FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food

Ministry of Health and Family Welfare, Government of India

MANUAL FOR FOOD SAFETY OFFICERS

A ready reckoner

MANUAL FOR FOOD SAFETY OFFICERS

SECOND EDITION - MARCH 2021

CONTENT

PREFACE

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Chief Executive Officer,
FSSAI

I am pleased to launch 2nd edition of "Manual for Food Safety Officers". This manual has been developed keeping-in-view the updated provisions of FSS Act, its rules and regulations vis-à-vis the role and responsibilities assigned to FSOs with particular emphasis on uniform approach to ensure transparency and consistency towards implementation and compliance of regulatory provisions.

This manual serves as a quick reference book and covers subjects such as the Food Safety and Standard Act 2006, its Rules and Regulations, Regulatory Authorities and their functions & duties, Registration and Licensing, Inspections, Surveillance, Sampling & Laboratory networks, Adjudication with Offences & Penalties, CODEX etc. which are expected to be in good knowledge of Food Safety Officers.

Food Safety Officer are the frontline officers engaged in ensuring food safety compliance to protect the health and wellbeing of consumers. Therefore, it is our responsibility to strengthen their capacity by providing training and guidance materials. Publication of a revised and up-to-date manual for FSOs is a significant step towards this objective.

Food Safety Officers are advised to study all chapters covered in this manual. They are also advised to visit FSSAI's website at regular intervals to keep themselves updated with all the regulations notified under the FSS Act 2006, its amendments and other related policies, guidelines, advisories, clarifications etc. that are issued from time to time for information.

I am hopeful that this manual will enhance the knowledge of FSOs and it can be used as ready reckoner towards discharge of their duties in a professional manner.

ACRONYMS

AGMARK	Agricultural Produce Grading and Marking
AO	Adjudicating Officer
APEDA	Agricultural and Processed Food Products Export Development Authority
BIS	Bureau of Indian Standards
CAC	Central Advisory Committee
CEO	Chief Executive Officer
CFL	Central Food Laboratory
CFS	Commissioner Food Safety
CLA	Central Licensing Authority
DART	Detect Adulteration with Rapid Test
DO	Designated Officer
EOI	Expression of Interest
FA	Food Analyst
FBO	Food Business Operator
FDA	Food & Drug Administration
FFRC	Food Fortification Resource Centre
FICS	Food Import Clearance System
FLRS	Food Licensing Registration System
FoSCoRIS	Food Safety Compliance through Regular Inspections and Sampling
FoSTaC	Food Safety Training and Certification
FoSCoS	Food Safety Compliance System
FSS Act	Food Safety and Standard Act, 2006
FSSAI	Food Safety and Standards Authority of India
FSO	Food Safety Officer
FSKAN	Food Safety Knowledge and Assimilation Network
FSMS	Food Safety Management System
FSM	Food Safety Mitra
FSS	Food Safety Supervisor

ACRONYMS

HACCP	Hazard Analysis and Critical Control Point
HFSS	High Fat Salt & Sugar
GAP	Good Agricultural Practices
GFSP	Global Food Safety Partnership
GHP	Good Hygiene Practices
GM	Genetically Modified
GMP	Good Manufacturing Practices
INfoLNET	Indian Food Laboratory Network
LSG	Local Self Government
MDM	Mid Day Meal
NABL	National Accreditation Board for Testing and Calibration Laboratories
NetProFan	Network of Professionals of Food & Nutrition
NFL	National Food Laboratory
NLRP	National Level Resource Person
PA	Product Approval
PFA	Prevention of Food Adulteration Act, 1954
QA	Quality Assurance
QC	Quality Control
RBIS	Risk Based Inspection System
RFP	Request for Proposal
RUCO	Repurpose Used Cooking Oil
SAC	State Advisory Committee
SC	Scientific Committee
SOP	Standard Operating Procedures
SHG	Self Help Group
TOT	Training of Trainers
TP	Training Partners
WHO	World Health Organization

IMPORTANT WEB LINKS

S.No.	Particulars	Web Links
1	**FSSAI**	https://fssai.gov.in
2	**Food Safety Standards Act, 2006**	https://fssai.gov.in/cms/food-safety-and-standards-act-2006.php
3	**FSS Rules**	https://fssai.gov.in/cms/food-safety-and-standards-rules--2011.php
4	**FSS Regulations**	https://fssai.gov.in/cms/food-safety-and-standards-regulations.php
5	**FoSCoS (Food Safety Compliance System)**	https://fssai.gov.in/cms/foscos.php
6	**FICS (Food Import Clearance System)**	https://fics.fssai.gov.in
7	**INfoLNET (Indian Food Laboratory Network)**	https://infolnet.fssai.gov.in/#
8	**Food Safety Connect, FSSAI (Android)**	https://play.google.com/store/apps/details?id=com.fssai&hl=en_IN&gl=US
9	**Food Safety Connect, FSSAI (Online portal)**	https://foodlicensing.fssai.gov.in/cmsweb
10	**FoSTaC (Food Safety Training and Certification**	https://fostac.fssai.gov.in/fostac/index
11	**FSWs (Food Safety on Wheels)**	https://fssai.gov.in/cms/mobile-labs.php
12	**Eat Right India**	https://eatrightindia.gov.in/EatRightIndia
13	**NetProFan (Network of Professionals of Food\ & Nutrition)**	https://fssai.gov.in/NetProFaN
14	**Food Fortification**	https://ffrc.fssai.gov.in
15	**FSSAI Books, Reports and Manuals**	https://fssai.gov.in/knowledge-hub.php?hubname=Book,Report,Manuals
16	**FSKAN**	https://fssai.gov.in/fskan

IMPORTANT WEB LINKS

S.No.	Particulars	Web Links
17	**RUCO**	https://fssai.gov.in/ruco
18	**ITCFSAN (International Training Centre for Food Safety and Applied Nutrition)**	http://itcfsan.in
19	**National Milk Quality Monitoring System**	https://fssai.gov.in/MilkSurvey
20	**Safe Food, Share Food**	https://sharefood.fssai.gov.in
21	**FSSAI Food Hygiene Rating Scheme**	https://fssai.gov.in/hygieneRating/home
22	**FSSAI Video Library**	https://fssai.gov.in/fssaivideolibrary
23	**FSSAI Facebook page**	https://www.facebook.com/fssai
24	**FSSAI Twitter page**	https://twitter.com/fssaiindia
25	**FSSAI Youtube page**	https://www.youtube.com/c/FoodsafetyinIndia

CHAPTER-1

FOOD SAFETY REGULATORY ECOSYSTEM

1 FOOD SAFETY REGULATORY ECOSYSTEM

WHAT IS FOOD SAFETY ECOSYSTEM?

Ecosystem includes all the living and non-living things in a given area, interacting and influencing each other and determining the health of the entire earth system. **It also combines biosecurity meaning the protection from the environmental, economic and human health risks of potentially harmful plant and animal pests and diseases, alien invasive species and genetically modified organisms.** In many most of the countries, governments have created regulatory authorities to ensure food safety, animal health and plant health. These Authorities carry out inspections of the food chain "from farm to fork" with the aim to protect animal, plant and human life and health.

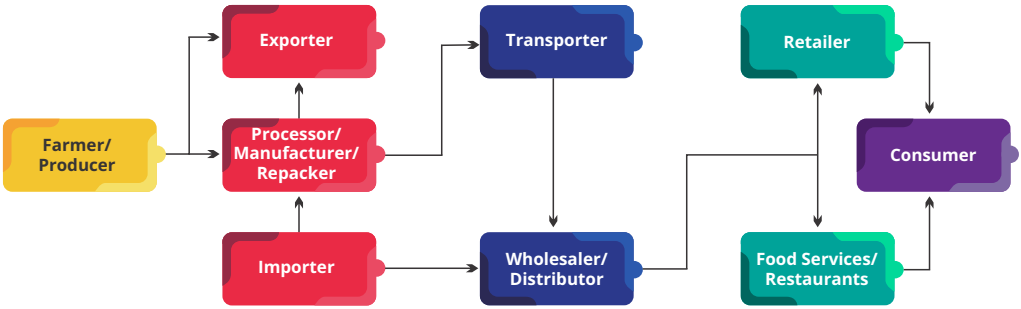
FOOD SUPPLY CHAIN

The term 'Food chain' was first introduced by African–Arab scientists and philosopher Al Jahiz in the 9th Century and later popularized in a book published in 1927 by Charles Elton, which also introduced the food web concept. Natural interconnections between food chains is called a food web starting from producer organisms and ending at apex predator species. In the context of food safety, the term ***"food supply chain"*** becomes relevant.

A food supply chain refers to the processes that describe how food from a farm ends up on our tables. The processes include production, processing, distribution, consumption and disposal. The food supply chain is a complex network consisting of small and medium sized enterprises that can interact with larger companies and retailers as well. The food we eat reaches us via food supply chain through which food moves systematically in domino-like motion from producers to consumers.

STAKEHOLDERS IN FOOD SUPPLY CHAIN

Different stakeholders are involved in the food production and supply chain as shown in the diagram below:

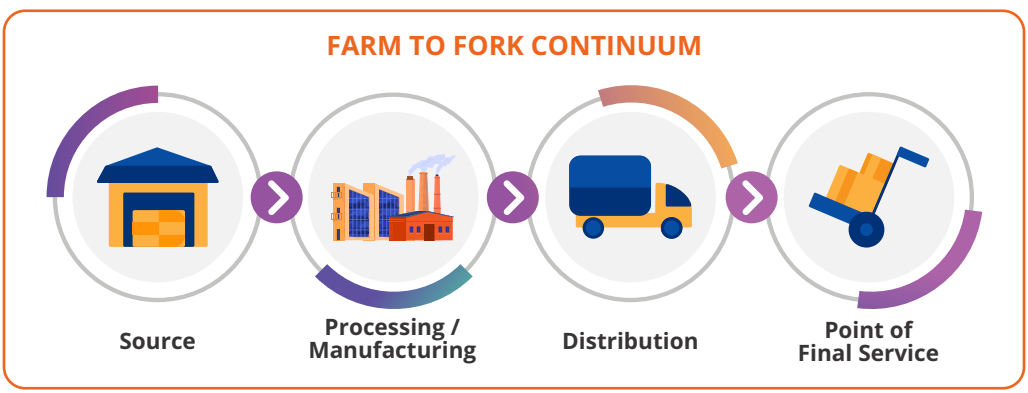


THE CONCEPT OF "FARM TO FORK"

The term 'food safety' as defined by CODEX Alimentarius Commission is the assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use. Food safety is related to the occurrence of food safety hazards and does not include other human health aspects related to, such as malnutrition.

Food safety is relevant at different stages of supply, preparation/processing, distribution and serving. The food chain starts on the farm and ends on the fork. During every stage, great care must be taken to ensure that the end product will be safe for human consumption.

In modern context, the concept of food safety is described by the 'Farm to Fork' model. This concept captures the essence of food safety and forms the backbone of food safety. The path from food source to the point of final service is called the ***farm to fork continuum***



From "***Farm to Fork***" traces the different stages of the food chain system and examines the practices and procedures that ensure the safety of our food. The factors that led to this Farm to Fork model of food safety are:

1. CHANGING FOOD PATTERNS

The industrial revolution, and more recently, modern food technology has changed the food patterns of all. The majority of people today is far removed from the sources of food they eat on daily basis. If we are living longer in a period of abundant, diverse and reliable food supply, it is in part due to the variety and safety of the food we eat.

2. THE FARM : BEGINNING THE FOOD CHAIN

The origins of most food products such as bread, milk, meat, fruit, vegetables, sugar, etc. are in agriculture. They are either produced directly on farms or based on food coming from farms. Farmers grow food, which they harvest, store and transport to markets or to processing plants for preservation and transformation into a variety of food products. To ensure that the produce whether vegetable or animal in origin coming out from farms is produced in a safe manner, **the farmers should make the correct use of fertilisers, pesticides, antibiotics and other products in crop and animal husbandry.**

3. FOOD PROCESSING

Almost all food must be processed in some way before it can be eaten. There are various levels of food processing and **the food processors rely on food safety management systems (FSMS) to ensure the quality and safety of the products they produce.**

4. TRANSPORT AND STORAGE

Transport and storage form vital links in the food chain between the farmer's field and the consumer's table. While the role of the farmer, the food processor and the retailer in the food chain is easily understood, the importance and role of well-managed transport and storage should not be forgotten. Maintaining high standards while transporting food products transporters must implement quality standards in transport and storage as specified in FSMS to safeguard food.

5. FOOD AND THE CONSUMER

Throughout the food chain, farmers, food processors, retailers and others utilise

numerous practices based on long experience to ensure the quality and safety of food. Collectively, these procedures are known as **"good agricultural practices", "good manufacturing practices"** and **"good hygienic practices".** It is very important for the consumer to understand and follow basic instructions and precautions set by professionals (as indicated on food labels) when purchasing, transporting, storing, preparing and consuming food. Good hygienic practices both in the home and outside can protect consumers against microbial contamination and the food borne diseases caused by it.

6. EATING OUTSIDE THE HOME

One link in the food chain from farm to fork which deserves special attention is the preparation of meals outside the home, restaurants, hospitals, nursing homes, child care establishments, schools, canteens, wedding parties, business conventions etc. Considering the vast number of meals consumed in such public settings FBOs, chefs and caterers do and should ensure protecting the public against food borne disease. **The consumer should look for recognised certificates of good hygiene (such as hygiene ratings) in public places.**

Food safety is a shared responsibility of everybody involved with food from the food business operator to regulator and consumer. All along the food supply chain, various procedures and good practices are implemented to ensure that the food which reaches the consumer's table is fit for consumption, that the risks of contamination are minimised and they get a safe and quality food. However, the responsibility for ensuring food safety should not only be the priority of FBOs but the consumer is also equally responsible to ensure the safety of food at home.

FSS ACT 2006, FSS RULES, 2011 AND OTHER REGULATIONS

GENESIS OF THE FOOD SAFETY AND STANDARDS ACT 2006

Prior to the enactment of Food Standards and Safety Act in 2006, there were a number of food related legislation administered by different Ministries of Government of India. **No less than eight legislation prescribed the minimum regulatory standards for various type of food and food products prior to FSS Act**. Over a period of time, this led to a state of multiplicity of food standards (often overlapping and sometimes contradictory to one another) and enforcement agencies. This created confusion among food businesses, consumers, traders, manufacturers and investors and hampered the growth of a modern

food processing sector in the country as well as fixation of safety standards. Further the existing laws on food had failed to match the rapid evolution of food related technologies and advancements in the production, distribution & marketing of the food.

The Second Schedule of the Act contains all the earlier food related legislations which are as follows.

1. *Prevention of Food Adulteration Act 1954 (Act No 37 of 1954)*
2. *Food Product's Order 1955*
3. *The Meat Food Product's Order 1973*
4. *The Vegetable Oil Products (Control) Order 1947*
5. *The edible oil's packaging (Regulation) Order 1998*
6. *The Solvent Extracted Oil, de-oiled meal, & edible flour (Control) Order 1967*
7. *Milk & Milk Product's Order 1992*
8. *Any Other Order issued under the essential commodities Act 1955 (10 of 1955) relating to food Under Section 99 of the Act, Milk & Milk Product's Order 1992 shall be deemed to be Regulation issued by the Authority under this Act.*

The intent of the Act lies in bringing almost all the food business areas within its scope & to promote the objective of ''Food Safety'' and not mere the'' Prevention of Food Adulterations ''as was the case with the previous laws

FOOD SAFETY AND STANDARDS ACT 2006

Realizing that how inadequate these Acts and Orders were proving, the Prime Minister's Council of Trade and Industry in 1998 recommended enactment of a comprehensive legislation of food subsuming all the present food laws to modernize the food sector and ensure safety of food. In 2004, the Joint Parliamentary Committee (JPC) emphasized that all the present food laws should be converged and there should be just one regulatory body for the whole of India. The Food Standards and Safety Bill, 2005 was passed by both the Houses of Parliament after extensive discussions, consultations with stakeholders and forging a consensus on contentious issues and became an Act on **2 August, 2006.**

OBJECTIVES, MANDATE AND SCOPE OF FSS ACT

The objective of the FSS Act, 2006 is to make available safe and wholesome food to the public, in keeping with changing needs and requirements. The Act also aimed to establish Food Safety and Standards Authority of India (FSSAI), as the single reference point for all matters relating to FSS Act, Regulations and enforcement, by moving from multi- level, multi-

departmental control to a single line of command.

