Current Regulatory Framework for Oils and Fats in India

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Presentation Agenda

• History and Evolution of Modern Regulations
  – Quality and standards
  – Modern Regulations

• Science behind regulations
  – Safety & Risk Assessment

• Recent regulatory changes for oils and Fats in India
Historical Evidence

• Arch logical study at Harappa BC-3000 (5000 Yrs Back) shown presence of Mustard as edible grain/spices

• Mention of Mustard in Gautam Buddha – BC 350

• Mention in Bible – By Jesus
  – How Kingdom of God should be? It is like Mustard seed – small in size but having potential to cultivate big plant – Ref Luke-17.6-10
Agriculture must continue to satisfy the demands of a complex global market

World population continues to expand
Per capita food consumption continues to rise
Consumers continue to demand improved taste, convenience, nutrition and health
**Definition of Food Chain**

Sequence of stages and operations involved in production, processing, distribution, storage & handling of a food & food ingredients from primary production to consumption.
Evolution of Supply Chains

For centuries, traditional market was the only supply chain to handle goods

From simple to complex supply chains have evolved

Source: Presentation by the World Bank in MACP Workshop
OILs Vs Food

• Oils and Fats are consumed since time immemorial by human being as source of energy every day
• Oils and fats are part of food products produced and consumed different forms.
• Most of the regulations for food are also applicable in case of edible oils
Birth of Modern Regulations

Food Safety

• Mother of all Control Orders & Consumer Protection Law

Eating food is a risky process

Innate Immunity and traditional culinary practices are major protective factors
Food Safety: Why??????

A suitable product which when consumed orally either by a human or an animal does not cause health risk to consumer.

OR

Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

Changing food habits
Increased processing and handling
Changing processes, products
Globalization of food trade
SURVEY RESULTS ON FOOD SAFETY - EXAMPLE

Do you fear that branded milk may be adulterated and unsafe to drink?

Yes 60%  No 13%  Can’t say 27%

What is your regular source of milk supply?

DMS 12%  Mother Dairy 38%
Milkman/Private Dairy 50% (Pasteurization ?)

Delhiites Say

Food adulteration is rampant & the law against it remains only on paper 93%

Checking, testing and enforcement machinery must be revamped and strengthened 96%

Awareness must be built up among public so that they are also vigilant. 98%

Telephonic poll conducted by TNS-MODE among 249 Delhiites on May 31 to June 2.
Global food safety issues

- Drug residues
- GMO
- Allergens
- Mycotoxins
- Plant diseases
- Sanitation/quality
- Food born bacteria
Regulatory Evaluation

Hazard Based approach

1940 -1990

Control

Product Specifications Inspections

Q.C

Procedures Monitoring Feedback System

Q.A

Risk Based approach

Yr 2000 onwards

Trust

Supplier/ Customer C.O.P.Q

Problem solving continuous Improvement

T.Q.A

Management Systems

Culture change

Enterprise Wide

Control Driven

Culture / Behavior Driven

Involvement / Commitment

High

Low

1940 -1990

Q.C

Q.A

T.Q.A

T.Q.M

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Food Regulatory Transition

Simple

Complex

Products evolved, so have the regulations
Science behind Regulation
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.


2011 : FSSRR 2011

2012 – Import Regulation

2016- Nutraceutical Regulations /Product Recall
FSSA Legislative Frame

FSS RULES 2011

FSS REGULATION 2011

FSSAI 2006

Advisories
Pre FSSAI Scenario

Nine different laws and eight different ministries governing the food sector

Laws framed by different Ministries/Depts. With different perspective and enforcement approach

Overlapping laws with different quality standards & labelling requirements
India’s food regulatory system

Policy
The forum (FSSAI)
FSS Act, 2006, Rules and Regulations
Standards setting
FSSAI-Mandatory
BIS, DMI-Voluntary

Enforcement & Surveillance
State/UT governments
Indian Regulatory System

Regulation for Food:

• Food Safety and Standard Act, 2006
• Legal Metrology Act, 2009 & Packaged Commodities Rules, 2011
• The Essential Commodities Act, 1955
• Bureau of Indian Standards (BIS)
• AGMARK
• Consumer Protection Act
FSSA

The PFA Act, 1954
FPO 1995
MFPO 1973
EOP Order 1988
MMPO 1992
VOP Order 1947
Solvent Extracted Oil, De-oiled Meal and Edible Flour (Control) Order, 1967

FOOD SAFETY AND STANDARD ACT 2006
Objectives of FSSA

1. To consolidate multiple laws and establish single point reference system
2. To establish Food Safety and Standards Authority
3. To regulate the manufacture, storage, distribution, sale and import of food products
4. To ensure availability of safe and wholesome food for human consumption
How FSSA integrates?

- Vegetable Oil Products (Control) Order, 1947
- Edible Oils Packaging (Regulation) Order, 1998
- Solvent Extracted Oil, Deoiled Meal, and Edible Flour (Control) Order, 1967
- Milk and Milk Products Order, 1992
- Any other order under Essential Commodities Act, 1955 relating to food
- Prevention of Food Adulteration Act, 1954
- Fruit Products Order, 1955
- Meat Food Products Order, 1973
Regulatory Mechanism

Food Authority and the State Food Safety Authority

Central Advisory Committee
Close cooperation and coordination between Centre, States and other Stakeholders in the field of food including consumer org.

