



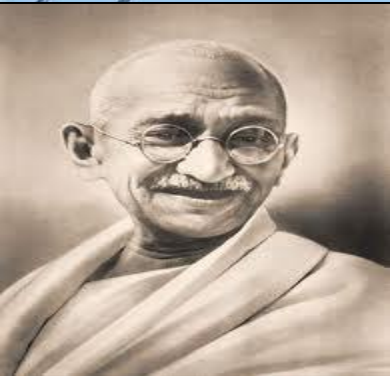
CIFTI-FICCI

Commencement of Business –In light of FSSAI

9th AUGUST 2012
AHMEDABAD

Prabodh Halde
VP AFST (M)
Head –Regulatory Marico

Good Morning Ahmedabad



Objectives of FSSA



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

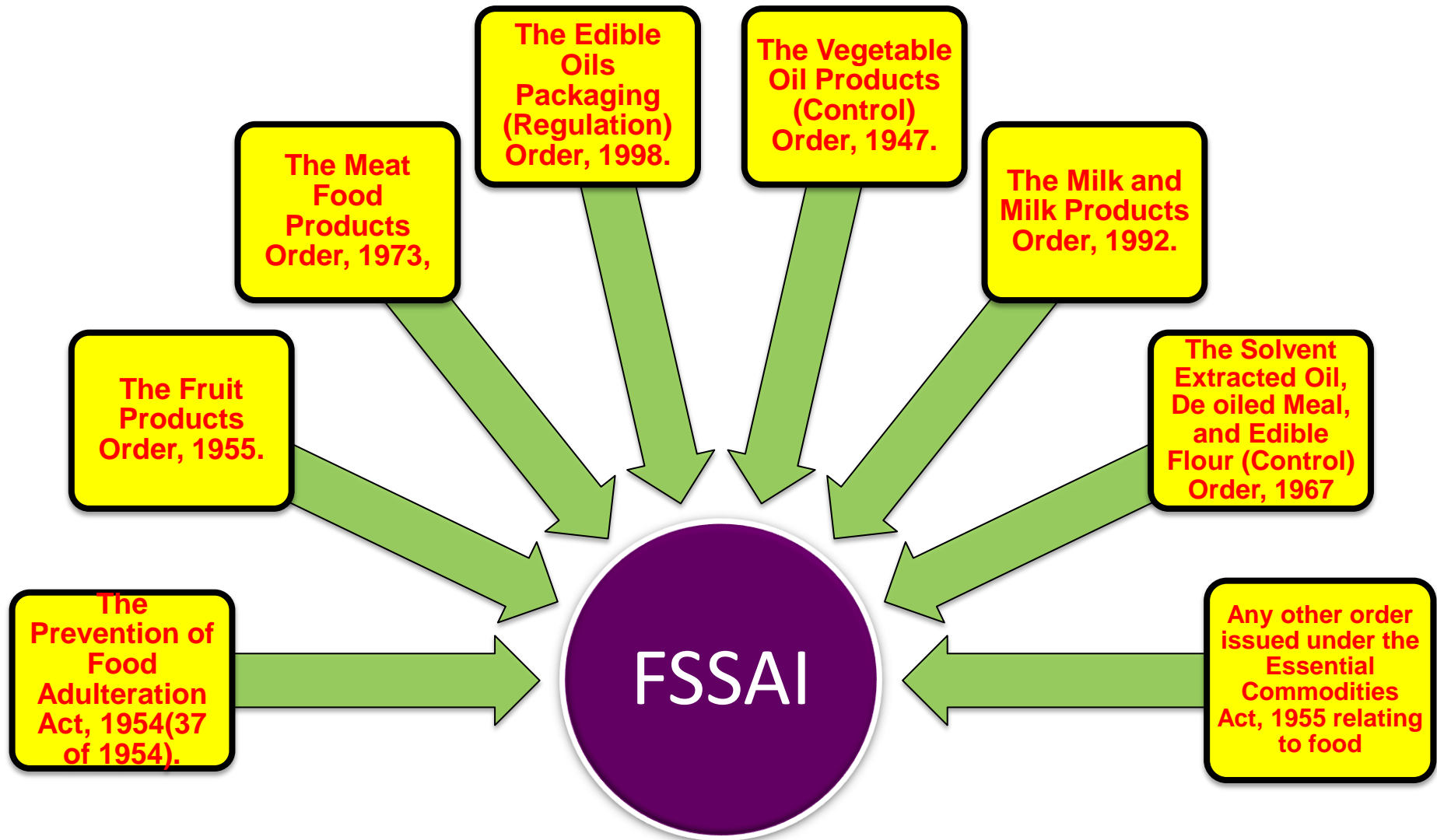
- To regulate the manufacture, storage, distribution, sale and import of food products