The major areas of departure of FSS Act from PFA act are:

- Food safety is the primary responsibility of the Food Business Operator (FBO) as it knows best how the food is manufactured and how safety can be compromised.
- Risk assessment must form the basis of standard setting. The regulator needs to monitor the latest scientific development in the food sector, emerging safety issues across the world and anticipate safety risks before they actually hit.
- FBOs at various stages in the food chain need to adhere to applicable safety and hygienic practices as contamination can occur at any point in the food chain. Certification of food safety processes or safety audits become important to ensure food safety.
- Transparency in setting standards wherein stakeholders are provided with reasonable time to give suggestions on proposed regulations as well as sufficient time to FBOs to make necessary changes in their processes to adopt the new regulations.
- FBOs have a clear means of contesting the findings of government food laboratories by appealing to accredited referral laboratories.

In addition, the Authority in exercise of powers conferred by Sub-Section 1 of Section 97 of the Act, has also repealed the enactment and orders in the Second Schedule of the Act with effect from 5th August, 2011.

All kinds of food, whether unprocessed/semi-processed/processed, are covered under the scope of the FSS Act. It also includes all kinds of substances and water that is used in the preparation of food. It is important to mention that, the Act considers live animals or products of agriculture, horticulture or animal husbandry as food only when it has already passed on from the hands of a farmer. Thus all activities throughout the food value chain, after primary production through distribution to retail and catering are under the ambit of the Act. The Act does not discriminate between a small hawker or a huge FBO and makes it mandatory for everyone handling food to keep it safe and fit for human consumption. Therefore, this Act is applicable to every person that is in the food business.

FOOD SAFETY AND STANDARDS RULES 2011

Food Safety and Standards Rules, 2011 have been framed by the Central Government. The broad coverage of such Rules & Regulations are stipulated under Section 91 & Section 92 of the Act. The Rules mainly cover the administrative structure & functioning of FSSAI and various bodies under it. In addition, there are three amendments made in these Rules from time to time.

The Food Safety and Standards Rules, 2011 comprises ***of three chapters:***

Chapter 1

Provides the ***general description*** about the Rules and ***definitions*** applicable under these Rules.

Chapter 2

Provides the detailed description about the ***enforcement structure and procedures***. It includes the qualifications, powers and duties of Commissioner of Food Safety, Designated Officer, Food Safety Officers and Food Analyst. It provides the procedural details of working of Food Safety Officers while conducting the inspections. Details of the documents and affidavits that are supposed to be extracted and other matters connected therewith. The manner the Food Safety Officers can take sample for analysis and also seize the articles of food. It also specifies the sampling and analysis procedures and the manner of sending samples for analysis to the food laboratories. The way the food analyst should receive the samples and analyze the same within the stipulated time periods (Regulatory samples, import samples and survey samples). In addition, this chapter also specifically describes action of Designated Officer on the report of Food Analyst and how the consumer (Section 40 of FSS Act) and food business operator may have the food analysed.

Chapter 3

This is about the adjudication proceedings the qualification and term of office of presiding officer of an Appellate Tribunal and procedure for appeal to Appellate Tribunal and connected matters therewith.

Complete details can be accessed through the link given below:
https://www.fssai.gov.in/upload/uploadfiles/files/FSS_Gazete_Rules_2011.pdf

THE FOOD SAFETY AND STANDARDS REGULATIONS

Section 92 (1) of Food Safety and Standards Act, 2006 empowers the Food Authority to make regulations/standards in consistent with this Act and Rules made there under. After the enactment of the FSS Act, 2006, FSSAI has drafted six principle regulations through extensive consultation and deliberations with various stakeholders. These regulations were notified in the gazette of India on **1st August, 2011 and came into force on 5th August, 2011.**

Six principle regulations notified on 1st August, 2011

1. Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011
2. Food Safety and Standards (Prohibition and Restriction of Sales) Regulation, 2011
3. Food Safety and Standards (Packaging and Labelling) Regulation, 2011
4. Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011
5. Food Safety and Standards (Laboratory and Sampling Analysis) Regulation, 2011
6. Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011

Other regulations notified till date under FSS Act, 2006 are appended below:

- **Food Safety and Standards Authority of India (Transaction of Business at its Meetings) Regulations, 2010**
- **Food Safety and Standards Authority of India (Procedure for Transaction of Business of the Central Advisory Committee) Regulations, 2010**
- **Food Safety and Standards Authority of India (Salary, Allowances and Other Conditions of Service of Officers and Employees) Regulations, 2013**
- **Food Safety and Standards Authority of India (Transaction of Business and Procesdures for the Scientific Committee and Scientific Panel) Regulations, 2016**
- **Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016**
- **Food Safety and Standards (Food Recall Procedure) Regulation, 2017**
- **Food Safety and Standards (Import) Regulation, 2017**
- **Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017**
- **Food Safety and Standards (Organic Food) Regulation, 2017**
- **Food Safety and Standards (Alcoholic Beverages) Regulation, 2018**
- **Food Safety and Standards (Fortification of Food) Regulation, 2018**

- **Food Safety and Standards (Food Safety Auditing) Regulation, 2018**
- **Food Safety and Standards (Recognition and Notification of Laboratories) Regulation, 2018**
- **Food Safety and Standards (Advertising and Claims) Regulation, 2018**
- **Food Safety and Standards (Packaging) Regulation, 2018**
- **Food Safety and Standards Authority of India (Recruitment and Appointment) Regulations, 2018**
- **Food Safety and Standards (Recovery and Distribution of Surplus food) Regulation, 2019**
- **Food Safety and Standards (Safe food and balanced diets for children in school) Regulations, 2020**
- **Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020**
- **Food Safety and Standards (Labelling and Display) Regulations, 2020**

ESTABLISHMENT OF FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

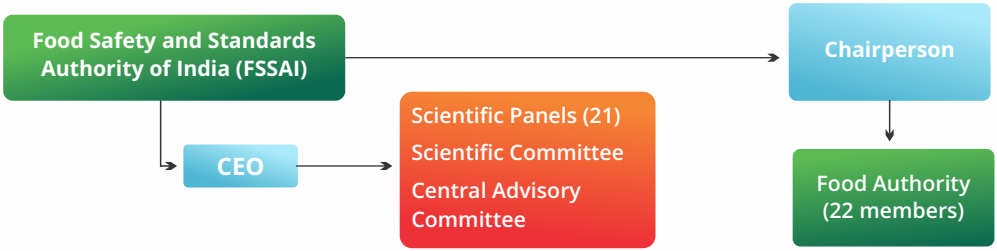
The Executive Authority under the Act is assigned to the Ministry of Health & Family Welfare, Government of India (MOHFW). On 5th September, 2008, Government of India notified the establishment of Food Safety & Standard Authority of India (FSSAI or the Authority) under Section 4 of the Act which is the central authority for enforcement & implementation of the Act. As per the Act the head quarter for FSSAI shall be in Delhi and will establish its offices in other parts of India.

MANDATE OF FSSAI

The mandate assigned to FSSAI is develop science-based standards for food andto regulate and monitor the manufacture, processing, storage, distribution, sale and import of food, so as to ensure the availability of safe and wholesome food for human consumption.

FSSAI under the legal frame work of FSS Act 2006 has both the administrative and technical role to execute in order to establish food safety ecosystem in the country. The structure of FSSAI is illustrated as below :-

STRUCTURAL FRAMEWORK



Science & Standards	Standards development and work in coordination with Scientific Panels and Scientific Committee
Regulation / CODEX	Framing and notifying the food safety regulations As National CODEX Contact point the division coordinates CODEX related activities
Quality Assurance	Developing and upgrading the lab ecosystem of the country
Regulatory Compliance	Licensing and registration mechanisms
Imports	Monitors the Import of food products coming to the domestic market
SBCD	Social and behavioural changes among the stakeholders including consumers
Information Technology	All matters related to Information Technologies for FSSAI.
Finance	All matters related with Finance, Account and Audit
Vigilance	All vigilance matters in respect of FSSAI's officials
International Cooperation	All matters related with International Cooperation
HR	Overall Human Resource Management for FSSAI
General Arrangement	All matters related to general arangements including public grievances, RTI, Parliament questions and Rajbasha
Legal	All legal matters pertain to FSSAI
Training	Training of FBOs, Regulatory Staff and FSSAI's Officials

FOOD AUTHORITY

Food Authority is the apex body under FSS Act and a single reference point related to food safety and standards in the country. It comprises of 22 members, of which atleast one-third are women representing various relevant Ministries and Departments such as Agriculture, Commerce, Consumer Affairs, Food Processing, Health, Legislative Affairs and

other stakeholders representing farmers, scientists & technologists, small scale enterprises and consumer bodies. All members of the Food Authority are appointed by the Central Government, except for seven ex-officio members from various Departments of the Central Government who are selected by the selection committee formed under Section 6 of FSS Act 2006.

The Food Authority meets as per the directives of the Chairperson and decides on the questions coming up before any meeting of the Food Authority and takes decisions by a majority of votes of the members present and voting. Chairperson will have a casting vote. Chief Executive Officer of FSSAI is the member Secretary of the Food Authority.

The Food Authority is assisted by Scientific Committee and various Scientific Panels in setting standards of food products and by the Central Advisory Committee (CAC) in coordination with enforcement agencies.

SCIENTIFIC PANELS

As per Section 13 of the FSS Act, FSSAI may establish as many scientific panels as deem necessary consisting of independent scientific experts/scientists. The FSSAI however must establish scientific panels on:

- Food additives, flavourings, food additives, processing aids and materials in contact with food
- Pesticides and antibiotics residues
- Genetically modified organisms and foods
- Functional foods, nutraceuticals, dietetic products and other similar products
- Biological hazards
- Contaminants in the food chain
- Labelling
- Methods of sampling and analysis

Till date 21 Scientific panels have been constituted under the Act and the list is available in **Chapter 3** of this manual.

SCIENTIFIC COMMITTEE

As per *Section 14* of FSS Act, FSSAI has constituted a scientific committee consisting of

scientific experts. Chairpersons of all the Scientific Panels are also its members and besides the Chairpersons of all the Scientific Panels, it consists of six independent scientific experts who are not associated to any of the Scientific Panels. Scientific Committee is responsible for providing scientific opinion to the Authority and has a power to hold public hearings where necessary.

CENTRAL ADVISORY COMMITTEE (CAC)

The main purpose of CAC is to ensure close cooperation between the Authority and the enforcement agencies operating in the field of food and specifically looks after prioritization of work identifying potential risks, pooling of knowledge etc. The CAC consists of two members each representing from Food Industry, Agriculture, Consumers, relevant Research Bodies and Food Laboratories, Commissioners of Food Safety and the Chairperson of the Scientific Committee. The CEO of the Authority is the Ex- Officio Chairperson of the CAC.

CHAIRPERSON

The functional head of the Food Authority is the Chairperson appointed for the period of three years by the Government of India from amongst the persons of eminence in the field of food science or amongst the person from the Administration holding or has held the position of not below the rank of Secretary to the Government of India.

CHIEF EXECUTIVE OFFICER

The Authority has a full time Chief Executive Officer appointed by Government of India who supervises the day to day administrative work, draws up proposals for work in consultations with CAC, implements those and ensures appropriate scientific technical and administrative support for the scientific panel and the scientific committee. CEO is also the legal representative of the Authority and responsible for the functions listed as in *Section 10* of FSS Act. The statutory functional capacity of the CEO is of the Commissioner of Food Safety while dealing with the matters related to food safety.

THE MAIN ROLE OF FOOD SAFETY & STANDARDS AUTHORITY OF INDIA (FSSAI)

The main role of Authority is to regulate and monitor, manufacture, processing, distribution, sale and import of food while ensuring safe and wholesome food to the consumers. The Act lays down the following main functions for discharge by the Authority.

- Prescribing the Standards & Guidelines in relation to food and specified appropriate system for enforcement.

- Specifying limits for Additives, Contaminants, Pesticides & Veterinary Drug Residues, Heavy Metals, Processing Aids, Mycotoxins, Antibiotics and Pharmacological active substances and Irradiated Foods.
- Lay down food labelling standards including claims on health, nutrition, special dietary uses and food category system for foods.
- Lay down methods of sampling, analysis and exchange of information among enforcement agencies prescribing procedures and guidelines for accreditation of certification bodies and laboratories.
- Taking up, summarizing and analysing relevant scientific and technical data on incidence and prevalence of biological or emerging risk, residues of various contaminants and introduction of rapid alert system among others.
- Prescribing the procedure and the enforcement of quality control in relation to any imported article of food in to India.
- Creating an information network across the country to disseminate rapid reliable and objective information about food safety and issues of concern.
- Providing Training Programs for persons who are involved or intent to get involved in food businesses.
- Promoting general awareness about food safety and food standards and promoting coordination of work on food standards undertaken by International Governmental and Non-Governmental Organization.

RESPONSIBILITIES AS TO FOOD SAFETY

The Food Authority shall also:

- Provide scientific advice and technical support to the Central Government and the State Governments in matters of **framing the policy and rules** in areas which have a direct or indirect bearing on food safety and nutrition.
- Promote, co-ordinate and issue guidelines for the development of risk assessment methodologies and monitor and conduct and forward messages on the health and nutritional risks of food to the Central Government, State Governments and Commissioners of Food Safety
- Provide scientific and technical advice and assistance to the Central Government and the State Governments in implementation of crisis management procedures with

regard to food safety and to draw up a general plan for crisis management and work in close co-operation with the crisis unit set up by the Central Government in this regard.

- Establish a system of network of organizations with the aim to facilitate a scientific co-operation framework by the co-ordination of activities, the exchange of information, the development and implementation of joint projects, the exchange of expertise and best practices in the fields within the Food Authority's responsibility.
- Provide scientific and technical assistance to the Central Government and the State Governments for improving co-operation with international organizations.
- Provide directions from time to time, on matters relating to food safety and standards, to the Commissioner of Food Safety, who shall be bound by such directions while exercising his powers under Section 16(5) of this Act.

PROVISIONS RELATED TO IMPORTS OF ARTICLES OF FOOD

As per Section 25 of the Act, no person shall import into India that is unsafe or misbranded or substandard or containing any extraneous matter. The importer shall require a license as per the Act for importing the articles of food in accordance with the conditions of the license.

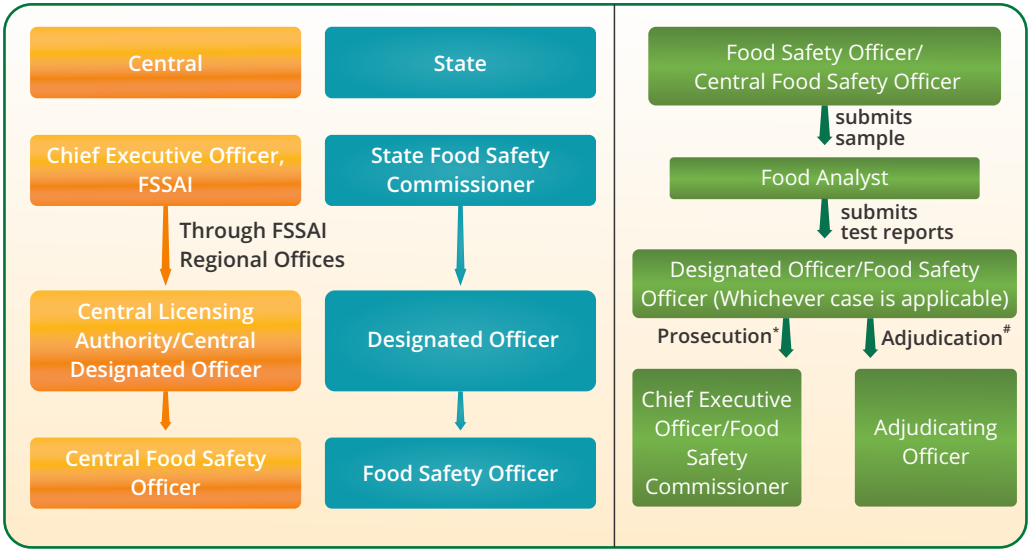
The Central Government shall, while prohibiting, restricting or otherwise regulating import of article of food under the Foreign Trade (Development and Regulation) Act, 1992 (22 of 1992), follow the standards laid down by the Food Authority under the provisions of this Act and the Rules and regulations made there under.