Scientific Committee
Consists of heads of scientific panels & 6 scientific experts. They will provide the scientific opinion on multi sectoral, cross-cutting issues

Scientific Panels
Nine panels on Food Additives, Pesticide Residues, GM Food, Biological Hazard, Labeling, Functional Food, Method of Sampling, Contaminants and Fish & Fisheries.
Stakeholders

- Food Safety Research institutes/laboratories
- Industry
- Farmers organizations
- Govt. Agencies
- Regulators
- Consumer organizations
## Building blocks

<table>
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<tr>
<th>Science based Food Quality &amp; Safety Standards</th>
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<td>Regulations and science based standards for all types of foods</td>
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<td>Harmonize Domestic and International Food Standards</td>
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<tr>
<th>Effective Food Safety Regulation &amp; Integrated Food Quality Testing &amp; Risk based Surveillance</th>
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<td>Enforcement through States</td>
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<td>Networked Laboratories for Food Testing</td>
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<td>Surveillance through Risk based Approach</td>
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<th>Support Services &amp; Communication</th>
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<tr>
<td>Capacity Building, Training &amp; Education for all Stakeholders</td>
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<tr>
<td>Community Outreach promotion Programmes to increase the confidence of the consumer</td>
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</table>
A leap forward

Single authority

Safety

Monitoring and surveillance

Full time officers

Laboratories in public and private sectors involved
The Various Regulations

Licensing and Registration
Packaging & Labelling
Food Standards
Food Additives
Contaminants & Toxins
Prohibitions and Restrictions
Laboratory sampling and Analysis
The Repeals

SECOND SCHEDULE (Section 97) – Following Acts /Orders get repealed

The Fruit Products Order, 1955.
The Vegetable Oil Products (Control) Order, 1947.
The Solvent Extracted Oil, De oiled Meal, and Edible Flour (Control) Order, 1967.
Any other order issued under the Essential Commodities Act, 1955 (10 of 1955) relating to food.

- All provisions of these will get covered in the new regulations
Basis of FSSA Regulations

- Science Based
- Safety Assessment
- Risk Analysis
Safety

• The condition of being protected from or unlikely to cause danger, risk, or injury

• Food safety” means assurance that food is acceptable for human consumption according to its intended use
Science Based

- With scientific rationale
- Tested through scientific methods
- Repeatability
- Predictability
Risk Based Approach

Risk analysis

- Risk analysis is powerful tool for carrying out science based analysis and for reaching sound, consistent solution for food/cosmetic safety problems

- Risk is basically combination of two concepts
  - Probability of occurrence-
  - Severity of Hazard
Recent Updates
Regulatory Changes - Flow

Flow of Regulatory Process at FSSAI

8 step process at different levels of Authority once application is filed

Timeline required for any regulatory process: Any thing from 1 year to 4 years
Recent Amendments

• Inclusion of Alkali Blue indicator for the determination of Acid Value of rice bran oil in place of phenolphthalein

• Revision of iodine value of cottonseed oil from 98-112 to 98 to 123

• To increase the Unsaponifiable value of Blended edible vegetable oils blended with physical refined rice bran oil up to 4% (Not more than 4.0 percent by weight; provided that oryzanol content be minimum of 0.20% (by weight) with rice bran oil at 20% level and with an increment of 0.05% with every 5% rise in rice bran oil content in the blend.”)

• Maximum pack size permitted for blended edible vegetable oils to be changed from 15 litres to 15 kg
Recent Amendments

• Palm stearin as edible fat and permitted to use in the manufacture of vanaspati and interesterified fats

• To redefine Interestified Vegetable Fat into Interestified Vegetable Fat/Oil To include Enzymatic degumming process in the refining process

• Declaration of trans fatty acids and saturated fatty acids contents in food may only be placed in the Nutritional Panel to avoid duplicity in declarations

• Removal of BR reading for IE- fat

• Voluntary Fortification of Edible Oil with Vitamin A & D – 4.5 /25IU

• Exemption from refining for Expelled/Pressed coconut oil imported in
Recent Amendments

- Operationalization of HS, SMP, NF and Nutraceutical draft Regulation
- Operationalisation of new additive regulations
- Operationalisation of import guidelines
- Operationalisation of Proprietary food regulations
- **Guidelines for operations of e-commerce food business operators**
- Palm and Palm kernel Oil Standards: FFA Not more than 10
- Exception of imported raw coconut oil for refining
- **Enforcement notice w.r.t repeated use of edible oil**
Food Categorization as per FSSA
Food categories

- **Health Supplements**: Supplement to normal diet
- **Nutraceuticals**: Isolates/extracts providing health benefit
- **FSDU**: Supplement dietary reqt arisen due to health condition
- **FSMP**: Dietary management of patients
- **Probiotic Foods**: Food containing microbes beneficial to human health
- **Prebiotics**: Food with prebiotic ingredients
- **Specialty Foods**: Food containing plant or botanical ingredients conferring health benefit
- **Novel Foods**: No history of safety/new technology
• Palm and Palm kernel Oil Standards: FFA Not more than 10.

