FOOD SAFETY & STANDARDS AUTHORITY OF INDIA
Dr. G. SRINIVASAN,
DEPUTY DIRECTOR&DESIGNATED OFFICER,(CENTRAL LICENSING)FSSAI,REGIONAL OFFICE,CHENNAI
India is one of the world’s largest food producers.
- China: 856 million tonnes
- USA: 608 million tonnes
- India: 601 million tonnes
- Second largest producer of fruits (46.64 million tonnes) after Brazil.
- Second largest producer of vegetables (78.19 million tonnes) in the world, next to China.
(13% of world’s production)
India At A Glance

India will be world power in Food & Agriculture by 2020

John E. Peters
M Dr. A.P.J Abdul Kalam
Hon’ble Ex. President
INDIA 2020  a Vision for the new Millenium ( Chapter 4 Food, Agriculture & Processing )
Food processing sector

- Meat & Poultry
- Oils and Fats
- Dairy
- Fruits & vegetable processing
- Marine processing
- Grain processing
- Beer and Alcohol
- Consumer products (Biscuits, Snacks, Beverages)

PRESENT VALUE 4 LACS CRORE
Food Safety and Standards Bill piloted by MOFPI, passed by parliament in Monsoon session and approved by President in September, 2006
Why FSS Act?

- Multiplicity of food laws, standard setting and enforcement agencies for different sectors of food
- Varied Quality/Safety standards restricting innovation in food products
- Thin spread of manpower, poor laboratories infrastructure and other resources non-conducive to effective fixation of standards
- Standards rigid and non-responsive to scientific advancements and modernization
- Poor Information dissemination to consumer level
FOOD SAFETY & STANDARDS ACT, 2006

Mandate:

- To consolidate the Laws relating to food
- To establish the Food Safety and Standards Authority of India for
  - Laying down science based standards for articles of food
  - To regulate their manufacture, storage, distribution, sale and import of food
  - To ensure availability of safe and wholesome food for human consumption
FSS Act: Integrates

- Food Safety and Standards Act, 2006
- Prevention of Food Adulteration Act, 1954
- Fruit Products Order, 1955
- Meat Food Products Order, 1973
- 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
India then and now......
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.
DEFINITION OF FOOD UNDER PFA ACT, 1954

“Food” means any article used as food or drink for human consumption, other than drugs and water and includes:-
DEFINITION OF FOOD UNDER FSSA ACT, 2006

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 (zx), 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 but does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption, plants prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances:
Salient features

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

- Emphasizes on the need for risk assessment; not trade restrictive

- Provisions relating to functional and novel food

- Prescribes graded penalties for offenses/violations

- Improvement notices
Legislative Frame

- FSSAI 2006
- FSS RULES 2011
- FSS REGULATION 2011
- FSSAI 2006
FUNCTIONS OF AUTHORITY

- To regulate, monitor the manufacture, processing, distribution, sale and import of food to ensure its safety and wholesomeness.
- To specify standards, guidelines for food articles
- Limits for Food additives, contaminants, veterinary drugs, heavy metals, mycotoxin, irradiation of food, processing aids.
- Mechanisms & guidelines for accreditation of certification bodies engaged in FSMS certification
- Quality control of imported food
- Capacity building of all the stakeholders
- To establish Surveillance mechanism for food safety
- Scientific advice and technical support to central / state governments
<table>
<thead>
<tr>
<th>Change: PFA to FSSAI</th>
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<tbody>
<tr>
<td><strong>PFA</strong></td>
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<tr>
<td>- All manufacturing units under Local authorities</td>
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<tr>
<td>- Inspection not compulsory</td>
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<tr>
<td><strong>FSSAI</strong></td>
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<tr>
<td>- Big manufacturing units under central licensing FSSAI (Delhi)</td>
</tr>
<tr>
<td>- Pre Inspection compulsory before giving license</td>
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</tbody>
</table>
Change: PFA to FSSAI

- **PFA**
  - No provisions of improvement notices
  - GMP/GHP Not mandate
  - No provision of annual returns

- **FSSAI**
  - Provision of improvement notices
  - GMP/GHP Mandatory
    - (schedule 4)
  - Provision of annual returns before 31st May
Change: PFA to FSSAI