DECENTRALIZED REGULATORY DELIVERY (CENTRE VS STATE ROLE)

India is a vast country with over 1.3 billion populations and the sheer magnitude of food safety enforcement is a challenging task. The Food Authority and the State Food Authorities jointly share this responsibility. While Food Authority provides policy intervention through notification of various food safety regulations, provides direction and coordination at National level, States/UTs conduct enforcement at the field level to verify compliance by FBOs to food standards. FSSAI provides support in the form of imparting training and capacity building of the enforcement staff of States/UTs. The Food Safety Authority in States/UTs is headed by the Commissioners of Food Safety for efficient implementation of FSS Act, Rules and Regulations made thereunder. All Commissioners of Food Safety are members of CAC and the CAC ensures close cooperation between Food Authority and state enforcement

agencies. The CAC advises the Food Authority on its work programme, prioritization of work, identifying potential risks and pooling of knowledge.

ENFORCEMENT STRUCTURAL AND FUNCTIONAL FRAMEWORK



* in case of unsafe
\# in case of misbranded/substandard or both

STATE FOOD AUTHORITY STRUCTURE AND FUNCTIONS

The enforcement of the Act in states is carried out through the State/UT Commissioner of Food Safety (CFS) and Designated Officer, Food Safety Officer, Food Analyst and Panchayat Raj/Municipal bodies.

COMMISSIONER OF FOOD SAFETY

As per Section 30 of FSS Act, the State Government appoints the Commissioner of Food Safety not below the rank of Commissioner & Secretary to the State Government for efficient implementation of Food Safety & Standards Act. The Chief Executive Officer of FSSAI under Section 10 of the Act shall exercise the powers of the Commissioner of Food Safety while dealing with matters relating to food safety of such articles. The powers and duties of the Commissioner of Food Safety are as follows:

- Prohibit in public health interest, the manufacture, storage, distribution or sell of any article or food in the whole of the State for a maximum time of one year.
- Carry out survey of the food industrial unit in the State for compliance to standards

notified by the Food Authority for various articles of food.

- Conduct or organize training program for the regulatory staff and generating awareness on food safety.
- Ensure an efficient and uniform implementation of the standards and other requirements as specified and also ensure a high standard of objectivity, accountability, practicability, transparency and credibility.
- Sanction prosecution for offences punishable with imprisonment and also perform other function prescribed by the State Government in consultation with the Food Authority.

DESIGNATED OFFICER (DO)

As per Section 36, the Commissioner appoints the Designated Officers to be in charge of Food Safety Administration in a specified area. Further, as per Rule 2.1.2 Designated Officer must be a whole time officer not below the rank of Sub Divisional Officer or equivalent. Each district or a specified area must have at least one DO. The functions to be performed by the Designated Officer are as follows:

- To issue or cancel licence of food business operators
- To prohibit the sale of any article of food which is in contravention of the provisions of this Act and Rules and Regulations made thereunder
- To receive report and samples of article of foods from Food Safety Officer under his jurisdiction and get them analysed
- To make recommendations to the Commissioner of Food Safety for sanction to launch prosecutions in case of contraventions punishable with imprisonment
- To sanction or launch prosecutions in cases of contraventions punishable with fine
- To maintain record of all inspections made by Food Safety Officers and action taken by them in the performance of their duties
- To get investigated any complaint which may be made in writing in respect of any contravention of the provisions of this Act and the Rules and Regulations made thereunder
- To investigate any complaint which may be made in writing against the Food Safety Officer and
- To perform such other duties as may be entrusted by the Commissioner of Food Safety.

FOOD SAFETY OFFICER

As per Section 37, Commissioner of Food Safety appoints Food Safety Officers for such local areas as the Commissioner may assign to them for the purpose of functioning under the Act & Rules & Regulation made thereunder. The appointment will be according to the need and through issuance of notification, once the FSO has successfully completed the training as specified by Food Authority. The qualifications, role and functions of FSO are provided in detail in the next Chapter **(Chapter 2).**

FOOD ANALYST

As per Section 45, Commissioner appoints Food Analysts for specified local areas as deemed fit by the Commissioner. Different Analysts may be appointed for different articles of food. However, any person who has any financial interest in manufacture or sale of any article of food cannot be appointed as an Analyst. The qualifications, role and functions of a Food Analyst are provided in detail in the **Chapter 6** of this book.

ADJUDICATING OFFICER

For the purpose of Adjudication, the State Government are required to notify Adjudicating Officers not below the rank of Additional District Magistrate of the district. The Adjudicating Officer has the power of the civil court and all the proceedings before him shall be deemed to be judicial proceedings within the meaning of Section 193 and 228 of the Indian Penal Code.

FUNCTIONS OF ADJUDICATING OFFICER

The Adjudicating Officer shall have the powers of a civil court.

All proceedings before him shall be deemed to be judicial proceedings within the meaning of Section 193 and 228 of the Indian Penal Code (45 of 1860) and shall be deemed to be a court for the purposes of Section 345 and 346 of the Code of Criminal Procedure, 1973 (2 of 1974). While adjudicating the quantum of penalty to be decided by Adjudicating Officer shall be as specified in section 49 of FSS Act, 2006.

AUTHORIZED OFFICER (FOR IMPORT SAMPLES)

Authorized Officer, is an officer appointed by the CEO, FSSAI by an order for the purpose of performing functions at different ports of entry, for import clearance of food. The Authorized Officer, under Clause (5) of Section 47, shall take the samples of imported food

articles and send to the Food Analyst of notified laboratory for analysis who shall send the report within a period of five days to the Authorized Officer.

The Authorized Officer shall have the following powers and duties:

- To receive applications for food import clearance.
- To make such inquiry and inspection as may be necessary to verify that the import of articles of food is not in contravention of any provision of the Act, rules and regulations made thereunder.
- To ensure compliance of all the conditions specified in regulation.
- To draw samples for testing of the imported food, if all the conditions specified in regulations are complied with and forward the samples to a food analyst of a notified laboratory in proper manner for analysis and receive the report of the laboratory analysis.
- To inform the Food Authority of any novel food or food ingredients, previously unknown hazards, or any other technical difficulties.
- To maintain record of food imports, inspection, sampling and related activities, action taken, review process within the jurisdiction of customs ports assigned to him and such other duties assigned by the Food Authority from time to time in writing and by photographs and audio.
- To report to the concerned Licensing Authority of any violation of any conditions of licensing by the Food Importer.
- To recommend destruction or re-export of imported articles of food with necessary conditions as he may deem fit and ensure compliance of the same.
- To seek data or information on imported articles of food consignment from the customs authorities.
- To store the remaining parts of the food sample in appropriate conditions for re-analysis at referral food laboratory on the basis of appeal or application received from the Food Importer or return to the Food Importer with acknowledgement, after issue of no objection certificate
- To issue no objection certificate or non-conformance report, as the case may be, to the customs authorities and Food Importer.
- To carry out any other duties as may be assigned by Food Authority from time to time.

NOTES

CHAPTER-2

FOOD SAFETY OFFICER ROLES & RESPONSIBILITY

2 FOOD SAFETY OFFICER ROLES & RESPONSIBILITY

FOOD SAFETY OFFICER

Commissioner of Food Safety, shall by notification, appoints such person as he thinks fit, having the qualification prescribed by the central government as Food Safety Officers (FSO) for such local areas as he may assign to them for the purpose of functioning under the Act & Rules & Regulation made thereunder. The State Government may authorize any officer of the State Government having the prescribed qualification to perform the functions of the Food Safety Officers. The Food Safety Officer is appointed as a whole time officer.

QUALIFICATION OF FOOD SAFETY OFFICER

An officer must have the following qualifications before he can be appointed as a Food Safety Officer:

- A degree in Food Technology, Dairy Technology, Biotechnology, Oil Technology, Agricultural Science, Veterinary Sciences, Bio-Chemistry, Microbiology, Master's Degree in Chemistry or a degree in medicine from a recognized University or any other equivalent/recognized qualification notified by the Central Government.

  The reason the Central Government has prescribed such technical qualifications for FSOs is because the FSO must be able to understand the technical nature of food and the factors that affect the composition of food in order to effectively discharge the functions assigned to him/her under the Act. The FSO is required to successfully complete training as specified by the FSSAI.

- No person who has any financial interest in the manufacture, import or sale of any article of food can be appointed as a FSO. This is to prevent any situation where there may be a conflict of interest for a FSO. A person, who has already been appointed as a Food Inspector under the erstwhile PFA Act, 1954, may perform the duties of the FSO if notified by the State/Central Government and if the necessary conditions are met. Similarly, in states where a Medical Officer was performing the functions of a Food Inspector under the PFA Act, such an officer may be assigned as a FSO under the FSS Act. This will help provide a smoother transition from the PFA Act regime to the FSS Act regime.

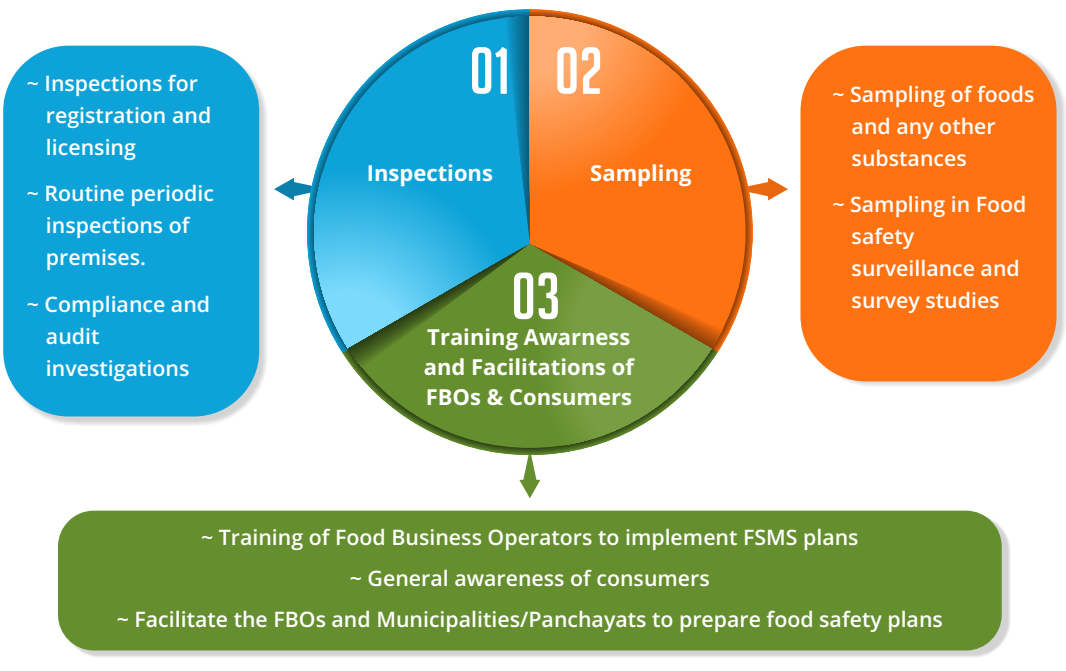
POWERS OF FOOD SAFETY OFFICER IN TERMS OF FSS ACT AND RULES

The FSO holds an extremely delicate and important role under the FSS Act. The FSO is

the face of food legislation and FSSAI who interacts directly with the Food Business Operators (FBOs) on a frequent basis. Thus, it is important that the FSO imbibes and personifies the intent of the FSS Act and acts as a counsellor and guide to the FBOs in our country. More importantly, it is the functions and duties of the FSO that will ensure that safe food is produced and consumed in India. Because the FSO interacts most closely with the FBOs and the food industry as a whole, he can play a crucial role of increasing awareness of the Act and encouraging compliance. Keeping this in mind, inspections should not just involve a military checking for non-compliance, rather it should be based on coaxing and enabling compliance and thus ensuring more sustainable food safety in India. FSOs should play the role of enablers rather than strict enforcers.

Food safety is a collective responsibility of the Regulators, Industry and Consumers. However, the Regulators are responsible for carrying out measures to protect public health by ensuring availability of safe and wholesome food to the consumers. Besides having a thorough knowledge of food law and regulation, Food Safety Officers must know and understand all the elements of their role in food safety.

Role and Responsibilities of Food Safety Officer



DUTIES AND FUNCTIONS OF FOOD SAFETY OFFICER

1. The FSO may **carry out inspections during the registration and licensing process.**

2. The FSO has to **carry out periodic inspections of licensed food establishments** within his area. He must check for compliance of all licensed FBOs and report his findings to the DO.

3. The FSO does the **sampling of food articles for enforcement and surveillance** purposes and send it to the food analyst for analysis and additionally has the power to lift extracts of books and records of a FBO. **The FSO must remember that when drawing samples for surveillance, survey and research, such samples cannot be used for prosecution against the person from whom the samples have been lifted. The prime objective of carrying out surveillance is to be able to identify and assess the food safety hazards and he can guide the FBO about the corrective measures to be followed.**

4. The FSO **must maintain records of all inspections** made and action taken by him with respect to FBOs such as, taking of samples and seizure of stocks etc. As a good practice, a copy of all such records should be made available to the DO as soon as possible. The importance of record keeping will be discussed in following sections in more detail. However, the key point to remember here is that all this information will be helpful for risk analysis and risk assessment.

5. The FSO **must maintain a database of all Food Businesses** within the area assigned to him/her. This also relates to record and information keeping.

6. The FSO **can recommend the issue of improvement notices by the DO to FBOs.** A DO can issue an improvement notice to a FBO if the DO has reasonable grounds for believing that there is some noncompliance with the provisions of the FSS Act. While the **FSS Act does not prescribe a format, it does prescribe the content of the improvement notice. The objective of the improvement notice is to ensure that an opportunity is given to the FBO to correct any deficiency that may exist in his operations.**

7. The FSO also **serves the Prohibition Order on FBOs on instruction of the court** which issues the Prohibition Order. Where the Prohibition Order relates to restricting a person from participating in the management of a food business, the FSO must affix a copy of the order at a conspicuous place on the premises used for the food

business. **The process of lifting of the Prohibition Order starts with the FSO.** The FBO approaches the FSO and if the FSO is convinced that the FBO has taken adequate measures to justify the lifting of the Prohibition Order then the FSO may issue a certificate to this effect. The FSO must undertake inspections and must be completely satisfied before issuing such a certificate as this certificate must withstand the scrutiny of the courts. After issuing such a certificate, the FBO approaches the court that issued the Prohibition Order to request a lifting of the order. The court will do so only if it is convinced that it is proper to do so after having regard to all circumstances especially the conduct of the FBO while the Prohibition Order was in place.

8. The FSO has the duty to **serve an Emergency Prohibition Order on FBOs on instruction of the DO.** The FSO must serve a copy either to the FBO or must affix a copy of the order at a conspicuous place on the premises used for the purpose of the business. An Emergency Prohibition Order is issued by the Food Safety Commissioner of the State (the Commissioner) who will do so on the recommendation of the Designated Officer (DO).

9. The **FSO initiates the adjudication process on instruction of the DO.** Once the DO instructs the FSO to do so, the FSO must immediately file the application to commence the adjudication process before the adjudicating officer appointed for the area. **While the FSS Act does not prescribe any time period within which this application must be filed, the FSO must ensure that it is done immediately. Any delay in such an initiation may have an impact on the outcome of the adjudication process.**

10. The FSO **can search and seize any adulterant** if he has reasonable doubt that such adulterant may be involved in the commission of any offence relating to food. This has been discussed in greater detail in the later sections.

11. **The FSO can have persons engaged in selling, handling or manufacturing any article of food to be examined by a qualified medical professional duly authorized by the DO** if he has reason to believe that such a person is suffering from or harbouring the germs of any infectious disease. **If such a person is a female, the FSO must ensure that a qualified lady medical professional duly authorized by the DO is carrying out the examination.** After the examination, if it is found that such a person is in fact suffering from any such disease, the FSO may by an order in writing, under intimation to the DO, direct such person not to take part in selling or manufacturing any article of food. A suggested format for both the medical

examination and the order stopping a person from participating in the food business has been provided at Annexure 5. This format may be used subject to any modifications, clarifications or instructions issued by the FSSAI in this regard. The FSO **must investigate any complaint** which may be made to him in writing in respect of any contravention of the provisions of the FSS Act.

12. **The FSO can stop and inspect any vehicle suspected to contain any unsafe food** or food which does not comply with the provisions of the FSS Act and Rules, intended for sale or delivery for human consumption. However, the FSO may only inspect vehicles within his jurisdiction and should be mindful of the intended purpose of the food products being transported, i.e., it must be meant for human consumption.

The FSO must also be careful only to stop the vehicle for inspection and not to seize the vehicle itself. The products in the vehicles may be seized subject to the products being food products meant for human consumption and provided that all the mandatory procedures for seizure of food products are followed. The aim here is to ensure that all throughout the food supply chain, including transportation; compliance with the FSS Act is maintained.

