifiable
- Received with knowledge of being unsafe

✓ **Seller shall be liable only for**

- Sale after expiry
- Handled or kept in unhygienic conditions
- Misbranded
- Manufacturer unidentifiable

Penalty

Punishment for carrying out a business without licence

- FBO commencing food business without license is punishable with imprisonment for a term of max. 6 months and a fine of max. 5 lakh rupees.

What we must do

Actionable

- Obtain a valid license from Central/State licensing authority for all the manufacturing facilities and warehouses/distributors
- Convert the existing PFA licenses to license under FSSAI if not yet done
- Ensure compliance with all the conditions of license & Schedule 4 requirements at all times
- Product approval for required products.
- File returns in Form “D1” every year before 31st of May and separate returns for every license to be filed

Actionable

- File the nominations with the Licensing Authorities in Form IX for all units/branches
- Technical person needed as a supervisor in production
- Testing of contaminants in edible oil to be done once in six months
- Business to be performed with only licensed/registered vendors
- Monitoring/Surveillance/Improvement notices
- Product recall/traceability procedure compulsory

Actionable

FBO	License for what	Central/State
Head office	Import /Rellebeller/Marketer	Central
Manufacturing units	Manufacturing and storing	As per capacity
2P/3P	Repacker /manufacture	As per capacity
Company Depots	Storage	Central/State
C&FA	Storage	State
Distributors	Wholesale trade	State
Transporters	Transportation	State
Retailer	Retailing	State

Eligibility Criteria for Licensing

	Central Licensing	State Licensing	Registration
Units processing & producing vegetable oil by the process of solvent extraction and refineries including oil expeller unit	More than 2 MT per day	Up to 2 MT per day and turnover above 12 lakh	Less than 12 lakh
For FBOs operating in two or more states-			
Storage capacity	Capacity more than 50,000 MT	Capacity upto 50,000 MT	
Packer/Repacker	Turnover greater than 20 crores	Turnover upto 20 crores	
Relabeller	Turnover greater than 20 crores	Turnover upto 20 crores	
Marketer	Turnover greater than 20 crores	Turnover upto 20 crores	
Transporters transporting edible oil	Having more than 100 vehicles or turnover more than 30 crores	Having upto 100 vehicles or turnover upto 30 crores	

Compliance and Penalties

Liability for Compliance (section 27)

- ✓ **Manufacturer** shall be liable for
 - meeting all requirements under this Act

Wholesaler/distributor shall be liable only for

- Sale after expiry
 - stored or supplied in violation of the safety instruction
 - Unsafe or misbranded
 - Manufacturer unidentifiable
 - Received with knowledge of being unsafe
- ✓ **Seller shall be liable** only for
 - Sale after expiry
 - Handled or kept in unhygienic conditions
 - Misbranded
 - Manufacturer unidentifiable

Justice Dispensation System under the Act



For Misbranding
and sub standard
food



ADJUDICATING

Fine

For unsafe Food



COURTS

Fine with
Punishment

Fine and Penalties

Penalty for substandard food	Rs 5 lacs
Penalty for misbranded food	Rs 3 lacs
Penalty on misleading advertisement	Rs 10 lacs
Food containing extraneous matter	Rs 1 lac
Penalty for failure to comply with food safety officer	Rs 2 lacs
Penalty for unhygienic processing of food	Rs 1 lacs
Punishment for unsafe food/Not having valid license	six months to 10 yrs of imprisonment

Review of standard process

1. Receiving suggestions - 31st March, 2012
2. Examination of suggestions by SRC-02 months
3. Report of the specially constituted expert committees as per requirement - 02 months
4. Consideration by Scientific Panel - 02 months
5. Consideration by Scientific Committee - 02 months
6. Consideration by Food Authority - 2 months
7. Approval by the Government and draft notification - 02 months
8. Time given for receiving public comments and notification to WTO, SPS/TPT etc - 02 months
9. Disposal of comments and finalising the draft - 03 months
10. Approval of the Government and final notification - 02 months

-20 Months





Thank You Any Query.....

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