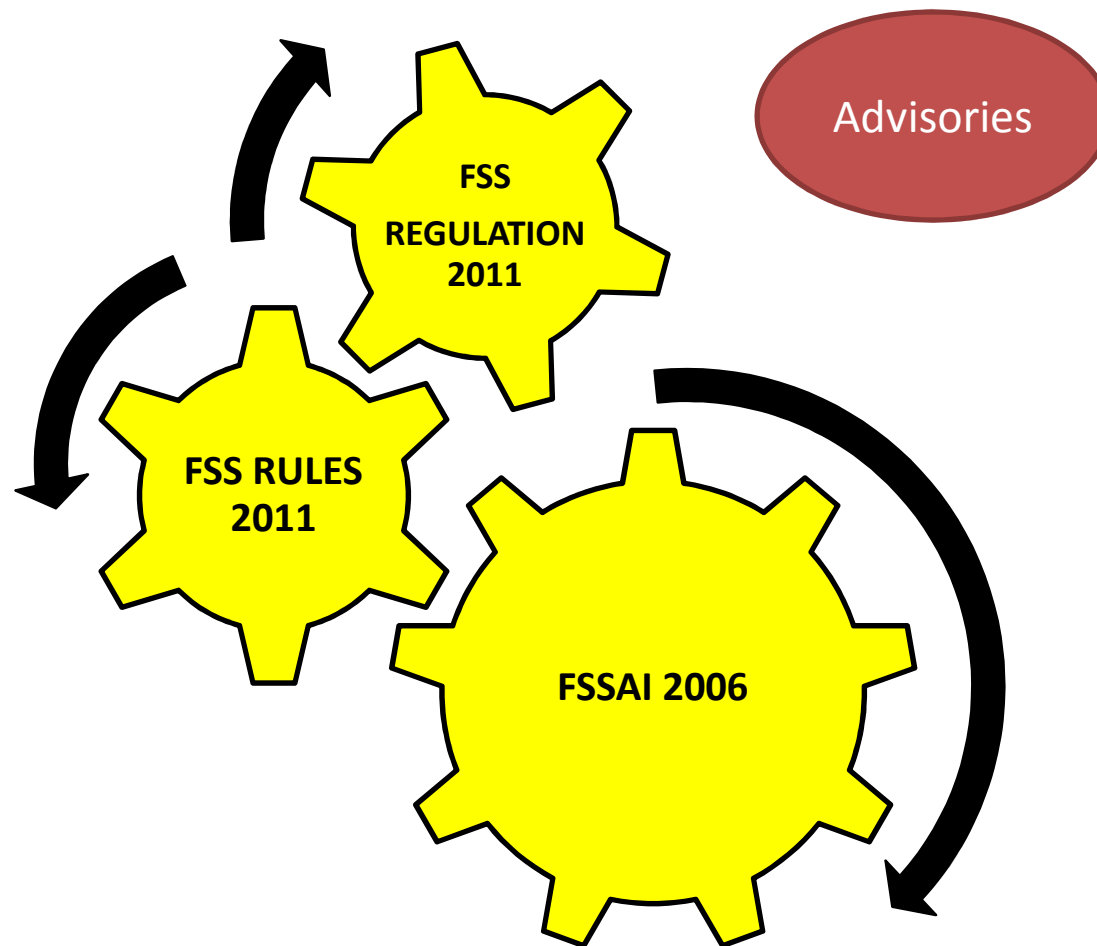


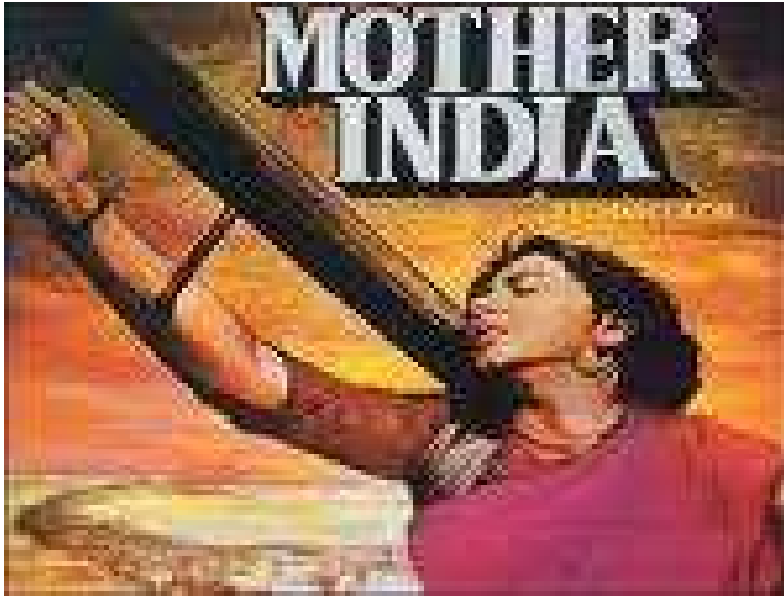
Licensing Process

- Dr Prabodh Halde

FSSAI Legislative Frame



India then and now.....