The priority for the FSO should be to check for compliance with the safety and hygiene requirements for transportation. Thus the FSO must be well versed with safety, sanitary and hygiene requirements prescribed under the FSS Act and Regulations for different stages of food production and handling.

13. The FSO has to **track cases of food poisoning in his area** and to send report to and assist the DO in taking corrective action. This will enable both the FSO and DO to take corrective actions to ensure that the food poisoning event does not occur in future.

14. In addition to the above, the FSO **must also perform any other duties and tasks that may be assigned to him by the DO or the Commissioner.**

OTHER RESPONSIBILITIES OF FSO

1. Under Schedule IV of Food Safety and Standards (Licensing & Registration of Food Businesses) Regulations, 2011, the food premises of every food business operator where food is processed or prepared must develop, maintain and follow a Food Safety Plan to ensure that a health hazard does not occur in the operation of the facility. **FSO has to facilitate in preparation of Food Safety Plans for Panchayats and Municipalities** in accordance with the parameters and guidelines given in Schedule IV of the said regulation . Food Safety Plans should focus on the critical steps within the preparation of the food to prevent hazards from entering the food chain.

2. **Awareness generation among FBOs regarding the FOSTAC training,** implementation of FSMS plan and **organising programmes to make consumers aware about the Eat right India initiatives of FSSAI.**

LIABILITY OF FOOD SAFETY OFFICER IN CERTAIN CASES

Under Section 39 of the Act any FSO while exercising powers under this Act or the Rules and Regulations is found to vexatious and without any reasonable ground seize any article of food or adulterant or commits any other act not necessary for the execution of his duty he/she shall be guilty of an offence under this Act and shall be liable to a penalty which may extend to one lakh rupees. In case any false complaint is made against a Food Safety Officer and it is proved so, the complainant shall be guilty of an offence under this Act and shall be punishable with fine which shall not be less than fifty thousand rupees but may extend to one lakh rupees.

SEARCH, SEIZURE, INVESTIGATION AND PROSECUTION PROCEDURES

SEARCH

The clause (2) of Section 41 of the FSS act, 2006, states the provision of CrPC relating to search and shall apply to all the actions taken by the FSO under the FSS Act 2006.

Under this provision, the FSO may search any place, seize any article of food or adulterant, if there is a reasonable doubt about the involvement of the FBO in commission of any offense related to food.

On demand of the FSO, if the person against whom action is sought to be taken does not provide access to the place the FSO acting under sub Section 2 of Section 100 read with subsection 47 of CrPC can break open any outer or inner door or window of any premises. However, if such premise is an apartment and the occupant is a female (not being a person against whom action is sought to be taken) who, according to the customs of the country does not appear in public, the FSO must allow her to withdraw and give her reasonable facility to withdraw, and then may break open the apartment and enter it.

OTHER PRINCIPLES TO BE KEPT IN MIND

- If any person is "reasonably suspected" of concealing in his person any article for search needs to be made, the FSO may search that person except if the person is a woman than the search should be made by a woman with strict regard to decency.

- Before making the search the FSO has to call upon two or more independent witness of the locality and if none comes forward, issue an order in writing to them to do so and the search should be made in their presence.
- A list of all things seized in the course of the search and the places in which they are respectively found should be prepared by the FSO and signed by the witness.
- The occupants of the place searched or the attendants should be all the time present at the time of search and the copy of the list prepared by the FSO signed by the witness should be given to him/ them.

SEIZURE

Clause (1) of Section 38 empowers the FSO to seize any article of food which appears to be in contravention of the Act or the Regulations made thereunder. Clause (2) of Section 42, further states the provisions of CrPC relating to seizures shall apply to all actions taken by the FSO under this FSS Act.

This power can be exercised against both licensed and unlicensed persons under the Act. Further the FSO has to thereafter inform the Designated Officer of the actions taken by him in writing. Every FSO has the discretionary power to seize (in suitable cases) and carry away any article of food which is found under circumstances which create suspicion of the commission of any offence.

FOOD SAFETY SURVEILLANCE AND RECALL PROCEDURE

The food safety surveillance is done with this objective so as to determine whether a food safety hazard exists, assess the nature and extent of the issue, and take appropriate actions to eliminate or minimize potential risks to consumers. FSO should be a part of food safety surveillance and recall procedure, when there is an evidence that food for consumers is potentially contaminated with some hazard and can pose health risk.

Steps for Food Safety Surveillance

1. **Prepare a food safety surveillance plan** for identification and addressing safety hazards in their jurisdiction. The plan should be based on focussed commodities to be taken up for survey.
2. **Start sampling on targeted food products** and the number of samples to be lifted has to be statistically calculated

3. **Get the samples analysed in food laboratories**. For FSSAI organized surveillance projects, the samples have to be tested in prescribed laboratories.
4. **Upload Laboratory Analysis Report into the database** for further analysis and interpretation
5. **State Food Authority and FSSAI will use the data** for hazard identification and other risk assessment activities

Learning from food safety surveillance

- *Points of contamination*
- *Areas for improvement in food production*
- *Knowledge on common & emerging pathogens associated with food borne illnesses*
- *Trend in food borne disease outbreaks*

FOOD RECALL PROCEDURE (SECTION 28)

Section 28 of the FSS Act, 2006, emphasizes the need for product recall, if a food business operator considers or has reasons to believe that a food which he has processed, manufactured or distributed is not in compliance with this Act, or the Rules or Regulations, made thereunder, he shall immediately initiate withdrawal of the food product from market and inform competent authorities of the risk and also the action taken.

PROCEDURE FOR LAUNCHING PROSECUTION

1. The Food Safety Officer shall be responsible for inspection of food business, drawing samples and sending them to Food Analyst for analysis.
2. The Food Analyst after receiving the sample from the Food Safety Officer shall analyse the sample and send the analysis report mentioning method of sampling and analysis within fourteen days to Designated Officer with a copy to Commissioner of Food Safety.
3. The Designated Officer after scrutiny of the report of Food Analyst shall decide as to whether the contravention is punishable with imprisonment or fine only and in the case of contravention punishable with imprisonment, he shall send his recommendations within fourteen days to the Commissioner of Food Safety for

sanctioning prosecution.

4. The Commissioner of Food Safety shall, if he so deems fit decide, within the period prescribed by the Central Government, as per the gravity of offence, whether the matter be referred to:–

    (a) A court of ordinary jurisdiction in case of offences punishable with imprisonment for a term up to three years; or

    (b) A special court in case of offences punishable with imprisonment for a term exceeding three years where such Special Court is established and in case no Special Court is established, such cases shall be tried by a Court of Ordinary Jurisdiction.

The Commissioner of Food Safety shall communicate his decision to the Designated Officer and the concerned Food Safety Officer who shall launch prosecution before Courts of Ordinary Jurisdiction or Special Court, as the case may be and such communication shall also be sent to the purchaser if the sample was taken under Section 40.

FOOD SAFETY INVESTIGATION

The food safety investigation is done with this objective so as to determine whether a food safety hazard exists, assess the nature and extent of the issue and take appropriate actions to eliminate or minimize potential risks to consumers. FSO should be a part of this investigation when there is an evidence that food for consumers is potentially contaminated with some hazard and can pose health risk.

GENERAL PRINCIPLES FOR FOOD SAFETY OFFICER

1. The FSO has an important role to play, as they can be a **counsellor for FBOs** in their effort to comply with the provisions of the FSS Act. For e g – if the FSO, on inspection identifies any contraventions by any FBO, then he can issue a caution stating the regulation to be followed for the contraventions and can also counsel the FBOs for various preventive and corrective actions to be taken for that contraventions. This is especially true for petty FBOs who may not be aware of the compliances required under the FSS Act.

2. **The FSO must stay updated with all the regulations, amendments, advisories etc. that are issued and notified under the FSS Act.** This is a technical legislation and compliance under this legislation involves scientific technical processes. The Act mandates scientific risk based analysis. To ensure the best in class vigilance, the FSO

should stay updated with all such relevant developments. **The FSO should also stay in touch with allied legislations such as the BIS Act, the Legal Metrology Act and other laws affecting safety of food such as environmental laws and municipal sewage and water mechanisms.** In this regard, the FSO may turn to the DO and the Commissioner of Food Safety, whenever he feels training is beneficial or if any clarifications are required.

3. It is very beneficial for FSO to have a background in or at least some exposure to food science and technology and in public health. This is because food processing and manufacturing has become a highly specialized, technology intensive sector involving complex physiological disciplines. There are also innumerable interactions between food components and with multiple external factors that may have an effect on the quality and safety of food. These factors may be microbiological, chemical, physical or sensory. **Thus a technical background will help the FSO understand the legislation and implement it better for the ultimate benefit of the consumers.**

4. **It is also important for an FSO to have a thorough understanding of prerequisite hygiene and sanitation programmes and also requires a prior knowledge of the properties of various types of cleaning and sanitizing compounds,** and their interactions with food matter, with each other and with other materials, particularly those materials that equipment is made of (e.g. chlorine and steel)

5. **The FSO should have a thorough knowledge about the Hazard Analysis and Critical Control Point (HACCP)** as its elements are useful for risk based inspections. Ideally, the FSO should have taken a course and been certified in the application of HACCP.

6. **The FSO should be well equipped to undertake risk analysis and risk communication.** There should be periodic studying of general risks that affect a category of food or food business. For example – by maintaining records of inspections etc., the FSO will be able to do risk analysis and judge what are the critical control points in a particular food business. This will help him understand what his inspections should focus on and what areas FBOs may require guidance for.

7. **The FSO should have good knowledge of testing techniques** so that he/she can make informed decisions about sampling methods and properly interpret the results of testing.

8. **The FSO must possess good communication skills to enable him/her to adequately** convey technical and regulatory information regarding safe food handling to others. In addition, the FSO must have professionalism and confidence.

NOTES

CHAPTER-3

UNDERSTANDING FOOD SAFETY & STANDARDS

3 UNDERSTANDING FOOD SAFETY & STANDARDS

WHAT IS FOOD?

Food is defined as any substance consumed to provide nutritional support for our body. It can be usually of plant or animal origin and contains essential nutrients such as carbohydrates, fats, proteins, vitamins or minerals that provide energy for activity, growth and all functions of the body such as breathing, digestion, for the growth and repair of the body and for keeping the immune system healthy. Fats, proteins and carbohydrates constitute the major sources of energy derived from food.

As per FSS Act 2006, the "Food" means any substance, whether processed, partially processed or unprocessed which is intended for human consumption and includes primary food, 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 psycho tropic substance.

As per the FSS Act, 2006 "food safety" means assurance that food is acceptable for human consumption according to its intended use.

Access to sufficient amounts of safe and nutritious food is key to sustaining life and promoting good health. Unsafe food containing harmful bacteria, viruses, parasites or chemical substances can cause more than 200 different diseases – ranging from diarrhoea to cancers. Unsafe food creates a vicious cycle of diarrhoea and malnutrition, threatening the nutritional status of the most vulnerable. Where food supplies are insecure, people tend to shift to less healthy diets and consume more "unsafe foods" – in which chemical, microbiological and other hazards pose health risk.

Each year, 1 in 10 people get ill by eating unsafe food. While food safety is a shared responsibility; individual consumers and food handlers play a huge role in preventing food borne diseases.

The "Five keys to safer food", developed by WHO to educate safe food handling behaviours to all consumers and food handlers to prevent food borne diseases are:

5 KEYS TO SAFER FOOD

KEEP CLEAN

- ✓ Wash your hands before handling food and often during food preparation
- ✓ Wash your hands after going to the toilet
- ✓ Wash and sanitize all surfaces and equipment used for food preparation
- ✓ Protect kitchen areas and food from inspects, pests and other animals

WHY?

While most microorganisms do not cause disease, dangerous microorganisms are widely found in soil, water, animals and people. These microorganisms are carried on hands, wiping cloths and utensils, especially cutting boards and the slightest contact can transfer them to food and cause food borne diseases.

SEPARATE RAW AND COOKED

- ✓ Separate raw meat, poultry and seafood from other foods
- ✓ Use separate equipment and utensils such as knives and cutting boards for handling raw foods
- ✓ Store food in containers to avoid contact between raw and prepared foods

WHY?

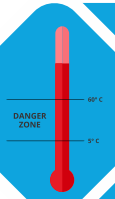
Raw food, especially meat, poultry and seafood, and their juices, can contain dangerous microorganisms which may be transferred onto other foods during food preparation and storage.

COOK THOROUGHLY

- ✓ Cook food thoroughly, especially meat, poultry, eggs and seafood
- ✓ Bring foods like soups and stews to boiling to make sure that they have reached 70°C. For meat and poultry, make sure that juices are clear, not pink. Ideally, use a thermometer
- ✓ Reheat cooked food thoroughly

WHY?

Proper cooking kills almost all dangerous microorganisms. Studies have shown that cooking food to a temperature of 70° C can help ensure it is safe for consumption. Foods that require special attention include minced meats, rolled roasts, large joints of meat and whole poultry.



KEEP FOOD AT SAFE TEMPERATURES

- ✓ Do not leave cooked food at room temperature for more than 2 hours
- ✓ Refrigerate promptly all cooked and perishable food (preferably below 5°C)
- ✓ Do not store food too long even in the refrigerator
- ✓ Do not that frozen food at room temperature

WHY?

Microorganisms can multiply very quickly if food is stored at room temperature. By holding at temperatures below 5°C or above 60°C, the growth of microorganisms is slowed down or stopped. Some dangerous microorganisms still grow below 5°C.

USE SAFE WATER AND RAW MATERIALS

- ✓ Use safe water or treat it to make it safe
- ✓ Select fresh and wholesome foods
- ✓ Choose foods processed safety, such as pasteurized milk
- ✓ Wash fruits and vegetables, especially if eaten raw
- ✓ Do not use food beyond its expiry date

WHY?

Raw materials, including water and ice, may be contaminated with dangerous microorganisms and chemicals. Toxic chemicals my be formed in damaged and mouldy foods. Care in selection of raw materials and simple measures such as washing and peeling may reduce the risk.

THE IMPORTANCE OF FOOD SAFETY

Why food safety is important?

- *Reduce food borne illness*
- *Protect and enhance the business reputation leading to increased profits to FBOs*
- *Enhance consumer confidence on domestic and international foods*
- *Reduce food wastage and associated costs*

FOOD BORNE DISEASE

Food borne diseases include a wide spectrum of illnesses and are a growing public health problem worldwide. Food borne diseases is a problem in both developing and developed countries. They are caused by ingestion of foodstuffs contaminated with microorganisms or chemicals. The contamination of food may occur at any stage in the process from food production to consumption ("farm to fork") and can result from environmental contamination, including pollution of water, soil or air. The symptoms may occur very quickly after eating the food or may take days or even weeks to appear. For most foodborne diseases, symptoms occur 24 -72 hours after the food has been eaten. Foodborne disease can lead to long-term health problems. The symptoms of foodborne diseases range from mild and self-limiting to debilitating and life-threatening (such as kidney and liver failure, brain and neural disorders, paralysis and potentially cancers), leading to long periods of absenteeism and premature death. The most common symptoms of food borne disease are nausea, stomach pains, vomiting and diarrhoea.

CLASSIFICATION OF FOODBORNE ILLNESS

Infection	Caused by eating food that contains living disease causing microorganisms, example Salmonella.
Intoxication	Caused by eating food that contains a harmful toxin or chemical produced by bacteria or other source example Clostridium Botulinum
Toxin mediated infection	Caused by eating a food that contains harmful microorganisms that will produce a toxin once inside the human body, Example staphylococcus toxin

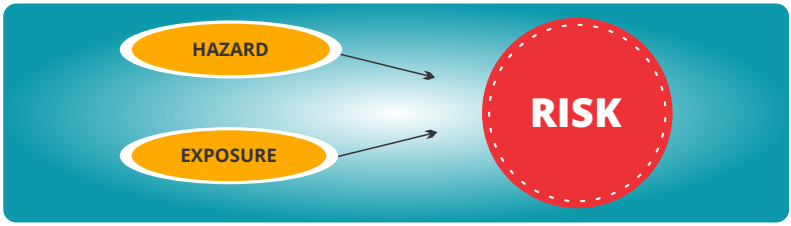
FOOD SAFETY RISK ANALYSIS

In order to manage safe food production, it is important to have a thorough knowledge of food safety hazards and the associated risks which can enter at any stage in the food supply chain.

International Agencies like Food & Agriculture Organisation (FAO) and World Health

Organisation (WHO) as well as CODEX Alimentarius Commission recommend Risk Analysis Approach for managing the risk in the food production process.

WHAT IS RISK?