Y

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

FSSAI replaced the following Acts :



One year Window Period Extended..... 6 months.



5th August 2011

4th February 2013


Only for Licensing

Recent Advisory

STATUTORY ADVISORY

Subject: - Extending time period for seeking conversion/ renewal of existing licenses/ registrations granted under the repealed Orders by FBO

As per the provisions given under Clause 2.1.2 of Licensing/ Registration of Food Businesses Regulation, 2011, the food business operator has to apply for conversion / renewal of registration/ license within one year from the date of notification. This time period was to expire on 4th August, 2012. The approval of the Competent Authority is hereby conveyed for extending ^{the} time period granted to food business operators for seeking conversion/ renewal of licenses by another six months with effect from 5th August, 2012.


(S.S. Ghonkrokta)
Director(Enforcement)
Tel:23220994

What we must do

Actionable

- Obtain a valid license from Central/State licensing authority for all the manufacturing facilities and warehouses/distributors
- Product approval as required.
- Product safety study by independent institute if required.
- Convert the existing PFA/FPO/VOP licenses to FSSAI license under by 5th July 2012
- Ensure compliance with all the conditions of license & Schedule 4 requirements at all times

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 to be done once in six months
- Compliance to Schedule 4
- Testing of water once in a year for Potability.
- Business to be performed with only licensed/registered vendors

Actionable

- License number to be printed on the pack.
- File returns in Form “D1” every year before 31st of May and separate returns for every license to be filed.
- FSMS Plan or Certificate
- Monitoring/Surveillance/Improvement notices
- Product recall/traceability procedure compulsory