- **PFA**
  - Punishment through court
  - No import regulation

- **FSSAI**
  - Fine/Penalty through adjudication.
  - Punishment through court
  - Special import regulation
General Impact

• All Big manufacturing facilities will need to be licensed by **Central Licensing Authority FSSAI**

• Small players /warehouses/distributors will need to obtain a valid license from **State Licensing Authority**

• All the licensed establishments will be subject to **periodical inspections** and food safety audits by respective licensing authorities

• FSMS Plan and Food Recall process
General Impact

- Reduction in court cases by adjudication process
- Import regulations.

- New section of food categorization: Section 22
  - Functional food and Nutraceuticals
  - More scope for product innovation

- New documents of label claims & Claim substantiations.

- New formats will come under food
  - Capsules/syrup/tablets
1. Requirement: Employ at least one technical person to supervise the production process.

2. Requirement: No producer or manufacturer of vegetable oil, edible oil and their products shall be eligible for license under this Act, unless he has own laboratory facility for analytical testing of samples.

3. The equipments are made of stainless steel /galvanised iron/ non corrosive materials.

4. No edible oil is sold/distributed/offered for sale/dispatched or delivered for purpose of sale unless it is packed, marked and labelled in the manner specified in the regulations.
- **Requirement**: The food products are bought/sold by the manufacturer/importer/distributor only from or to licensed/registered vendors and records are maintained.

- **Schedule 4 requirements mandatory**
  - Auditing agencies are declared.

- Water analysis report

- Food safety Management plan or certificate

- Heavy **metal analysis** once in six months.
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
Major Functionaries in the State

- Food Safety Commissioner
- Designated Officer
- Food Safety Officer
- Food Analyst
- Accredited Lab
- Referral Lab
- Food Safety Appellate Tribunal
- Special Courts (whenever required)
- Adjudicating Officer
## Fine and Penalties

<table>
<thead>
<tr>
<th>Fine and Penalties Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penalty for substandard food</td>
<td>Rs 5 lacs</td>
</tr>
<tr>
<td>Penalty for misbranded food</td>
<td>Rs 3 lacs</td>
</tr>
<tr>
<td>Penalty on misleading advertisement</td>
<td>Rs 10 lacs</td>
</tr>
<tr>
<td>Food containing extraneous matter</td>
<td>Rs 1 lac</td>
</tr>
<tr>
<td>Penalty for failure to comply with food safety officer</td>
<td>Rs 2 lacs</td>
</tr>
<tr>
<td>Penalty for unhygienic processing of food</td>
<td>Rs 1 lacs</td>
</tr>
<tr>
<td>Punishment for unsafe food/Not having valid license</td>
<td>six months of imprisonment/5 lakhs</td>
</tr>
</tbody>
</table>
FOOD FOR CELEBRATION!

NOW ASSURED BY
FOOD SAFETY & STANDARDS RULES, 2011
(Under Food Safety & Standards Act, 2006)

FSSAI - IMPLEMENTING
THE NEW FOOD LAW FOR ENSURING
FOOD SAFETY & BUSINESS SUCCESS

Rather than having six to seven separate food laws for meat, milk, edible oil, fruits and vegetables, etc, the new integrated food law, Food Safety and Standards rules 2011, has laid down uniform standards and a central mechanism on safety. It focuses on the entire supply chain: production, processing, distribution, and marketing, creating a single window convenience for the food businesses, as well as ensuring consumers get food that is safe and healthy. The Centre, states, municipalities and panchayats will help implement it. For the consumers, it’s a blessing. For the businesses, it’s a guiding light towards sustainable success.

ADVANTAGES:
- Less inspection & more audit system have been initiated.
- More scientific standards of Food Safety have been set.
- All Food operators will be licensed.
- Small operators to be exempted from licensing, but will be registered.
- Penalty will be imposed if the regulator is found harassing food operators.