Probability of risk is associated with the exposure to hazard. The likelihood of occurrence of risk is when there is exposure to hazard and the rate of the likelihood of a specific risk can be high, medium or low.

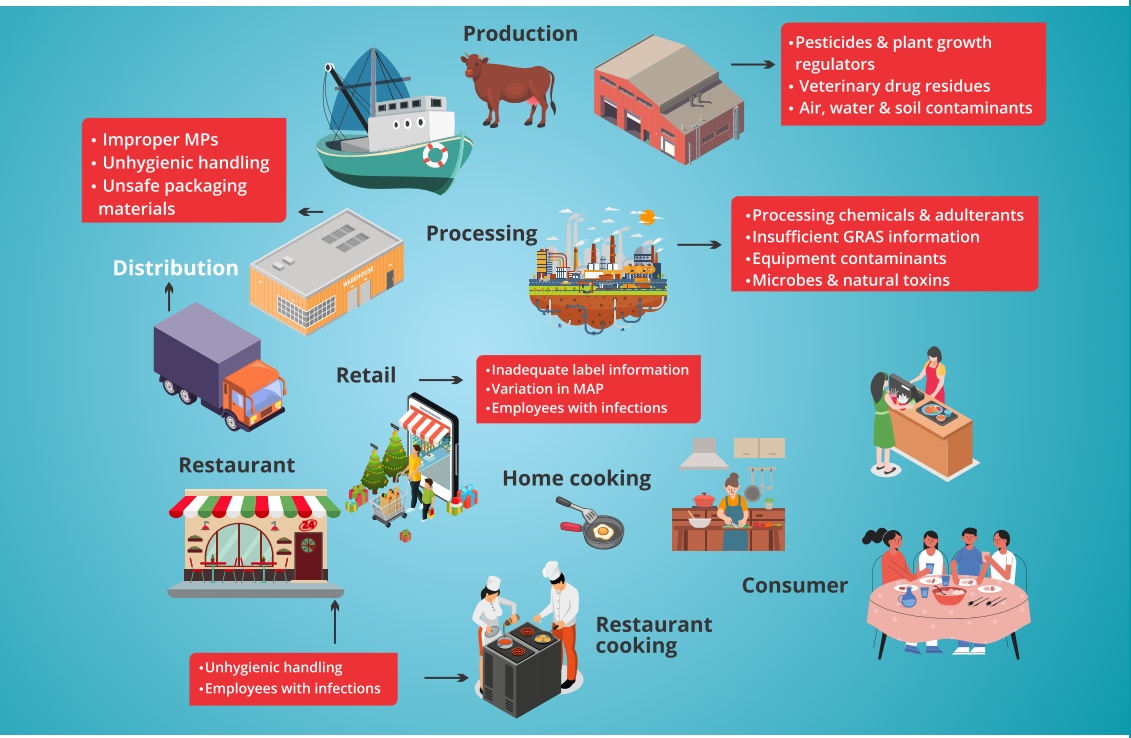
How Risk can enter in to the food chain?

Production: Poor agriculture practices

Processing: Improper handling and processing, storage and packaging

Transportation: Improper unhygienic transportation

Retail: Poor hygiene and sanitation



FOOD HAZARDS-THE BIGGEST THREAT TO FOOD SAFETY

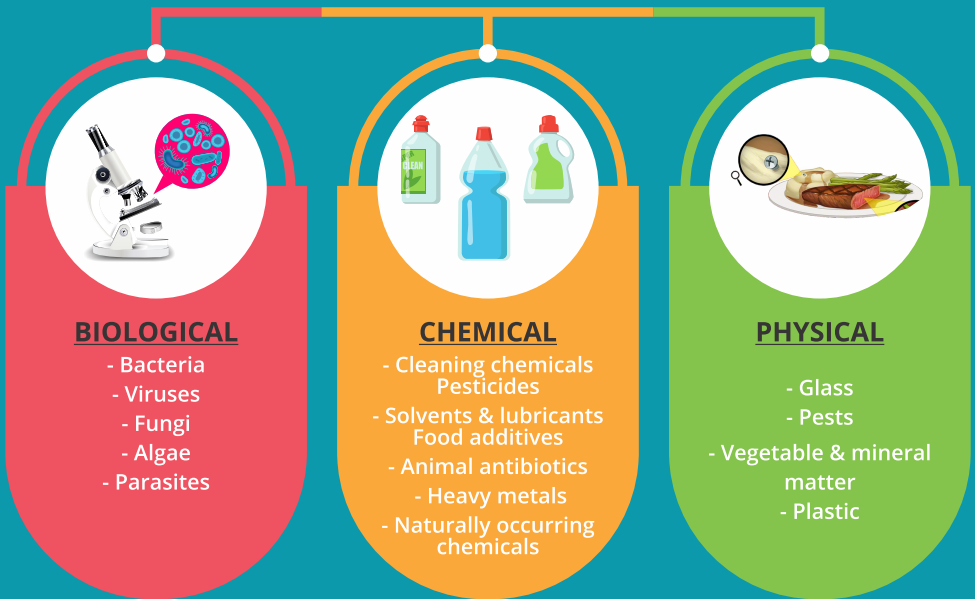
Hazard is defined as a biological or chemical or physical agent in a food or condition of the food with the potential to cause an adverse effect.

Biological hazard are living organisms, including microbiological organisms, bacteria, viruses, fungi and parasites.

Chemical hazard are in two categories: naturally occurring poisonous substances and chemicals or deleterious substances. The first group covers natural constituents of foods that are not the result of environmental, agricultural, industrial or other contamination examples being aflatoxins and shell fish poison. The other group covers poisonous chemicals or deleterious substances which are intentionally or unintentionally added to food at some point in the production chain, examples are pesticides and fungicides as well as lubricants and cleaners.

Physical hazard is any physical material not normally found in food which causes illness or injury. Physical hazards include glass, wood, stone, bone and metal.

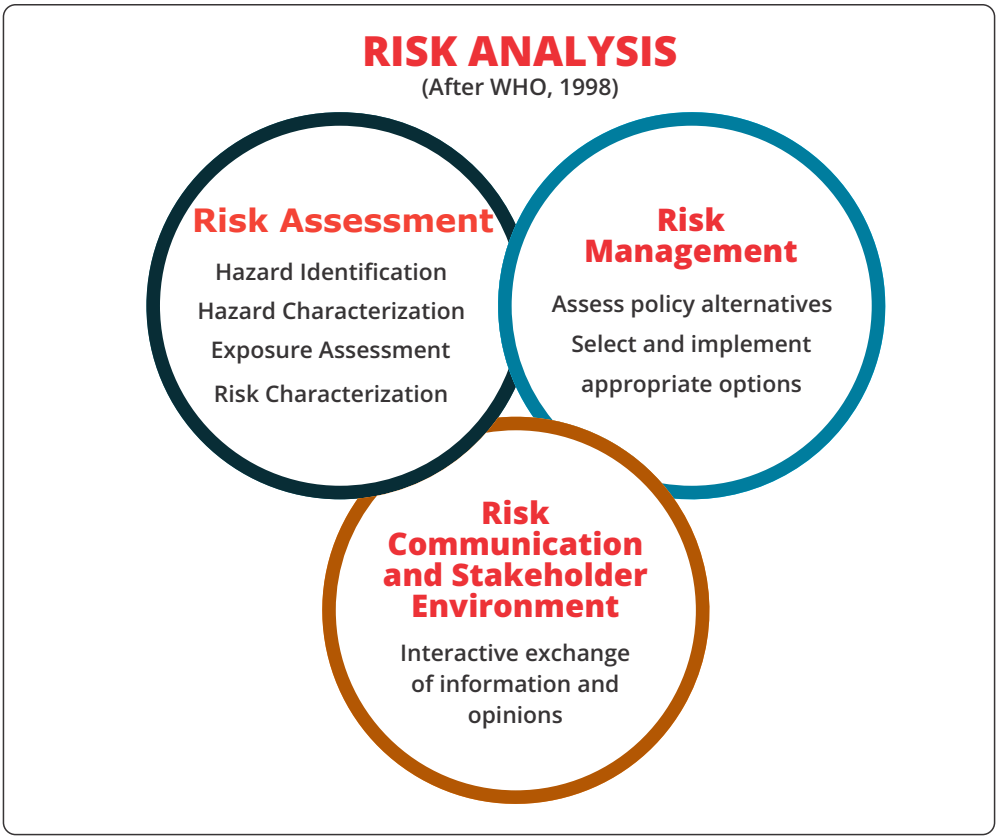
This diagram illustrates examples of hazards in each of the hazard categories



RISK ANALYSIS APPROACH

Risk analysis plays an important role for a National Food Control System. It is a powerful tool to carry out science based analysis and to achieve a sound and consistent

solution to food safety problems. It provides information on hazard in food to be linked directly to data on the risk to human health and to improve food safety decision making process. It comprises of three stages:



Risk analysis involves identifying the risk and weighing their likelihood and impact on health and then establish system to reduce or mitigate the risks.

The FSS Act 2006 defines:

Risk assessment: is a scientifically based process consisting of four steps:

Step 1 Hazard identification: "Could this food or anything in it be harmful?" Risk assessors collect and review scientific data and identify biological or chemical hazards in food.

Step 2 Hazard characterisation: "What effects do the hazards cause?" Risk assessors evaluate scientific data to determine whether evidence is strong enough to demonstrate that a substance has the potential to cause harm and the nature of the harm.

Step 3 Exposure assessment: "Who may be harmed and at what level of exposure may be harmful?" Experts estimate how much of the food or ingredient consumers in general

population groups (e.g. infants, children, adults) or sub-populations (e.g. vegetarians, vegans) are likely to be exposed to under real-life conditions where both dose and duration are considered. The exposure must be evaluated to determine if a hazard presents an actual risk (step 4). With increased exposure, the risk also increases.

Step 4 Risk characterisation: "How likely is it that people will experience exposure at a level that can cause harm in real life?" The level of exposure that can cause harm is compared to the actual level of exposure that someone would experience in real life. If the exposure level is higher than that which causes harm, there may be a safety concern for consumers in general or for specific groups.

Risk assessment is carried out by the independent Scientific Panels and Scientific Committee (of FSSAI) to provide scientific inputs on the risk and potential adverse effect of the risk to the health of the consumers. These inputs are based on sound scientific principles, data and evidence.

Risk management: It is the process of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and if needed, selecting appropriate prevention and control measures. A range of risk management options are available to FSSAI as risk managers for preventing or reducing health risks associated with food. These options can be regulatory i.e. those specified in the Regulations, such as end product standards or outcome based standards or non-regulatory, such as industry codes of practice, guidelines or information campaigns.

Risk Communication: is the interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties. FSSAI is responsible for risk communication, which is a two-way process and involves sharing the information internally with risk analysis team and with external stakeholders including general public in an open and transparent way including the explanation of risk assessment findings and the basis of risk management decisions. Risk communication is also important to bridge the gap which sometimes exists between the scientific assessment and consumers' perceptions of risk.

WHY SHOULD FSO KNOW ABOUT FOOD SAFETY RISK ANALYSIS?

A well established and integrated information and data generation system across the food chain on the occurrence of food safety hazards and associated risks are essential to complete the cycle of Risk Analysis. Information & Data generation should be of quality and precision, to the extent that will minimize uncertainty in the risk estimates. Purpose of such

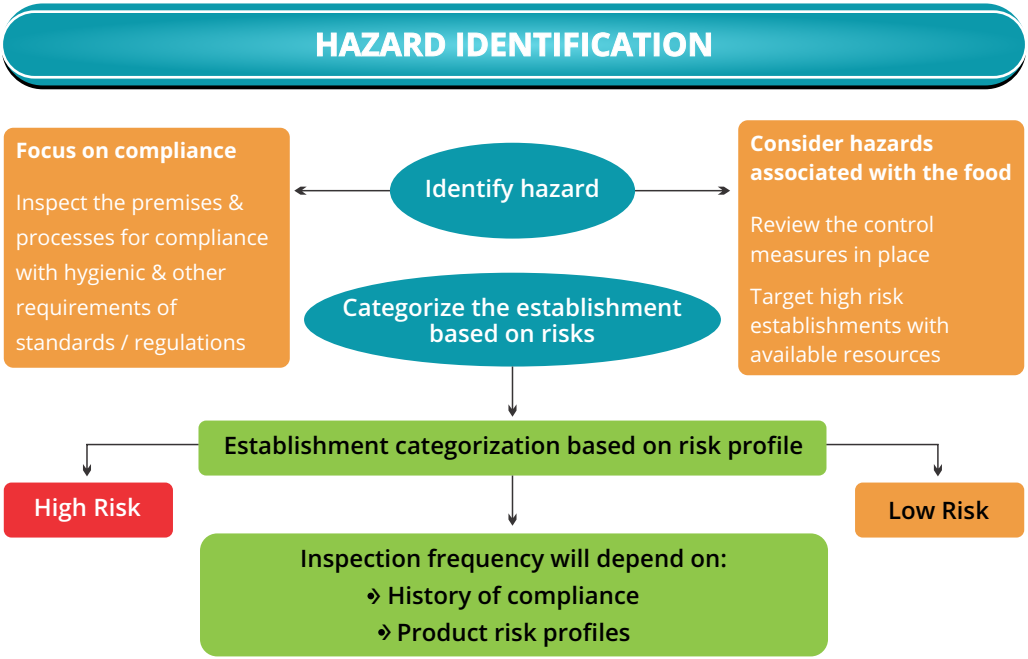
activity in our regulatory system is to find out, the food safety hazards and risk associated with the foods and such activities are being carried out by FSOs under the terms **"Monitoring"** and **"Surveillance".**

The role of FSO in identification of food safety hazards, capable of causing an adverse health effect becomes one of the important sources of input for risk assessors in completing the steps of Risk Assessment. Risk Analysis is the foundation on which food control policy and consumer protection measures are based. The scientific inputs from risk assessment will provide basis for policy decisions to risk managers for developing standards and guidelines to minimize or control the food safety risks.

HOW TO IDENTIFY HAZARD?

Hazards can enter the food supply chain at any point from production, packing, transporting, storing to distribution. Therefore, hazards need to be controlled and minimised from production, across all the steps to the consumer the approach called "Farm to Fork". Thus food safety is ensured through the combined efforts of all the stakeholders participating in the food chain.

Hazard identification will be predominately a qualitative process and Food Safety Officers will help in hazard identification and address this by carrying out Food Safety Surveillance. In an attempt to identify potential hazards, it is necessary to follow the process as mentioned below:



RISK IDENTIFICATION

Since food will always present some minimal risk, the approach used is to minimize the hazards and risks to a safe and acceptable level

Risk is the probability of a hazard occurring

Risks in food establishments depend on type of foods handled, process and products:

High risk establishments which are food establishment involved in processing and production of:

- *Ready to cook and ready to eat products*
- *Products like raw chicken/ meat and fish products as they naturally carry a high load of pathogenic bacteria. For such products, practices related to cross contamination*
- *Products having wide distribution & large consumption, products meant for children, infants, vulnerable segment of population pose more risk*

RISK CHARACTERISATION

The quality and/or quantitative estimation of the probability of occurrence and severity of adverse effects

Matrix to assign a priority ranking for inspections of establishments

Establishment compliance profile (*e.g. non-compliance and violations are reported*)	**Product risk profile** (*e.g. new products, new formulas, new processes*)	**Inspection priority profile**
Low	**High**	**Top Priority**
Low	**Low**	**Medium Priority**
High	**High**	**Medium Priority**
High	**Low**	**Low Priority**

The establishment categorization or priority level for inspection thus obtained should be reviewed and updated after each inspection.

FSSAI has developed sector-specific inspection checklists for facilitating FSOs to efficiently inspect the Food Business Operators (FBOs). The inspection checklists are based on revised Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011 and these are used to identify the level of compliance with each requirement that is set out in the regulation.

Benefits of risk-based food inspection

- *Emphasizes on a preventative approach rather than corrective approach*
- *Uses limited resources in a more effective manner*
- *Investigate & apply enforcement action proportionate to risk*
- *Provide advice & information to food industry workers & management*

FOOD STANDARDIZATION

The basic purpose of establishing food standards is protection of public health and risk, promoting fair trade in food also to prevent misleading or deceptive product and to enable consumers to make informed choice by providing adequate information. It is important that such standards should be uniform nationally so that FBOs in all parts of the country have only one set of requirements to be complied with and hence a level playing field.