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

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

Justice Dispensation System under the Act



For Misbranding
and sub standard
food



ADJUDICATING

Fine

For unsafe Food



COURTS

Fine with
Punishment

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

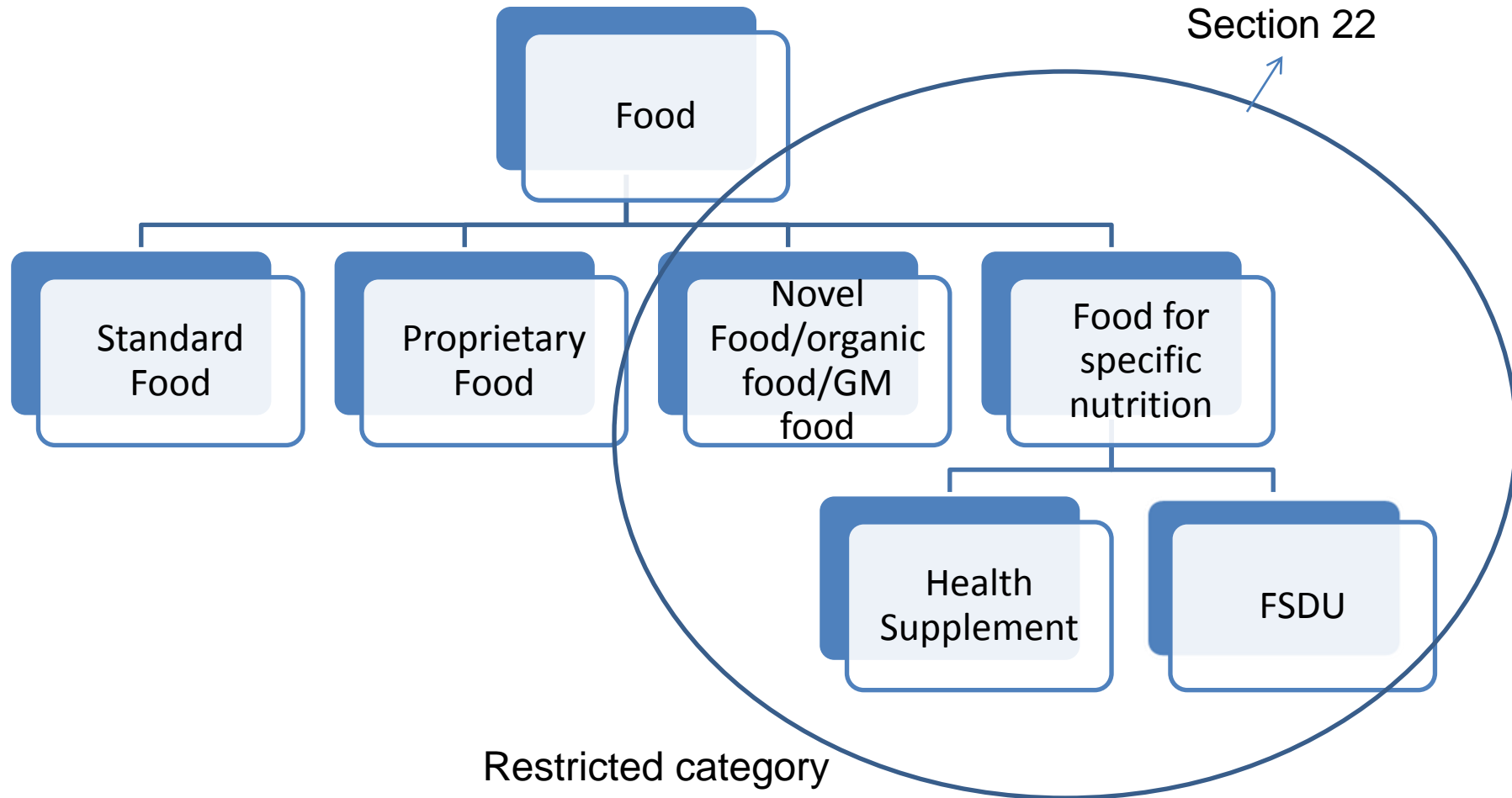
Eligibility Criteria for Licensing

	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	

Important Advisories

- Food Product approval advisory 8/8/2012
- Licensing Documents : 14:05:2012
- Advisory dated 4:07:2012
- Advisory on product approval /code – 10.07.2012
- Product approval – Dated 02.05.2012
- Product approval advisory : 23rd April 2012
- Advisory with regards to FSMS Plan : Dated 11.04.2012
- HS Code Advisory : Dated 10:04.2012
- Advisory on Licensing : Dated 25.01.2012
- Advisory/Clarification regarding expiry of licenses :
Dated 10:01:2012
- Advisory dated 03:10:2011

Food categorization



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

Mitigate

Prevent

**AYU.
DRUGS**

DRUGS

**Curative/preventive
/Confirmative claims**

Where I belong to?



FOOD



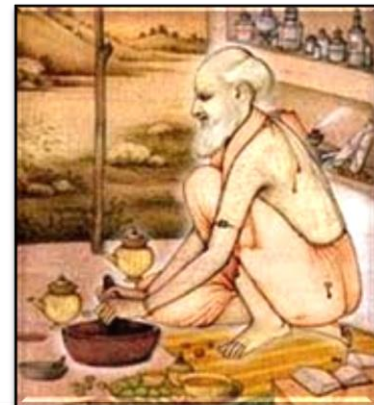
MEDICINE



Food Supplement



OTC-DRUG



AYURVEDIC MEDICINE

Approval required for.....

- New Additives
- New Ingredients to be used in Food
- Novel Foods
- Food For special Nutrition
- All Proprietary foods minus traditional proprietary foods.
- And Section 22 Foods

New Product Cell

- FSSAI Has established the ‘New Product Approval Cell’
 - FSSAI has made compulsory to get additives and New Product approval including proprietary foods.
 - Without Product approval or NOC for new products the license will be not issued.
 - Before 5th August 2012 every food business operator should apply for license.