1955

PFA

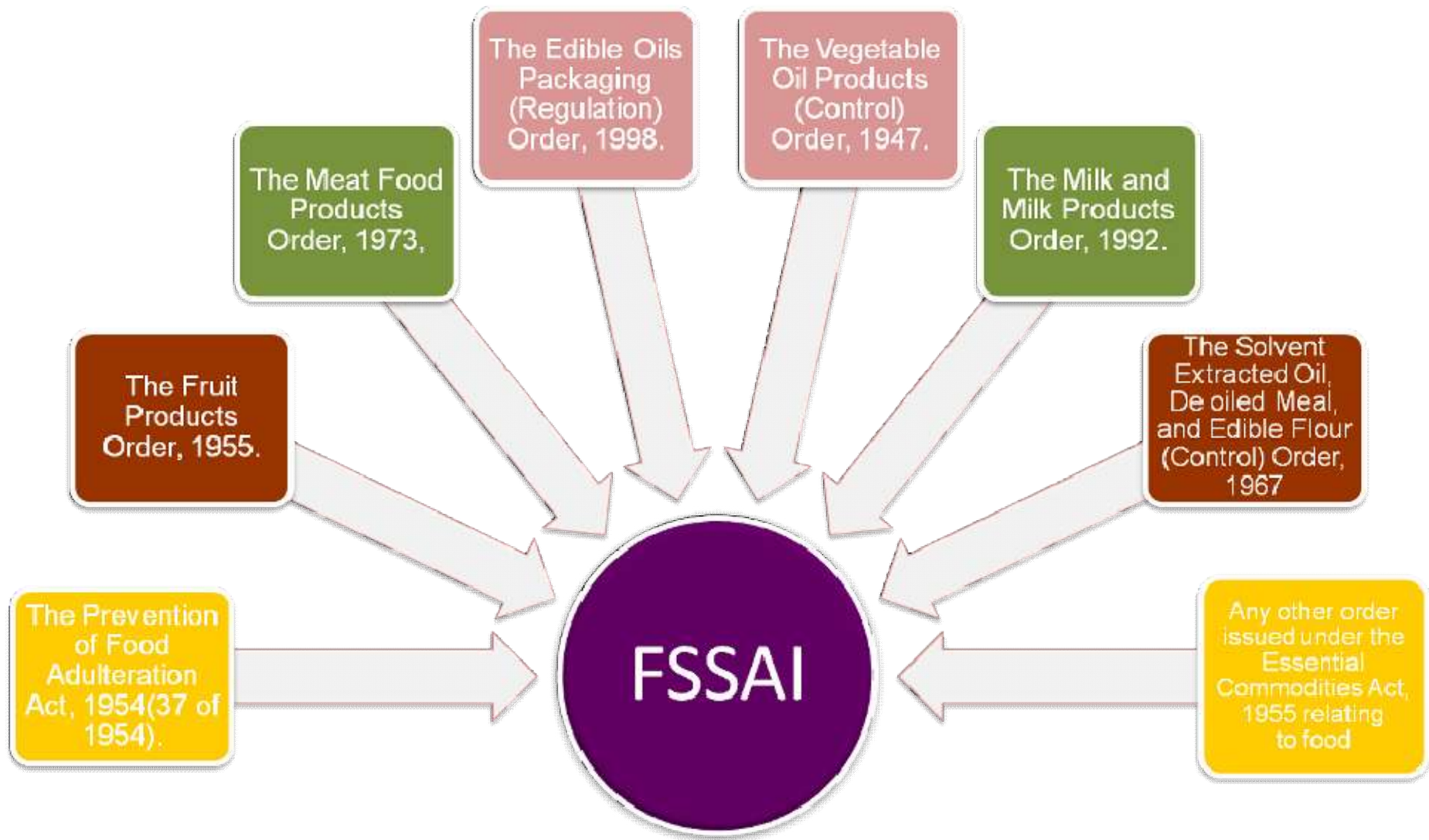


2006

FSSAI



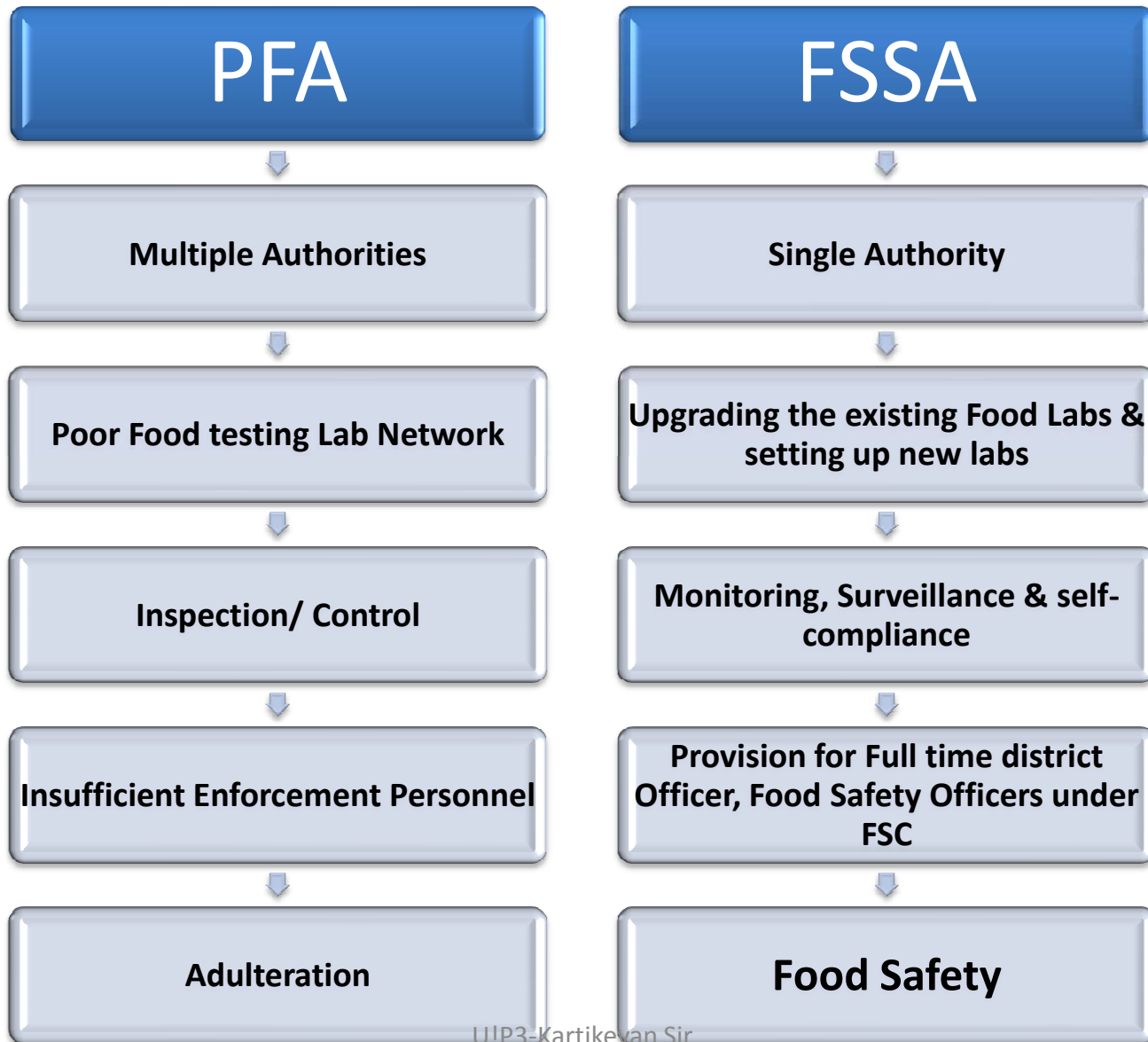
FSSAI replaced the following regulations



The Act

- *An Act to **consolidate** the laws relating to food and to **establish** the Food Safety and Standards Authority of India for laying down **science based standards** for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of **safe and wholesome food** for human consumption and for matters connected therewith or incidental thereto*

Critical Shifts



Introduction

- As per section 31 of the Act, (1) No person shall commence or carry on any food business except under a license
- Nothing contained in sub-section (1) shall apply to a petty manufacturer who himself manufactures or sells any article of food or a petty retailer, hawker, itinerant vendor or a temporary stall holder or small scale or cottage or such other industries relating to food business or tiny food business operator; but they shall register themselves with such authority

Salient Features

- Unified Licensing procedures - Single Window
- Complete online system
- Common application forms and procedures.
- Distinction between 'registration' and 'licensing'. Cut off limits for registration and licensing.
- Two tier system of licensing – Central & State
- Introduction of exhaustive Safety, Sanitary and Hygienic conditions mandatory for registration/licensing.