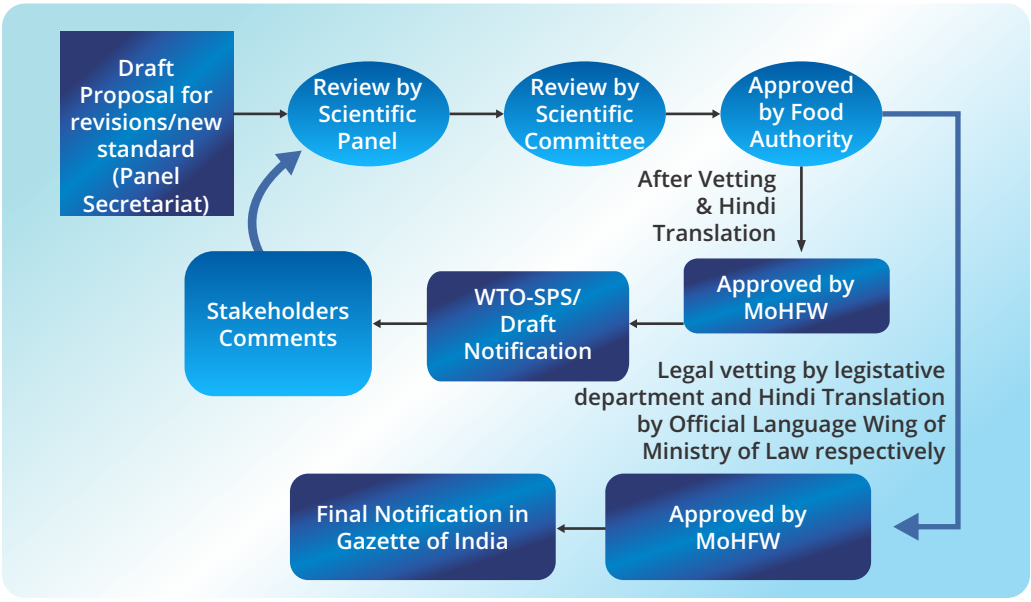
The entire process of standard setting is carried out in a transparent manner involving all stakeholders. FSSAI has constituted scientific bodies, namely the Scientific Committee and 21 subject specific Scientific Panels comprising of eminent independent subject experts/scientists. The Scientific Committee comprises of Chairpersons of all Scientific Panels and six independent experts, responsible for providing consistent opinion to Food Authority while harmonizing working methods of Scientific Panels. The Committee provides opinions on cross industry and sectoral issues and covers areas that are unique and not covered under the competence of the Scientific Panels

The scientific risk assessment and setting of standards is carried out on the basis of latest developments in food science along with various factors like emergence of new additives, changes in processing technology, identification of new risks associated with metalic contaminants, residues of veterinary drugs, microbiological contaminants, nutritional aspects, advances in analytical methods etc.

STANDARDIZATION (VERTICAL AND HORIZONTAL)

FSSAI notified standards are mandatory standards and compulsorily to be followed by the food businesses, there are other organizations and agencies that frame food standards which are voluntary standards. However, some of these are considered as a basic requirement for the FBO to obtain FSSAI licenses which include the BIS certification for manufacturing of packaged drinking water and" AGMARK" label for sale of some agricultural products.

The Scientific Panels and Scientific Committee provide the scientific opinion and assist Food Authority in development of standards through a well-defined process. The Scientific Panels are constituted under Section 13 of the Food Safety & Standards Act, 2006. Formulation of standards of any article of food involves several stages. After recommendation by the Scientific Panel and validation by the Scientific Committee, a standard is approved by the Food Authority and by Ministry of Health and Family Welfare. Thereafter, a draft notification is issued for inviting public comments for a period of 60 days. The comments received are then considered by the relevant Scientific Panel and after approvals of the Scientific Committee, Food Authority and the Ministry, the standard is finally notified as either an amendment to an existing regulation or a new/revised regulation.



FSS Act 2006 defines "standard", in relation to any article of food, means the standards notified by the Food Authority. FSSAI is also responsible for framing and notifying food product standards which include both vertical and horizontal standards and specify an appropriate system for enforcing various standards.

Horizontal Standards cut across various food categories and primarily relate to food safety covering limits for various contaminants (chemical and biological), toxins in food and also requirements for packaging, labelling and claims. These are covered under FSS (Contaminants, Toxins and Residues) Regulations, 2011, under Appendix B of FSS (Food Product Standards and Food Additives) Regulations, 2011 and FSS (Packaging and Labelling) Regulations, 2011.

Vertical Standards mainly include identity and compositional standards of specific food products and are covered under FSS (Food Product Standards and Food Additives) Regulations, 2011 and under FSS (Health supplements, Nutraceuticals, Foods for special dietary use, Foods for special medical purpose, Functional food and Novel food) Regulations, 2016.

Currently Food Authority has commissioned 21 scientific panels that comprise of 11 Vertical and 10 horizontal panels. The web-link for the same is appended below:

http://fssai.gov.in/cms/committees-panels-and-groups.phps

http://fssai.gov.in/cms/products-standards.php

All the vertical and horizontal SPs are listed below –

Horizontal Panels	Vertical Panels
Food additives, Flavourings, Processing aids & Materials in contact with food	Functional foods, Nutraceuticals, Dietetic Products and Other similar products
Pesticides Residues	Fish and Fisheries Products
Antibiotic Residues	Cereals, Pulses & Legume and their products (including Bakery)
Genetically Modified Organisms and Foods	Fruits & Vegetables and their products (including dried fruits and nuts)
Biological Hazards	Meat & Meat Products, including poultry
Contaminants in the Food Chain	Milk & Milk Products
Labelling and Claims/Advertisements	Oils & Fats
Method of Sampling and Analysis	Sweets, Confectionery, Sweeteners Sugar & Honey
Nutrition and Fortification	Water (including flavoured water) & Beverages (non-alcoholic)
Packaging	Spices and Culinary Herbs
	Alcoholic Beverages

The international food standards are set through the joint collaboration between FAO/WHO, CODEX Alimentarius. The work of CODEX provides governments with a valuable resource to achieve public health objectives such as food safety and nutrition, while providing a basis for trade to take place.

Harmonization of Indian food standards with global standards is one of the principles mandated under the FSS Act. Standards set by FSSAI are based on international best practices and all efforts are made to harmonize with CODEX so as to promote international trade and higher levels of food safety. The Indian Food Code is in harmony with the Food Categorization

System adopted from CODEX General Standard for Food Additives (GSFA). Wherever, suitable and appropriate, CODEX standards are considered for adoption with or without modifications provided they are in line with domestic industry and consumer practices. As a result of this, FSSAI in line with CODEX notified a list of more than 11,000 food additives which are permitted to be added in various food categories. The step has broadly facilitated food industry to innovate and create new opportunities in this area.

FOODS REGULATED UNDER SECTION 22 OF FSS ACT 2006

SECTION 22 IN THE FOOD SAFETY AND STANDARDS ACT, 2006

Defines genetically modified foods, organic foods, functional foods, proprietary foods and novel foods and states "Save as otherwise provided under this Act and regulations made thereunder, no person shall manufacture, distribute, sell or import any novel food, genetically modified articles of food, irradiated food, organic foods, foods for special dietary uses, functional foods, nutraceuticals, health supplements, proprietary foods and such other articles of food which the Central Government may notify in this behalf".

PROPRIETARY FOODS

In the FSS (Food Products Standards and Food Additives) Regulations, 2011, Proprietary Food is defined under the regulation 2.12. FSS (Food Products Standards and Food Additives), Amendment Regulations, 2016, and the sub-regulation 2.12.1 defines proprietary foods as an article of food that has not been standardised under these regulations and 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 except the ingredients which may be specified by the Authority from time to time. The proprietary product may deviate in quality parameters of a standardised food, as specified in the Food Safety and Standards Regulations made under the FSS Act, 2006. However, the Proprietary Foods shall have to comply with the horizontal parameters of the nearest product category it falls under.

Standards for Health supplements and Nutraceuticals are specified under FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016. These regulations cover eight categories of Functional Foods namely, Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Specialty food containing plant or botanicals, Foods containing Probiotics, Foods containing Prebiotics and Novel Foods.

FUNCTIONAL FOODS

Functional Foods are defined as products that resemble traditional foods but possess demonstrated physiological benefits and provide such benefits beyond basic nutrition and may play a role in reducing or minimizing the risk of certain diseases and other health conditions, as described in these regulations. The likely categories where functionalities can be linked to either ingredients or the products so made, have been created under these regulations and fall under the basic definition of 'Functional Foods'.

Health Supplements and Nutraceuticals are any substance that is a food or a part of food and provides medical or health benefits, including the prevention and treatment of disease.

FSS Act, 2006 (Section 22) defines Nutraceuticals and Health supplements as foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders and which are presented as such, wherein the composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature, if such ordinary foods exist and may contain one or more of the following ingredients, namely:

- Plants or botanicals or their parts in the form of powder, concentrate or extract in water, ethyl alcohol or hydro alcoholic extract, single or in combination;
- Minerals or vitamins or proteins or metals or their compounds or amino acids (in amounts not exceeding the Recommended Daily Allowance for Indians) or enzymes (within permissible limits);
- Substances from animal origin;
- A dietary substance for use by human beings to supplement the diet by increasing the total dietary intake;

Health supplements may be used to supplement the normal diet of a person above the age of five years. The health supplements shall contain concentrated source of one or more nutrients, namely, amino acids, enzymes, minerals, proteins, vitamins, other dietary substances, plants or botanicals, prebiotics, probiotics and substances from animal origin or other similar substances with known and established nutritional or beneficial physiological effect, which are presented as such and are offered alone or in combination, but are not drugs as defined in the clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder.

The health supplements shall contain any of the ingredients specified in Schedule I or Schedule II or Schedule IV or Schedule VII or Schedule VIII or enzymes only of Schedule VI of the said regulation.

Every package of health supplement shall carry the following information on the label, the words "HEALTH SUPPLEMENT" and other labelling requirements as specified in the regulations.

As per the regulations the nutraceuticals shall provide a physiological benefit and help maintain good health. A food business operator may extract, isolate and purify nutraceuticals from food or non-food sources, that is preparing amino acids and their derivatives by bacterial fermentation under controlled conditions the FBO can prepare and sell the nutraceuticals in the food-format of granules, powder, tablet, capsule, liquid, jelly or gel, semi-solids and other formats and may be packed in sachet, ampoule, bottle, and in any other format as measured unit quantities except those formats that are meant for parenteral administration.

The nutraceuticals shall contain any of the ingredients specified in Schedule-I or Schedule-II or Schedule-IV or Schedule-VI or Schedule-VII or Schedule-VIII of the said regulation.

Every package of food containing nutraceutical shall carry the following information on the label, the word "NUTRACEUTICAL" and other labelling requirements as specified in the regulations.

Food for Special Medical Purpose (FSMP) means food that is specially processed or formulated for the dietary management of persons to satisfy particular dietary requirements which exist because of a particular physical or physiological condition or specific diseases and disorders (or) for exclusive or partial feeding of persons with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites (or) for other medically determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by food for specific nutritional use, or a combination of them.

Foods for Special Dietary Uses (FSDU) are foods specially processed or formulated to satisfy particular dietary requirements which may exist or arise because of certain specific health conditions like underweight, obesity, diabetes, high blood pressure, pregnant and lactating women, aging population and celiac disease etc.

Novel Foods are those that:-

- May not have a history of consumption by humans; or

- May not have any history of consumption of any ingredient used in it or the source from which it is derived; or
- A food or ingredient that is obtained by using new technology and innovative engineering process. This procedure may change the size, composition, or structure of the food or its ingredients which may in turn change its nutritional value, metabolism or level of undesirable substances

In India, the Novel foods are classified under non-specified foods and have no defined safety parameters and approval is required for manufacture, distribution, sale, or import of these products. In order to regulate such products, the Food Authority provides the opportunity to Food Business Operators to get the approval for novel foods and any innovations in food products through FSS (Approval of Non-Specified Food and Food Ingredients) Regulations, 2017. The regulation covers the following articles of food or food ingredients:-

- Novel Food or novel food Ingredients or processed with the use of novel technology
- New additives
- New processing aids including enzymes
- Articles of food and food ingredients consisting of or isolated from microorganisms, bacteria, yeast, fungi or algae.

In European Union the Novel Foods or novel food ingredients is the food with no history of "significant" consumption prior to 15 May, 1997. Any food or food ingredient that falls within this definition must be authorised according to the Novel Food legislation.

In Canada, novel foods are regulated under the Novel Foods Regulations. The regulations define novel food as:-

- Products that have never been used as food,
- Foods that result from a process that has not been previously used for food or,
- Foods that have undergone genetic modification and have new traits.

WHAT IS ADULTERATION?

Food Adulteration is an act of intentionally debasing the quality of food offered for sale either by the admixture or substitution of inferior substances or by the removal of some

valuable ingredient,

Adulterated food is dangerous because it may be toxic and can affect health and it could deprive nutrients essential for proper growth and development.

"Adulterant" means any material which is or could be employed for making the food unsafe or sub-standard or misbranded or containing extraneous matter.

Food is declared adulterated if:-

- A substance is added which depreciates or injuriously affects it
- Cheaper or inferior substances are substituted wholly or in part
- Any valuable or necessary constituent has been wholly or in part abstracted
- It is an imitation
- It is coloured or otherwise treated to improve its appearance or if it contains any added substance injurious to health
- For whatever reasons its quality is below the Standard

Common Adulterated Foods

Some of the common adulterated foods are milk and milk products, atta, edible oils, cereals, condiments (whole and ground), pulses, coffee, tea, confectionary, baking powder, non-alcoholic beverages, vinegar, besan and curry.

TYPES OF ADULTERANTS

1. Poisonous or Deleterious Substances
2. Filth and Foreign Matter
3. Economic Adulteration
4. Microbiological Contamination and Adulteration

ADULTERATION IN MILK AND MILK PRODUCTS

History of milk adulteration is very old. Adulterants in milk mainly include addition of vegetable protein, milk from different species, addition of whey and watering which are known as economically motivated adulteration These adulterations do not pose any severe health risk. However, some adulterants are too harmful to be overlooked. Some of the major adulterants in milk having serious adverse health effect are ***urea, formalin, detergents,***

ammonium sulphate, boric acid, caustic soda, benzoic acid, salicylic acid, hydrogen peroxide, sugars and melamine.

ADULTERATION OF OILS AND FATS

Vegetable oils and fats (VOFs) have a big contribution in our diet as cooking or frying oil, salad oil or in food products formulation. Also, VOFs are so important by regard to economic point of view. Adulteration of vegetable oils with some non-edible oils can cause serious health problems in some cases like Spanish olive oil syndrome caused due to selling non-edible rapeseed oil as an edible rapeseed oil and even as olive oil. Another example is adulteration of mustard oil with poisonous argemone oil.

ADULTERATION OF HONEY

Because of its high nutritional value and unique flavour, Honey is susceptible to adulteration with cheaper sweeteners and adulterants that have been detected in adulterated honeys include sugar syrups and molasses inverted by acids or enzymes from corn, sugar cane, sugar beet and syrups of natural origin such as maple. Adulteration of pure honey with synthetic honey (based on C4 plant sugars) has become much more prevalent in recent years.

ADULTERATION IN SPICES AND CONDIMENTS

India is a leader in the global spice market and is known the world over as "the Home of Spices". It caters to 48 percent of the world demand for spices. Spices are consumed in various forms as whole spices, ground spices, oleoresins and extracts and are used to enhance the flavour and taste of processed foods. Spices most often sold in the ground of powder form makes it easy to adulterate them. To add weight to the spices less expensive or low-quality spices, flour, corn starch, sawdust and chalk powder are mixed into these spices. Sometimes toxic and carcinogenic dyes are also added to the old stock to enhance their appearance and hide the presence of the adulterants Adulteration is intended for economic gains but it leads to serious public health risk. Long-term consumption of adulterated spices may lead to stomach disorders, vomiting, diarrhoea, liver and skin disorders, neurotoxicity and even cancer.

Common adulterants in ground spices

1. **Turmeric powder –** Addition of lead chrome, metanil yellow, chalk powder or yellow soapstone powder and starch; substitution with other rhizomes like arrowroot.
2. **Chilli powder –** Addition of brick powder, sudan dye, salt powder or talc powder,

artificial colours and dyes, colour, grit, sand, dirt, filth, sawdust dried tomato skin

3. **Asafoetida (Hing) –** Addition of soapstone or other earthy material, starch and foreign resin.