Present Status

- India has more than 10,000 food products in Trade
- The Food Safety & Standards Regulation 2011 have given quality/safety specifications for nearly 320 food products.
- Rest all Products comes under category of Proprietary food.
- Section 22 has described the product for Nutraceutical/Novel Foods and Organic Foods etc

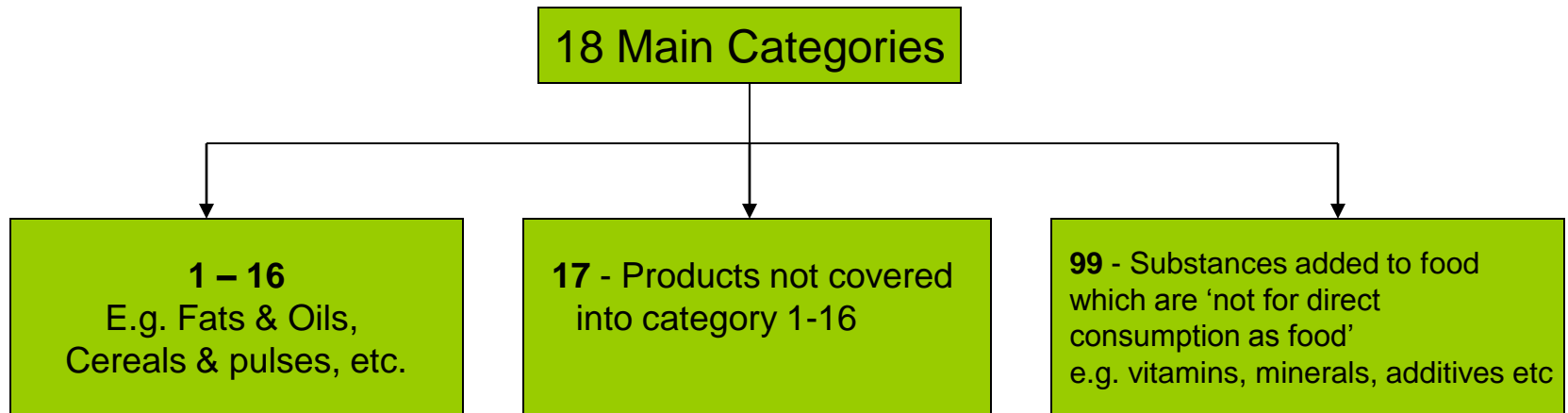
What is Proprietary Food?

As per Regulation 2.12.1

Proprietary food means a food that has not been standardized under these regulations In addition to the provisions including labeling requirements specified under these regulations, the proprietary foods shall also conform to the following requirements, namely:—

- (i) the name describing as clearly as possible, the nature or composition of food and/or category of the food under which it falls in these regulations shall be mentioned on the label
- (ii) the proprietary food product shall comply with all other regulatory provisions specified in these regulations and in Appendices A and B.