DEFINITIONS

Petty food manufacturer

- manufactures or sells any article of food himself or a petty retailer, hawker, itinerant vendor or temporary stall holder; or such other food businesses including small scale or cottage or such other industries relating to food business or tiny food businesses with an annual turnover not exceeding Rs 12 lakhs and/or
- whose production capacity of food (other than milk and milk products and meat and meat products) does not exceed 100 kg/ltr per day or
- production or procurement or collection of milk is up to 500 litres of milk per day or
- slaughtering capacity is 2 large animals or 10 small animals or 50 poultry birds per day or less

DEFINITIONS

- **“Food business”** means any undertaking, **whether for profit or not and whether public or private**, carrying out any of the activities related to any stage of manufacture, processing, packaging, storage, transportation, distribution of food, import and includes food services, catering services, sale of food or food ingredients;
- **“Food business operator”** in relation to food business means a person by whom the business is carried on or owned and is responsible for ensuring the compliance of this Act, rules and regulations made there under;

New Terms

- **“Licensing Authority”** - the Designated Officer appointed under section 36 of the Act for the local area and includes any other officer so appointed for the purpose of granting license by the Commissioner of Food Safety
- **“Central Licensing Authority”** - Designated Officer appointed by the Chief Executive Officer of the Food Authority of India in his capacity of Food Safety Commissioner. There should be one Designated officer for each district
- **“State Licensing Authority”** - Designated Officers appointed under Section 36(1) of the Act by the Food Safety Commissioner of a State or UT.

New Terms

- **“Registering Authority”** - Designated Officer/ Food Safety Officer or any official in Panchayat, Municipal Corporation or any other local body or Panchayat in an area, notified as such by the State Food Safety Commissioner for the purpose of registration as specified in these Regulations.
- **“District”** - revenue district in state and UTs. However, the Commissioner of Food Safety may, for the purpose of this Act declare any local area as a district on the basis of:
 - Concentration of specific type of food business which may need special attention
 - Risk assessment carried out by the authority from time to time
 - Any other specific Regulatory requirement

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



Petty Food Manufacturers with an annual turnover not exceeding Rs. 12 lakhs

Licensing and Registration of Food Business

**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.



All units having
installed capacity
less than
2MT/day

Licensing and Registration of Food Business

**Central Licensing
Authority**

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



All units falling
under Schedule I

Licensing Requirements

FBO	License for what	Central/State
Head office/Corporate 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 /Central
Distributors	Wholesale trade	State /Central
Transporters	Transportation	State
Retailer	Retailing	State