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA
FDA Bhavan, Next to Rashtriya Bai Bhavan, Kota Road, New Delhi - 110002, India. Email: admin@fssai.gov.in
www.fssai.gov.in Or Call 91 Toll Free Helpline: 011 111 111 11
Hope for Bright Tomorrow
Licensing & Registration - FSSA
Salient Features

• Unified Licensing procedures - Single Window

• Common application forms and procedures.

• Distinction between ‘registration’ and ‘licensing’. Cut off limits for registration and licensing.

• Two tier system of licensing – Central & State
Salient Features

• Introduction of exhaustive Safety, Sanitary and Hygienic conditions mandatory for registration/licensing.

• Less inspections, more audit of system

• 60 days time limit for processing of license.

• Thrust on Preventive Actions
New Terms

• **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
New Terms

• “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;
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.
License

- No person (other than petty food businesses) shall commence any food business without obtaining a valid license. (regulation 2.1)
- Existing Operator holding valid license/registration shall be granted a license within one year of notification of this Regulation
- No license fee for the remaining period of the validity of the earlier license.
License

✅ License for businesses mentioned under Schedule 1, shall be granted by the Central Licensing Authority and all others by State licensing Authority.

✅ Importers of food items shall obtain a license from the Central Licensing Authority in addition to license taken for any other food business.
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.

vi. 100% Export Oriented Units

vii. All Importers importing food items

viii. All FBOS manufacturing any article of food containing ingredients or substances or using technologies or processes or combination thereof whose safety has not been established through this regulations or which do not have history of safe use or food containing ingredients which are being introduced first time in to the country.

ix. Retail chains operating in three or more states.

x. Food catering services in establishments and units under Central government Agencies like Railways, Airlines and airport, Seaport, Defense etc.
Installed capacity more than 2 MT per day
**Procedure of Licensing**

1. **Filing of an Application**
2. **Unique Application Number**
3. **Require additional information on incomplete Application**
4. **Inspection of premises after receiving completed application & issue inspection report**
5. **Either grant or reject the license**
   - Within 60 days of receipt of completed application or within 30 days of inspection

**Application Form B Documents + Fees**

- **If no response**
  - **No inspection**
    - **FBO may start the business after 60 days**
  - **If inspection report not processed**
    - **Suspension**
    - **Cancelation**

- **Improvement Notice**
  - **No improvement**
    - **Fresh application After 90 days**
Registration/ License Fee Per Annum In Rupees

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

- 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

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

User Name: [ ] Password: [ ] Sign In

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

About Online System

- FSSAI provides an oppurtunity 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.

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.
<table>
<thead>
<tr>
<th>Requirement</th>
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<tbody>
<tr>
<td>1. Location and Surrounding</td>
<td>7. Food testing Facilities</td>
</tr>
<tr>
<td>2. Layout and Design of Food</td>
<td>8. Audit, documentation and Records</td>
</tr>
<tr>
<td>Establishment Premises</td>
<td></td>
</tr>
<tr>
<td>4. Facilities</td>
<td>Premises</td>
</tr>
<tr>
<td>5. Food Operations and Control</td>
<td>10. Personal Hygiene</td>
</tr>
<tr>
<td></td>
<td>12. Training</td>
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</tbody>
</table>
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.
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 FSSA

• Ensure compliance with all the conditions of license & Schedule 4 requirements at all times

• 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
Proposed Amendment

• In the sub-regulation 2.2.1, after clause 6 of Food Safety and Standards (Packaging and labeling) Regulations, 2011, the following clause shall be inserted, namely:-

(7) License number*

*for the existing products of a unit this provision will come into effect six months after the date of issue of license under these regulations”

This implies-
• Food Authority will issue a license number for every FBO applying for FSSA license
• It will replace the EOP, VOP and SEO license numbers
• This license number need to be printed on the label of the products
• Time period of six months is provided from issue date of license for implementing this requirement
Action initiated to meet challenges ....

- Implementation of the Act as per new enforcement structure at Centre & States.
- Thrust on Capacity Building & Training of all Stakeholders
- Food Laboratory in every district and networking of all the food testing laboratories
- Emergency Response and rapid alert centre at each State.
- IT based system for all licensing and registration offices and introduction of GPS based sampling collection system.
“We must be the change we want to see in the world”

M.K. Gandhi

THANK YOU