Food Categorization Structure



18 Categories

1.0 Dairy products and analogues

3.0 Edible ices, including sorbet

5.0 Confectionery

6.0 Cereals and cereal products

8.0 Meat and meat products

10.0 Eggs and egg products

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

14.0 Beverages

16.0 Prepared Foods

99.0 Substances added to food

2.0 Fats and oils, and fat emulsions

4.0 Fruits and vegetables

6.0 Cereals and cereal products

7.0 Bakery products

9.0 Fish and fish products

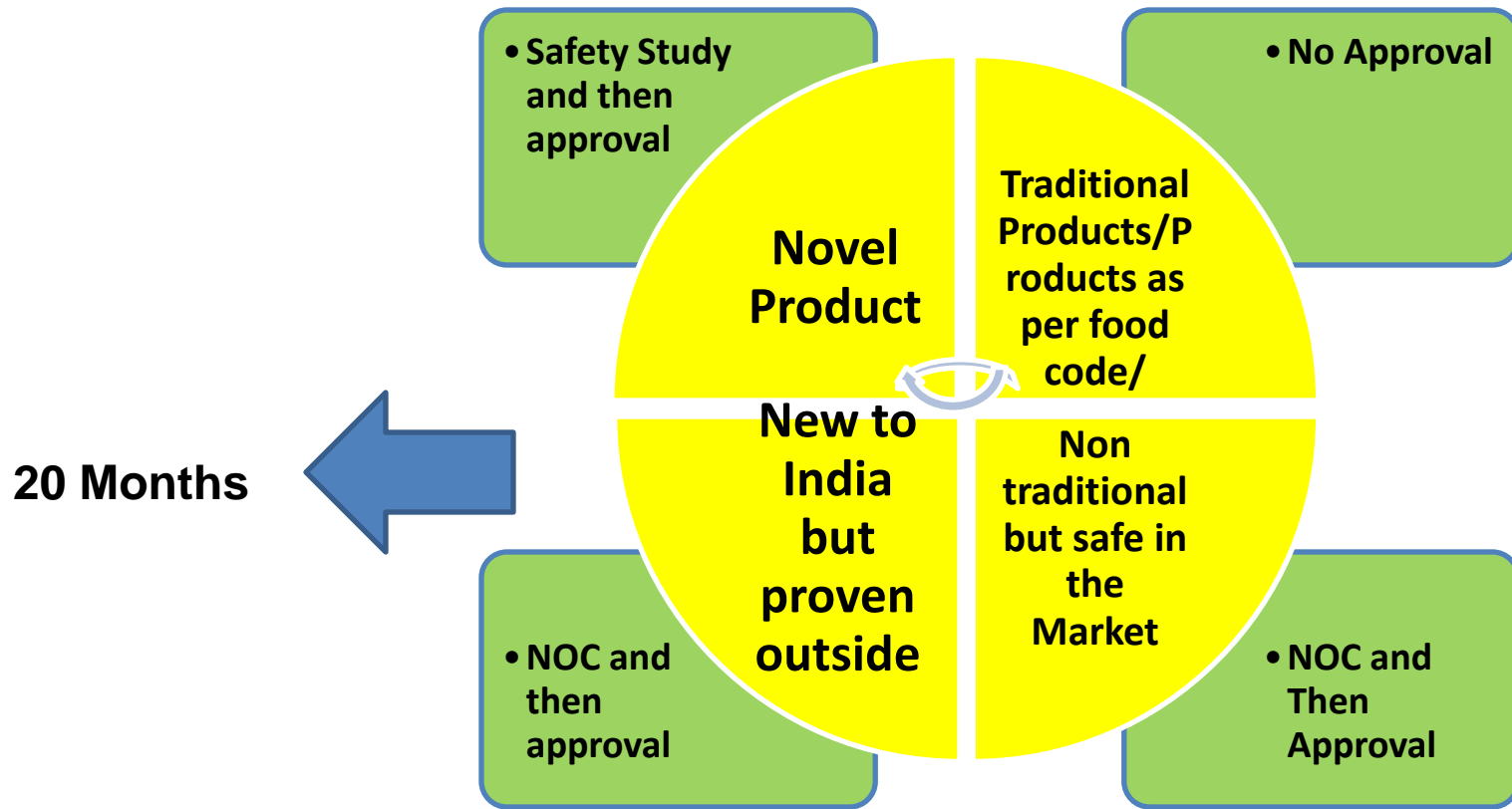
11.0 Sweeteners

**13.0 Foodstuffs intended for
particular nutritional uses**

15.0 Ready-to-eat Savories

17.0 Others

Proprietary Food Product Approval System



370 standard food
In market more than 10000 food products

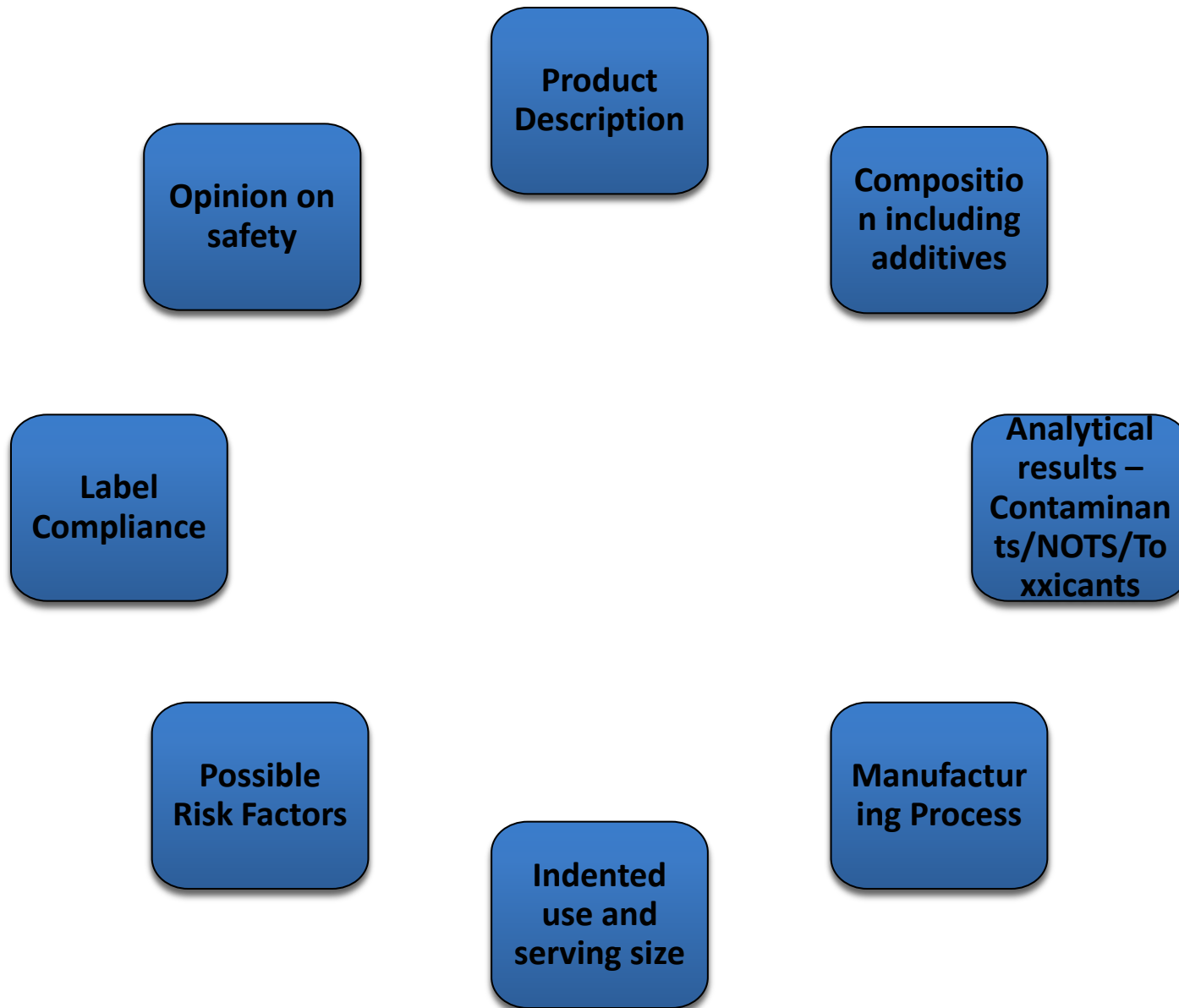
New Advisory

- All novel/first time use ingredient/food need approval
- Apply in prescribed form along with safety data and copy of label
- If product is as per 'Indian Food Code' separate product approval is not required.
- If product is approved for other company- same formulation need not to apply for product approval
- Pl see the list of NOCs issued so far
- NOC will be issued for the product which are using new additive (first time in India)
- Existing license holder will continue to do the business and apply for advisory as required
- Novel product will go for scientific Panel-No NOC will be issued.

New product Approval Tips

- Technological Function
- Specifications/ Purity
- Method of Manufacturing
- Safety Information
- Regulatory Status:
- Method of Analysis
- Shelf life study
- Dietary exposure
- Health claim /Nutritional claim support

Product Safety Certificate



New product Approval Tips

- All documents in original
- Safety assessment study by independent institute
- International CODEX/USDFA /EU support
- Claim substantiation details
- Undertaking
- Fees of Rs 25,000/- per category

Way Forward



WHAT WE NEED



Procedures (Path) should be very clear

WHAT WE NEED



Positive participation with authority for Regulation Making

WHAT WE NEED



Consumer safety is priority

WHAT WE NEED



No blind copy from west

WHAT WE NEED

NO OVER LOADING OF REQUIREMENTS



WHAT WE NEED



HOPES OF GOOD TOMORROW



Thank You Any Query.....

Prabodhh@maricoindia.net

9820278746