Common adulterants in Whole spices

4. **Cinnamon –** Substitution with cassia
5. **Saffron –** Addition of coloured dried tendrils of maize cob, sandalwood dust, Tartrazine and coconut threads
6. **Cardamom –** Substitution with de-oiled cardamom, artificial colorant like 'apple green' and malachite green
7. **Black pepper –** papaya seeds
8. **Cumin seeds –** grass seeds coloured, fennel seeds

The details of the rapid tests for detection of adulterants are described in DART Book ,and can be accessed through ***http://fssai.gov.in/dart/***

ARTIFICIAL RIPENING OF FRUITS USING CALCIUM CARBIDE

WHAT IS ARTIFICIAL RIPENING?

Unsaturated hydrocarbons such as acetylene, ethylene etc. can promote ripening and induce colour changes effectively. Although the cosmetic quality of such artificially ripened fruits improves, organoleptic quality gets impaired especially when harvested fruits are subjected to treatment without considering their maturity status. The quantity of ripening agent required to induce ripening for better cosmetic quality, including appearance will be much more than conventional dose, when properly mature fruits are not used for such purposes.

RIPENING WITH CALCIUM CARBIDE

The most commonly used chemical for artificial ripening is Calcium Carbide (CaC_2) and is popularly known as “Masala”, though banned under FSS (Prohibition and Restrictions on Sales) Regulations, 2011 made thereunder. As per sub-regulation 2.3.5 of the said regulation “no person shall sell or offer or expose for sale or have in his premises for the purpose of sale under any description, fruits which have been artificially ripened by use of acetylene gas, commonly known as carbide gas.

Calcium Carbide is colourless when pure, but greyish-white to black in colour

IDENTIFICATION OF CALCIUM CARBIDE RIPENED FRUITS

Quality Parameters	Fruit ripened using Calcium Carbide	Naturally ripened fruit
Weight per fruit	Fair	Good
Texture	Not very attractive but uniformly colored	Attractive but not uniformly colored
Aroma	Mildly good	Good
Firmness	Fair	Fair
Taste	In-core sour, mildly pleasant	Sweet, Longer
Shelf-Life	Shorter, Black Blotches appear on the skin in 2 or 3 days	Longer

otherwise, with garlic like odour. When it reacts with water, it produces acetylene gas (popularly referred to as carbide gas) which is an analogue to ethylene and quickens the ripening process. It is said to have the same effect as ethylene the natural ripening hormone. However, acetylene is not nearly as effective for ripening as is ethylene and acetylene is not a natural hormone as ethylene. Calcium Carbide contains traces of arsenic and phosphorous hydride. Calcium Carbide has carcinogenic properties and is used in gas welding. Being cheap and easily available in the local markets, CaC_2 is indiscriminately being used in preference to other recommended practices of inducing ripening in fruits.

EFFECTS OF CALCIUM CARBIDE ON FRUIT QUALITY

Fruits ripened with Calcium Carbide are overly soft, are inferior in taste and flavour. They also have a shorter shelf life. The fruit ripened with Calcium Carbide may develop uniform attractive surface colour, but the tissue inside would not be ripe or may remain green or raw. When Calcium Carbide is used in very raw fruit, the amount of the chemical needed to ripen the fruit has to be increased. This results in the fruit becoming even more tasteless, unhealthy and possibly toxic.

POTENTIAL HEALTH EFFECTS ASSOCIATED WITH CALCIUM CARBIDE

Calcium Carbide is a dangerous and corrosive chemical. Carbide ripened fruits on

consumption cause several harmful effects to human health. Calcium Carbide has cancer causing properties and contains traces of arsenic and phosphorous hydride. The early symptoms of arsenic or phosphorous poisoning include vomiting, diarrhoea with or without blood, burning sensation of chest and abdomen, thirst, weakness, difficulty in swallowing, irritation or burning in the eyes and skin, permanent eye damage, ulcers on the skin, sore throat, cough and shortness of breath. Higher exposure may cause a build-up of fluids in the lungs. It may affect the neurological system by inducing prolonged hypoxia which causes headache, dizziness, mood disturbances, sleepiness, mental confusion, memory loss, cerebral oedema (swelling in the brain caused by excessive fluids) and seizure. CaC_2 is banned in many countries because it has carcinogenic properties and hazardous effects.

Examples of fruits and vegetables where artificial ripening by use of Calcium Carbide is generally practised-Mango, Banana, Papaya and sometimes for Sapota (Chiku), Dates and Tomatoes.

CONTAMINANTS AND ITS TYPES

Contaminants are substances either added to food or not intentionally added to food in the process of their production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging transport or holding of articles of such food as a result of environmental contamination called **Crop Contaminants.** Since contamination generally has a negative impact on the quality of food and may imply a risk to human health, so measures to minimise contaminants in foods up to the levels that can pose no risk to human health are in place. The basic regulatory control of chemical contaminants in food are laid down in **FSS (Contaminants, Toxins and Residues) Regulation, 2011.**

There are three categories of food contamination:

1. **Physical**
2. **Chemical**
3. **Biological**

PHYSICAL CONTAMINANTS

Physical contaminants are any physical objects that can be present in food, and not meant to be in the food. This can include hair, glass, and insects. Some physical contaminants, such as hair, are not considered food safety concerns. While others, such as glass, are

considered food safety concerns.

Physical contaminants often enter the product through not following good manufacturing practices (GMPs) which include wearing proper protective equipment, such as hair nets. It also includes keeping the premises clean with well-maintained equipment and having a pest control policy in place to prevent infestation with insects and pests.

Chemical contaminants mean chemicals in food that are not meant to be in the food products and their presence in food is unintentional and undesirable. These include antibiotics residues, pesticides residues and cleaning agents. Many of these contaminants have food safety and quality concerns. Chemical contaminants may be harmful to health at certain levels. It is necessary to manage their levels in food and reduce dietary exposure of consumers. Several measures are required to be in place to manage the risk from these contaminants and reduce the levels at which they are present in food - including good practices and regulatory controls.

Examples of chemical contaminants include the following:

- Mycotoxins
- Heavy metals - lead and mercury, Arsenic, Cadmium
- Pesticides and dioxins
- Antibiotics and veterinary drug residues

1. MYCOTOXINS

Mycotoxins are toxic compounds that are naturally produced by certain types of moulds (fungi). Moulds that can produce mycotoxins grow on numerous foodstuffs such as cereals, dried fruits, nuts and spices. Mould growth can occur either before harvest or after harvest, during storage, on/in the food itself often under warm, damp and humid conditions. Most mycotoxins are chemically stable and survive food processing.

Several hundred different mycotoxins have been identified, but the most commonly observed mycotoxins that present a concern to human health and livestock include aflatoxins, ochratoxin A, patulin, fumonisins, zearalenone and nivalenol/deoxynivalenol. Mycotoxins appear in the food chain as a result of mould infection of crops both before and after harvest. Exposure to mycotoxins can happen either directly by eating infected food or indirectly from animals that are fed contaminated feed, in particular from milk.

HOW TO MINIMISE THE RISK FROM MYCOTOXINS

Moulds that produces mycotoxins can grow on a variety of different crops and foodstuff and can penetrate deep into food and do not just grow on the surface. Moulds usually do not grow in properly dried and stored foods, so efficient drying of commodities and maintenance of the dry state, or proper storage, is an effective measure against mould growth and the production of mycotoxins.

To minimize the health risk from mycotoxins, it is advisable to:

1. Inspect whole grains (especially corn, sorghum, wheat, rice), dried figs and nuts such as peanuts, pistachio, almond, walnut, coconut, hazelnuts etc. which are prone to contamination with aflatoxins for evidence of mould, and discard any that look mouldy, discoloured or shrivelled;
2. Avoid damage of grains before and during drying and in storage, as damaged grain is more prone to invasion of moulds and therefore mycotoxin contamination;
3. Buy grains and nuts as fresh as possible;
4. Make sure that foods are stored properly – kept free of insects, in dry and not too warm conditions;
5. Do not keep foods for extended periods of time before being used;

Aflatoxins are a class of mycotoxins produced primarily by Aspergillus Flavus and Aspergillus parasitic group of fungi. The spores of these fungi grow on a suitable food substrate under favourable conditions. Aflatoxins prevalence is aggravated in pre-harvest crops by conditions of drought, floods, delayed harvest, pest infestation, inadequate drying including improper postharvest handling and storage of crops and food.

REGULATORY STATUS

The maximum limits for mycotoxins including aflatoxins are prescribed under FSS (Contaminants, Toxins, and Residues) Regulations 2011. The table below contains the maximum limits of the aflatoxins in various food conditions as per the regulation.

S. No	Name of the Contaminants	Article of Food	Limit µg/kg
1	Aflatoxin	All articles of food	30
2	Aflatoxin M1	Milk	0.5
3	Patulin	Apple juice & Apple juice ingredients in other beverages	50
4	Ochratoxin A	A Wheat, barley & rye	20

CODEX Alimentarius Commission has developed code of practice for prevention and reduction of mycotoxin contamination in cereals (i.e. CAC/RCP 51-2003, it can be downloaded from link: C:/Users/Administrator/Downloads/CXP_051e_2014.pdf). It recommends practices based on good agricultural practices (GAP) and good manufacturing practices (GMP) at levels of pre harvest, harvest, transport and storage and it also provides complementary management systems to be considered in the future.

2. HEAVY METAL CONTAMINANTS IN FOOD

Heavy Metal contaminants in food crops is an issue of global concern that ultimately results in toxicity and diseases in humans and animals through consumption of contaminated soils and food crops. Metals such as arsenic, cadmium, lead and mercury that are naturally occurring chemical compounds present at various levels in the environment, e.g. soil, water and atmosphere can also occur as residues in food because of their presence in the environment. The presence of these metals in foods is the result of human activities such as farming, industry or from contamination during food processing and storage. People can be exposed to these metals from the environment or by ingesting contaminated food or water. Their accumulation in the body can lead to harmful effects over time. Due to the adverse effects of these heavy metals on humans, FSSAI has established maximum levels for these commonly occurring metal contaminants in foods. Additionally, these standards are in a constant state of revision because of ongoing studies. The commonly occurring metal contaminants found in food products are lead, copper, arsenic, tin, zinc , cadmium, mercury, chromium, nickel and their limits in ppm across different food products is prescribed in FSS (Contaminants, Toxins and Residues) Regulations, 2011.

3. PESTICIDES IN FOODS

Pesticide residues in food commodities and their entry into the food-chain has become a major cause of concern all-over the world. Food safety has become crucial for all involved in the value chain and consumers have to be assured that they are not exposed to an unacceptable level of pesticide residues. The presence of the residues above the permissible level is also a major bottleneck in the international trade of food commodities.

REGULATORY STATUS

FSSAI regulates the pesticide residues detected in various food items through FSS (Contaminants, Toxins and Residue) Regulations, 2011. The regulation covers more than 150 insecticides/pesticides whose tolerance limits have been prescribed under this regulation. There is a harmonized monitoring of pesticide residues in the country which started under

central sector scheme called, **"Monitoring of Pesticide Residues at National Level" (MPRNL)** in food commodities since 2005. Pesticide residues in the crops are monitored through the use of maximum residue limits (MRL), which are based on the analysis of the quantity of a given chemical remaining on food product samples. Regulating pesticides on the ground revolves around this regulatory yardstick called the MRLs of the pesticides in a food commodity.

4. ANTIBIOTIC RESIDUES AND AMR (ANTI-MICROBIAL RESISTANCE) – AN EMERGING ISSUE OF FOOD SAFETY

Antibiotics are naturally formed metabolites derived from fungi or bacteria or are produced by modern biotechnology and chemical synthesis as well. Antibiotics are able to kill microorganisms or inhibit their growth. In human and veterinary medicine, antibiotics are therefore used as drugs for the treatment of bacterial diseases.

REGULATORY STATUS

FSSAI has notified the FSS (Contaminants, toxins and Residues) Amendment Regulations, 2018 specifying 'Tolerance Limits' of antibiotics and other veterinary drugs in meat/meat products, poultry, fish and milk. Through this amendment , the existing regulations have been further expanded to include new tolerance limits for 103 antibiotics and veterinary drugs in meat/meat products (including poultry and fish) and milk.

Among the new provisions, tolerance limits for 76 antibiotics (these are either prohibited or not-intended for use in food producing animals) have been specified at 0.01 mg/kg of the listed food and largely reflects the level of detection of such antibiotics/drugs by existing method of analysis. The amendment also includes revisions to the prohibited list of antibiotics and veterinary drugs applicable to meat and meat products, and poultry and eggs, sea foods including shrimps, prawns or any variety of fish and fishery products.

ORIGIN AND HEALTH RISKS OF ANTIBIOTIC RESIDUES IN FOOD

The use of antibiotics as drugs for the treatment of diseased animals is a matter of animal welfare and therefore inevitable. As a result of application failures, such as non-compliance with the statutory withdrawal period or use of prohibited antibiotics, misuse of antibiotics as growth promoters, residues of antibiotics can occur in food of animal origin such as meat, milk or eggs and this can pose health risk for consumers.

The major public health significances of antimicrobial residues include the development of antimicrobial drug resistance, hypersensitivity reaction, carcinogenicity,

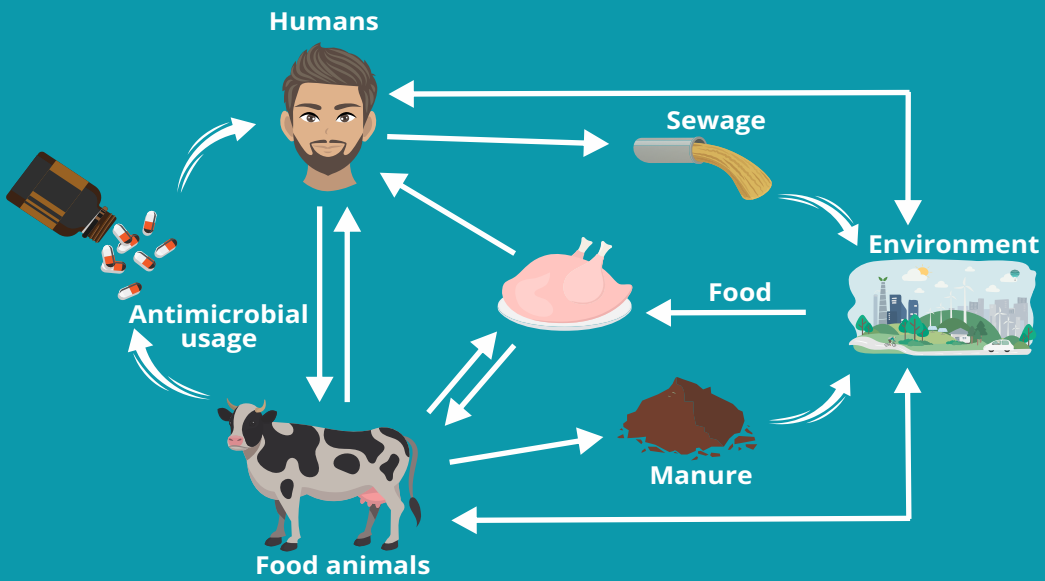
mutagenicity, teratogenicity, bone marrow depression, and disruption of normal intestinal flora. Indiscriminate use of antimicrobials in aquaculture is also resulting in occurrence of residues in aquaculture products and associated harmful health effects in humans and requires control measures to ensure consumer protection.

ANTIMICROBIAL RESISTANCE (AMR)

Antimicrobial resistance (AMR) has emerged as a major threat to public health estimated to cause 10 million deaths annually by 2050. India carries one of the largest burdens of drug-resistant pathogens worldwide. AMR develops when microbes develop mechanisms to evade the action of antimicrobials. The driving factors that contribute to AMR include:

1. Misuse /overuse of antimicrobial in Human and Animal sectors
2. Environmental contamination (including sewage and heavy metals)
3. Use of antibiotics for non-therapeutic purpose
4. Few regulations against non-therapeutic use of antibiotics.
5. No stringent implementation protocols even when there are regulations.
6. Poor sanitation plays a major role in the spread of antibiotic-resistant bacteria and acquiring of Antibiotic Resistant Genes (ARG).
7. No proper surveillance system in place.

TRANSMISSION DYNAMICS OF ANTI-MICROBIAL RESISTANCE



NATIONAL ACTION PLAN ON ANTIMICROBIAL RESISTANCE

In May 2014, the World Health Assembly requested the development of the Global Action Plan (GAP) on antimicrobial resistance. In May 2015, the Sixty-Eight World Health Assembly endorsed the GAP-AMR to tackle antimicrobial resistance, including the most urgent drug-resistant trend – the antibiotic resistance. India developed its AMR National Action Plan (NAP), aligned well with the Global Action Plan and released it in May 2017.