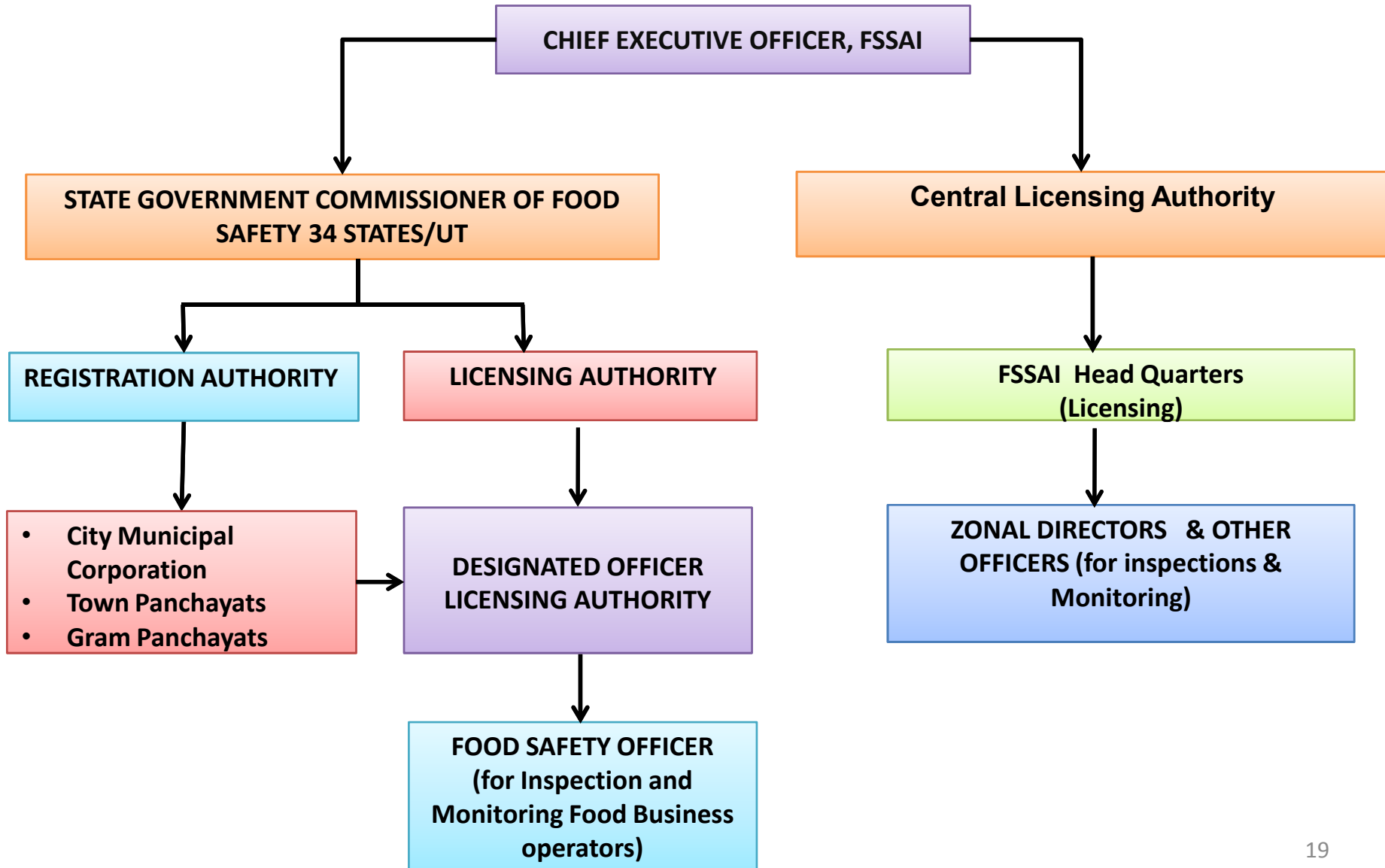
Eligibility Criteria for Licensing

	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	

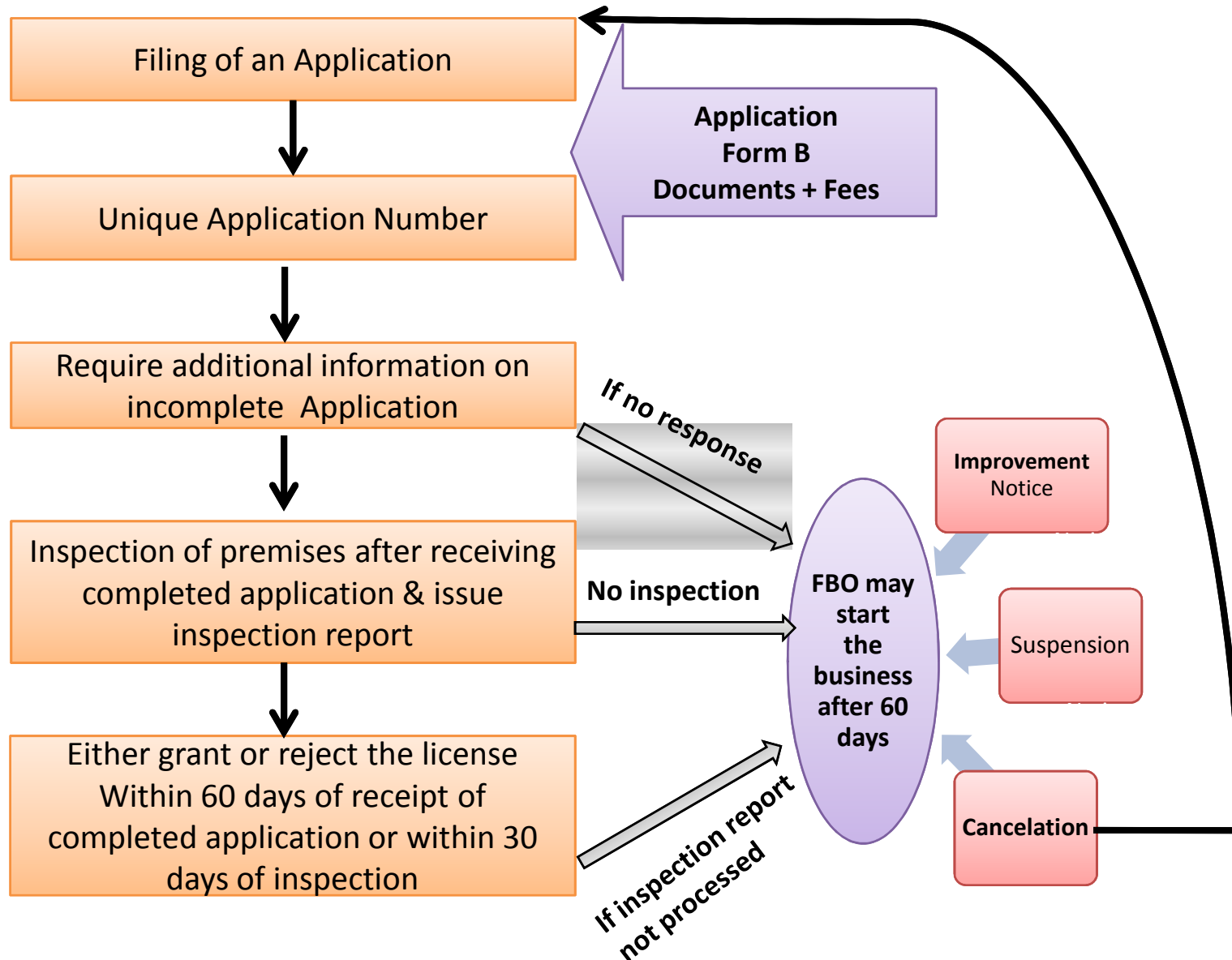
Schedule 1

- 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 FBO manufacturing any article of food containing ingredients or substances using technologies or processes or combination thereof whose safety has not been established though these regulations or which do not have a history of safe use
- iv. FBO's operating in two or more states
- v. Food catering services in establishments and units under Central government Agencies like Railways, Airlines and airport, Seaport, Defense etc.