Standards for Virgin coconut oils

• Standard for peanut butter

• The oils and fats covered under the regulation 2.2 shall comply with the fatty acid composition of the respective oils and fats given in the tables
New Agendas to be taken

- Review mandatory usage of Sesame seed oil in the manufacture of Vanaspati

- Unsap value to be revised (max 4.0) for Table margarine, fat spread, vanaspati ,IE when RBO is used. (Not more than 4.0 percent by weight; provided that oryzanol content be minimum of 0.20% (by weight) with rice bran oil at 20% level and with an increment of 0.05% with every 5% rise in rice bran oil content in the blend.)

- **Exemption from refining for Expelled/Pressed edible (Ground nut /Mustard /Flax seed and other) oils imported in India**

- Framing of Avocado Oil standards under edible oil category in line with Codex (Codex is framing the standards)

- Removal of Boudouin Test requirement for Blended edible Vegetable Oil

- Removal of hydrogen gas facilities from 2.2.6.(1).Vanaspati
## New Agendas for Mustard

<table>
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<tr>
<th>Revision of RI, BR and IV for mustard Oil</th>
<th>2.2.1 (6) Rapeseed/Mustard oil: Refractive Index 1.4646 to 1.4662 Butyro-refractometer reading 58.0 to 60.5 Iodine value 96-112</th>
<th>1. Revise the refractive index @ 40 C from 1.4646 - 1.4662 to 1.461-1.469 (in line with Codex) 2. In conjunction with increase in range of refractive index, the upper limit for B.R should also be increased from 58-60.5 to 58 -65.0 3. Iodine Value is in direct relation with refractive index( RI) so that also needs revision from 96-112 to 98-114 as per oil trend of last 10 yrs.</th>
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<td>Revision of Bellier Test from Mustard Oil specification</td>
<td>2.2.1 (6) Rapeseed/Mustard oil: Bellier test (Turbidity temperature Acetic acid Method) Oil 23.0 to 30C</td>
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<td>Standard for KGMO (Kachi Ghani Mustard Oil)</td>
<td>No current standards</td>
<td>1. Introduction of a standard for KGMO: a. Inclusion of Allyl isothiocyanate as a key factor responsible for pungency of KGMO. Proposed limit: 0.1 to 0.6 This has been derived from 1. Agmark standard (0.1 to 0.6 for raw grade II) 2. BIS (0.1 to 0.6 for raw grade II) b. Rest all parameters shall be similar to Mustard Oil.</td>
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New Agendas to be taken

Use of exotic fats like Shea, Illipe, dhrambe, Mowrah (Mahua) fats and their fractions may be allowed to be used in chocolate/confectionery products as CBE (Cocoa butter equivalent) ingredients and when added at 5% level in chocolate.

Use of Algal oils as source of EPA, DHA & ARA may be permitted in Infant food formulations & Dietary supplements as a vegetarian source of long chain w3 rich oils.
Other Important Activities

Standard Review group
1. The group has forwarded the 28 agenda file to FSSAI
2. Other agendas to work on separately:
   a) More than one oil for blending
   b) AGMARK issue

• Voluntary Fortification activity
1. The deadline given for the first phase to industries was 31st March 2017
2. To represent effectively about restricting the scope to refined oils only

• New FSMS document
1. New FSMS being designed for Oil industry
2. The document will consist of three sections: a) Oilseed crushing
   b) Oil manufacturing
   c) Oil Storage and transport
3. The document is still under process.
Future Regulatory Trends

• Harmonization & Equalization
• Clean Label
• Transparency
• Traceability
• Consumer Engagement
• Structural Enforcement
• Vulnerability Assessments
• Non GMO Claim
• Environment issues : Plastic Ban
Issues in implementation

Volume

Food Business Operators

- State licensing
  - Medium scale
- State licensing
  - Small Scale
- Petty Food Business Operators
- Central Licensing
  - Big Scale
E-Governance Initiatives

Adopting E-Governance initiatives the only way to manage the responsibility entrusted under the Act by ensuring transparency, accountability and reducing human interface

Y  Food licensing and registration system (FLRS)
Y  Food Import Clearance System (FICS)
Y  Food Product Approval System (FPAS)
Y  On-line Payment gateway system-made effective from 1st April 2014
Y  Food risk inspection prioritization system (FRIPS)-on the anvil
Prosecution – Punishable with Fine only

Punishable with Fine → Petty Manufacturer → Compounding u/s. 69

Other FBO’s → Order by Adjudication Officer

Enforcement

Appeal to Appellate Tribunal constituted by Central or State government
Conclusion

• Regulatory changes are dynamic

• Need to engage with regulators to understand the changes

• Consumers are empowered through social media

• Compliance is hygiene

• Cost of regulatory (non compliance) will be high
Thank You
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