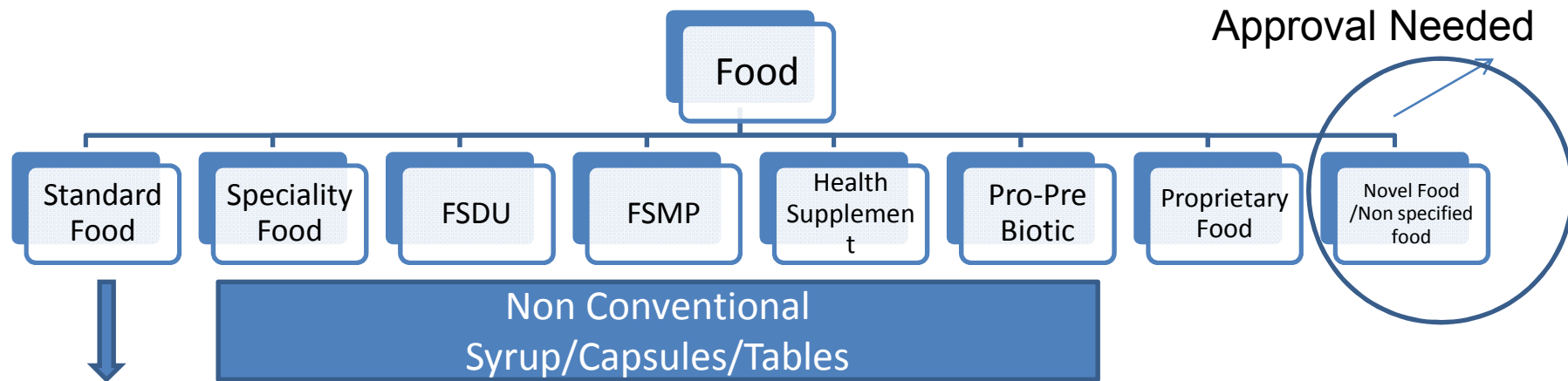
Framework For Registration/ Licensing/Monitoring Of Food Business Establishments



Application Process

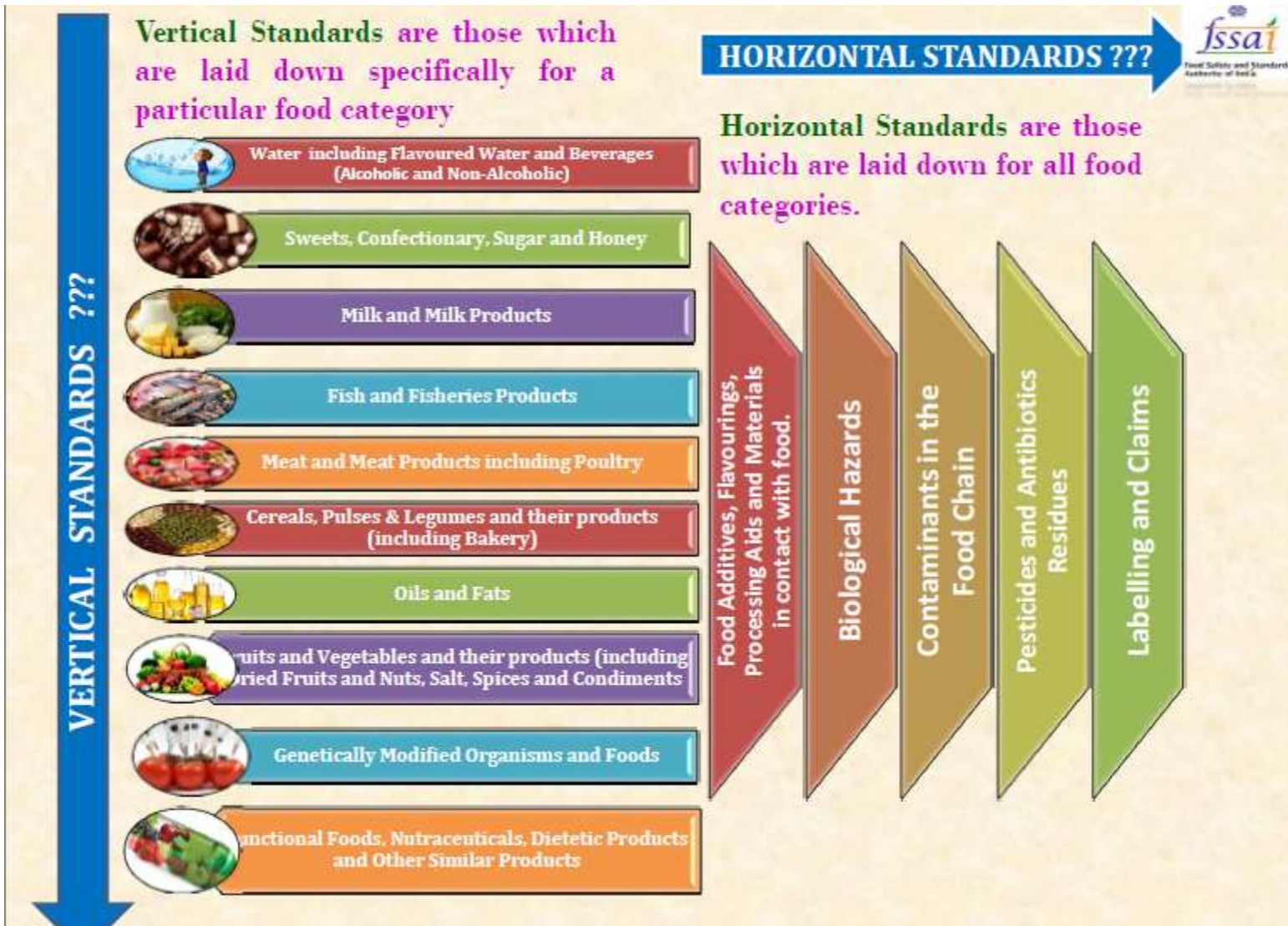


Food Categorization as per FSSA



As per FSSR Food Product Standards and Additives Regulations

Vertical Vs Horizontal



Proprietary Food

- Proprietary food means an article of food that has not been standardised under these regulations, but does not include novel foods, foods for special dietary uses, foods for special medical purposes, functional foods, nutraceuticals, health supplements and such other food articles which the Central Government may notify in this behalf.
 - In addition to this, the name of the food and/or the category under which it falls in these rules shall be mentioned
 - Also should comply with all regulations under this Act and Regulations
 - shall contain only those ingredients other than additives which are either standardised
 - or permitted for use in the preparation of other standardised food under these Regulations

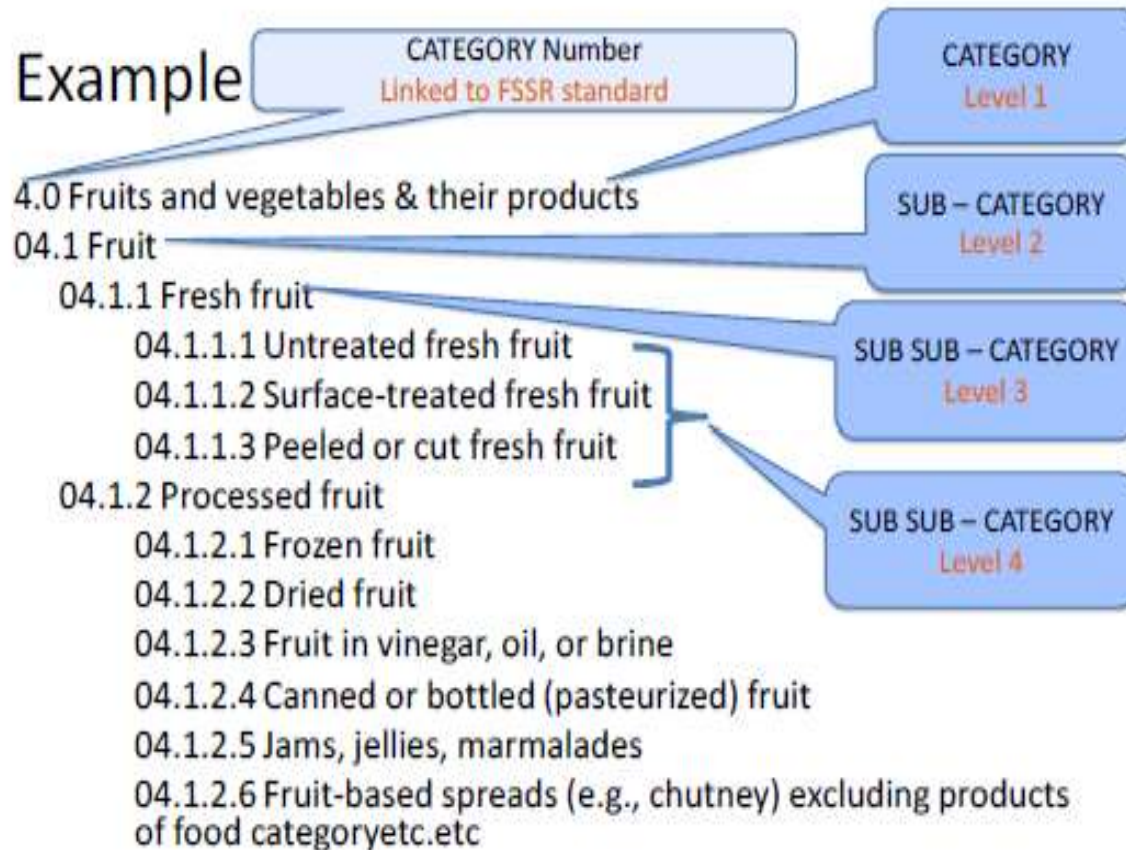
Product Category For License

- While applying for a new license or modification of a license, the category of the product needs to be selected in FSLRS
- This category is selected from the IFC (Indian Food Code)

Food Categories : For License and Additives

1.0 Dairy Products and analogues, excluding products of food category 2.0	9.0 Fish and Fish products
2.0 Fats and Oils, and fat emulsions	10.0 Eggs and egg products
3.0 Edible ices, including sherbet and sorbet	11.0 Sweeteners including honey
4.0 Fruits and vegetables, seaweeds and nuts and seeds	12.0 Salts, spices, soups, sauces, salads and protein products
5.0 Confectionery	13.0 Foodstuffs intended for particular nutritional uses
6.0 Cereal & Cereal Products	14.0 Beverages excluding dairy products
7.0 Bakery Wares	15.0 Ready to eat savouries
8.0 Meat and Meat products including poultry	16.0 Prepared Foods

Food Category System - Example



Food Categories and License

	State License	Central License
Standard Food	✓	✓
Specialty Food		✓
FSDU		✓
FSMP		✓
Health Supplements		✓
Pro/pre biotics		✓
Proprietary food		✓
Novel Food /Non Specified food		✓

License for Proprietary Food

- As per regulation, only Schedule I Food Business units need to apply for Central License
- FBO's with a turnover >2MT per day need to apply for Central License
- Products falling under the category of nutraceuticals, health supplements etc. will need to apply for Central License
- **However, by default application for proprietary food is processed under central license**

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.	
<i>Branch wise/office wise nomination.</i>	
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: _____	

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

Section 63 : 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

Demo

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Food Safety and Standards Authority of India
Licensing and Registration System V3.0

Home	License/Registration	Renewal	Modification	Duplicate / Surrender / Transfer	Food Concerns	Logout
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Logge

Apply for License/Registration

Clarification/Incident(s)

Application for Editing

Surrender Clarification/Incident(s)

Endorse Fortified Products

My Profile Reset Password

Kindly Click on the below button to go to Dashboard

Go To Dashboard

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Example of State License

Other food processing units

Sl.No.	Product Description	Quantity (MT/Day)	Kind of Business
1	Edible Oil 02.1.2	2	Manufacturer
2	Coconut Flour 06.2.1	0.175	Manufacturer
3	Coconut Sugar 11.1.3	0.033	Manufacturer
4	coconut dietary fiber 02.1.2	0.175	Repacker
5	coconut pediatric syrup 02.2	0.033	Repacker

Coconut Sugar is not a standard food; however when a FBO modifies the STATE license, he can directly select the IFC category and apply for the license

Example of Central License

Kind of Business : Manufacturer (Proprietary Food).

Sl.No.	Food Category	Name of Food Item(s)	Quantity (MT/Day)	Kind of Business
1	06.2.1 - Flours	Oats Atta (Oats Flour)	12	Manufacturer
2	06.3 - Ready -to -eat cereals, breakfast cereals, including rolled oats	Instant Oats Flakes, Jumbo Oats (Oats Poha), Oats Dalia (Steel Cut Oats), Oats Bran (Oats Fiber), Masala Oats - Veggie Twist, Masala Oats - Chinese Delight, Masala Oats - Classic, Italian Masala Oats, Tomato Oats, Oats Keshar with Kishmish Flavour, Oats Strawberry Flavor with Apple, Tomato Medly, Panjabi Tashan Masala Oats, Naughty Masala Oats, Mumbai Masti Masala Oats	50	Manufacturer

Coconut Sugar is not a standard food; however when a FBO modifies the CENTRAL license, the license shows a specific kind of business as 'proprietary food'

Way forward

- Streamlining and uniformity amongst authorities of different states
E.g. FBO A having a state license can modify his license and include a category like upma without having to apply for proprietary food under central license
- Correction of system glitch in FSLRS that directs proprietary food application to central license
- FBO's to be able to modify the license and include the main category and not individual sku's/variants

Thank You