OBJECTIVES OF NAP-AMR

1. Define the timeline and allocate the budget to slow the emergence of AMR in India and to strengthen the coordination between various organisations.
2. Strengthen the surveillance; optimise the use of antibiotics in all sectors enhanced investments in AMR activities, research and innovations.
3. Monitor and evaluate the NAP-AMR implementations.

STRATEGIC PRIORITIES OF NAP-AMR

1. Improve awareness and understanding of AMR through effective communication, training and education.
2. Strengthen knowledge and evidence through surveillance
3. Reduce the incidence of infection through effective infection prevention and control.
4. Optimize the use of antimicrobial agents in health, animals and food.
5. Promote investments for AMR activities, research and innovations.
6. Strengthen India's leadership on AMR.

FOOD SAFETY MANAGEMENT SYSTEM (FSMS)

FSSAI recognizes that the responsibility for the supply of food that is safe, healthy and nutritious is shared along the entire food chain - by all involved with the production, processing, trade and consumption of food, as food can be contaminated at any step in the food chain unless effective controls are not put in place. This approach encompasses the whole food chain from primary production to final consumption and the stakeholders include farmers, food processors, transport operators, distributors (wholesale and retail) and

consumers. In fact, the food chain approach extends to the very end of the food chain -- the consumer -- by advocating training and education on the safe storage, preparation and consumption of food.

One weak link can make the whole food chain collapse. This necessitates the adoption of practices in food production, post-harvest treatment, processing and handling that reduce the risk of microbiological, chemical and physical hazards from entering the food chain (or controlling at source, if feasible). There are some cases in which the hazard simply cannot be removed from foodstuffs, for example, those hazards involving chemical contaminants. The adoption of sound practices along the food chain – based on the principles defined in Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) – are the keys to discharging this responsibility along the food chain.

Keeping this in view, FSSAI has laid down detailed sanitary and hygienic practices that should be followed by FBOs irrespective of their position in the food chain in order to ensure food safety. These practices are commonly called as **Schedule 4 requirements** provided under Schedule 4 of FSS (Licensing and Registration of Food Business) Regulations, 2011. Compliance to these practices has to be ensured by FBOs in the same way as compliance to standards of end product.

Schedule IV requirements and its significance

To provide assurance of food safety, FBOs should strive to implement an effective Food Safety Management System (FSMS) based on Hazard Analysis and Critical Control Point (HACCP) and suitable pre- requisite programmes by actively controlling hazards throughout the food chain starting from food production till final consumption.

Every licensed FBO must have a documented Food Safety Management System (FSMS) plan and is required to comply with Schedule 4 of FSS (Licensing and Registration of Food Business) Regulation, 2011. Schedule 4 introduces the concept of FSMS based on implementation of Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP) by food businesses and is divided into five parts as under:

Schedule 4	General Requirements
Part 1	General hygienic and sanitary practices to be followed by food business operators applying for registration - Petty food operators and Street food vendors
Part 2	General hygienic and sanitary practices to be followed by food business operators applying for license - Manufacturing/processing/packaging/ storage/distribution
Part 3	General hygienic and sanitary practices to be followed by food business operators applying for license - Milk and milk products
Part 4	General hygienic and sanitary practices to be followed by food business operators applying for license - Slaughter house and meat processing
Part 5	General hygienic and sanitary practices to be followed by food business operators applying for license - Catering

Note: *The details of the sanitary and hygiene requirements for the different kinds of businesses have been given in Chapter-5.*

ADVANTAGES OF FSMS

- Continuous prevention of foodborne illness and related public relations disasters
- Food safety compliance during routine inspections
- Improved inventory control
- Reduction in product loss
- More consistency in product preparation and improved product quality
- Increased employee understanding and involvement in food safety
- More effective communication and collaboration with industry regulators

FSMS GUIDANCE DOCUMENTS

A series of sector specific Food Safety Management System (FSMS) Guidance Documents have been developed with the help of domain experts with the intent to provide implementation guidance to food businesses (especially the small and medium businesses) involved in manufacturing, packing, storage and transportation to ensure that critical food safety related aspects are addressed throughout the supply chain.

These documents are primarily based on Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011 and lay down general

requirements on good hygienic practices to be followed by Food Business Operators & indicate practical approaches which a business should adopt to ensure food safety. The documents are recommendatory in nature and provide the basic knowledge and criteria for implementation of Hazard Analysis and Critical Control Point (HACCP) system by the food businesses. Sample HACCP Plans have been included from some established practising industries. These plans could be used as reference by the industry and modified or altered based on their operations. Inspection checklists for FBOs to audit their facility & operations are also included in these documents. The FBOs can evaluate themselves based on the indicative scoring. Also, these documents provide important templates and forms to facilitate the FBOs to maintain the records. These include mandatory forms as prescribed by FSSAI & few templates for maintaining records of processes critical for food safety. FSSAI has developed FSMS documents as guidance to the food businesses of following sectors:

- Spices
- Fish and Fish Products.
- Meat and Meat Products(Poultry).
- Health Supplements and Nutraceuticals.
- Vegetable edible oils and fats sectors
- Bakery sector
- Foodgrain warehouses
- Flour milling sector
- Catering sector

FOOD SAFETY DISPLAY BOARDS (FSDB)

As per the FSS Regulation, there is a mandatory requirement of displaying FSSAI License/Registration number at food premises. Usually, the FSSAI license number is not visible to the consumers. Thus, to change the overall consumer perceptibility and to strengthen food safety, FSSAI introduced Food Safety Display Boards (FSDBs) for various food businesses on a voluntary basis.

FSDB is an informative board which primarily displays basic food safety and hygiene practices to be followed by FBOs in their establishment. FBOs are required to display them at a prominent location.

fssai
License No. (Please Mention Your License no.) _____

Restaurant

With Us You Will Get Safe Food

We Follow These 12 Golden Rules

Hygiene Rule Codes		Hygiene Rule Codes	
1	Keep premise clean and have regular pest control 	 Wear clean clothes/ uniform	7
2	Use potable water for food preparation 	 Wash hands before & after handling food and after using toilets, coughing, sneezing, etc.	8
3	Cook food thoroughly. Keep hot food above 60°C and cold food below 5°C 	 Use water proof bandage to cover cuts or burn wounds	9
4	Store veg & non veg food, raw & cooked food in separate containers 	 Do not handle food when unwell	10
5	Store cold food below 5°C and frozen products at -18°C or below 	 Use clean and separate dusters to clean surfaces and wipe utensils	11
6	Use separate chopping boards, knives, etc. for raw/ cooked & veg/non veg food 	 Keep separate & covered dustbins for food waste	12

If any concern

Call toll free
1800 112 100

SMS or Whatsapp
9868686868

Always quote FSSAI Number for quick action

Give your Feedback to Company Name

(Company Name)
(Contact Details)

Download FSSAI APP
or Logon to https://foodlicensing.fssai.gov.in/cmsweb

Connect with us:
Food Safety and Standards Authority of India
fssaiindia

FOOD SAFETY TRAINING AND CERTIFICATION (FOSTAC)

Food Safety Training & Certification (FOSTAC) is a large scale training and capacity development programme initiated by FSSAI for training of food handlers working in the food businesses at supervisor level, to ensure that the establishments in which food is being handled, processed, manufactured, stored, distribute conform to the food safety requirements. This initiative was started with the aim to enhance the availability of skilled manpower in order to ensure better implementation and self-compliance to FSS Regulations.

Once trained the food handlers are certified as "Food Safety Supervisor". Recently, FSSAI has mandated that all food businesses having Central Licences or State Licenses should have at least one trained and certified food safety supervisor for every 25 food-handlers on all their premises.

There are 19 courses in three levels, Basic, Advanced and Special. The FSSAI provides these training programs for people who are in the food businesses, whether as food business operators or employees or otherwise through authorised training partners.

FOOD SAFETY AUDITS

Section 44 of the Food Safety and Standards Act, 2006 empowers the Food Authority to recognize an organization or an agency for carrying out food safety audit and checking compliance with the Food Safety Management Systems and Section 16(2)C of the Act, provides for a mechanism and guidelines for accreditation of certification bodies for Food Safety Management System (FSMS).

To strengthen the food safety surveillance system, FSSAI has developed a framework for conduct of food safety audits of FBOs to ensure compliance to sanitary and hygienic

requirements, through Recognized Auditing Agencies as per FSS (Food Safety Auditing) Regulations, 2018. It is envisaged to use food safety audits as a complement to regulatory inspections by Central or State FSOs thereby leading to less frequent regulatory inspections except for regulatory sampling. This will strengthen food safety surveillance system and encourage self-compliance while at the same time assuring safe food to the consumers.

Food Businesses are required to get their businesses timely audited by recognised Auditing Agencies. Food Businesses having undergone satisfactory audits will be subjected to less frequent audits by Central or State licensing authorities. Food Authority shall classify some food businesses for mandatory Food Safety Audits and these Food Businesses shall be liable to get their businesses timely audited by recognised auditing agencies. This classification will be based on factors like food type, intended customer, nature of activity of the business, volume of the business, compliance history of the FBO, method of processing/any other factors prescribed by Authority. Food businesses which are not subject to mandatory food safety auditing can also go for auditing of their businesses on voluntary basis.

Note: *Detailed description is available in Chapter -5*

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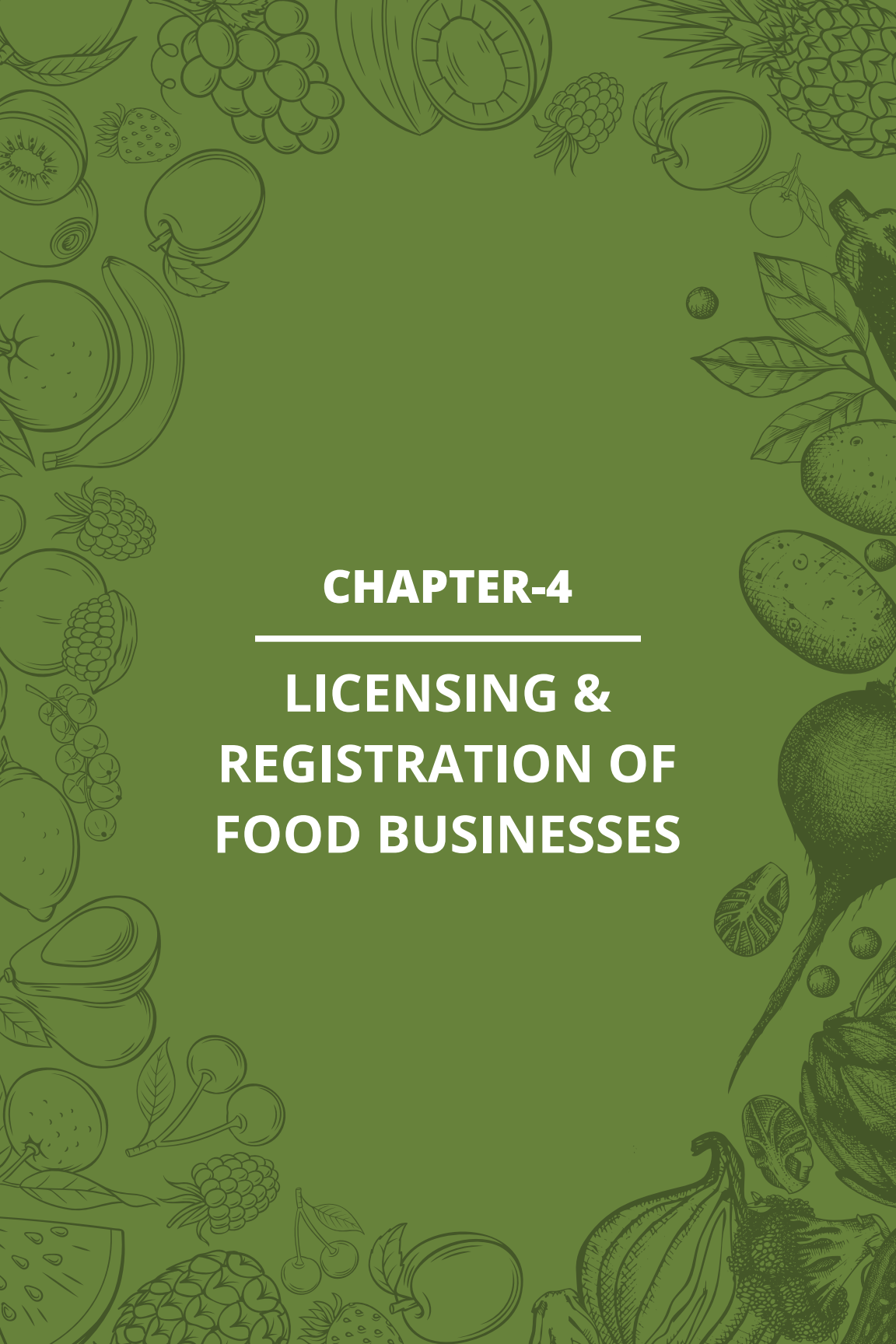


CHAPTER-4

LICENSING & REGISTRATION OF FOOD BUSINESSES

4 LICENSING & REGISTRATION OF FOOD BUSINESSES

Under Section 31 of Food Safety and Standards Act 2006 to commence or carry on any food business, licensing/registration of food businesses is mandatory. Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation 2011 prescribe the procedure for licensing and registration of food businesses. Licensing/registration conditions, sanitary and hygienic requirements for all food businesses have been covered under these regulations. All Food Business Operators in the country will have to be registered or licensed in accordance with the procedures laid down in the Act and Regulation made thereunder. As mandated by the Act, distinction has been introduced between "**Registration**" and **"Licensing**" as per the annual turnover, capacity of production and other qualifying conditions.

SECTION OF FSSA, 2006 RELEVANT FOR LICENSING & REGISTRATION

1. Section 3 (j) :

Definition of "Food" means any substance, whether

- Processed, partially processed or unprocessed,
- Intended for human consumption and includes primary food,
- Genetically modified or engineered food
- Food containing such ingredients, infant food, packaged drinking water, alcoholic drink, chewing gum
- Any substance, including water used into the food during its manufacture, preparation or treatment
- Does not include any animal feed, live animals unless they are prepared or processed for placing on the market for human consumption
- Does not include plants, prior to harvesting, drugs and medicinal products, cosmetics, narcotic or psychotropic substances

2. Section 3 (n) :

"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 , includes food services, catering services, sale of food or food ingredients;

3. Section 3 (o) :

"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 thereunder.

4. Section 3 (zk) :

"Primary food" means an article of food, being a produce of agriculture or horticulture or animal husbandry and dairying or aquaculture in its natural form, resulting from the growing, raising, cultivation, picking, harvesting, collection or catching in the hands of a person other than a farmer or fisherman.

5. Section 31:

It states that –

- No person shall commence or carry on any food business except under a License/Registration.
- Premise based License/Registration of FBO Units
- Appeal against order of rejection for grant of license lies before Commissioner Food Safety.

6. Section 32 : Improvement Notice – (Detail covered in Chapter 5)

Definitions (Regulations):

1. **"Central Licensing Authority"** means Designated Officer appointed by the Chief Executive Officer of the Food Safety and Standards Authority of India in his capacity of Food Safety Commissioner.
2. **"State Licensing Authority"** means the Designated Officer appointed under section 36 (1) of the Act by the Commissioner of Food Safety of the state or U.T.
3. **Registering Authority"** means 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.

4. **"Petty Food Manufacturer"** means any food manufacturer, who

(a) Manufactures or sells any article of food himself or a petty retailer, hawker, itinerant vendor or temporary stall holder or distributes foods including in any religious or social gathering except a caterer or

(b) 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:

(i) Production capacity of food (other than milk and milk products and meat and meat products) does not exceed 100 kg/ltr per day or

(ii) Procurement or handling and collection of milk is up to 500 litres of milk per day or

(iii) Slaughtering capacity is 2 large animals or 10 small animals or 50 poultry birds per day or less.

AUTHORITIES RESPONSIBLE FOR LICENSING & REGISTRATION

Registration Authority

Designated Officer or Food safety Officer or Any Official in Panchayat, Municipal Corporations or any other local body or panchayat Area notified by the State Food Commissioner for the purpose of Registration

State Licensing Authority

Designated Officer Appointed under Section 36 (1) of FSS Act by the Food Safety Commissioner of the State or UT

Central Licensing Authority

CLA appointed by the Chief Executive Officer of the Food Safety & Standards Authority of India in his capacity as Food Safety Commissioner.

List of food businesses falling under the preview of Central Licensing Authority is as below:

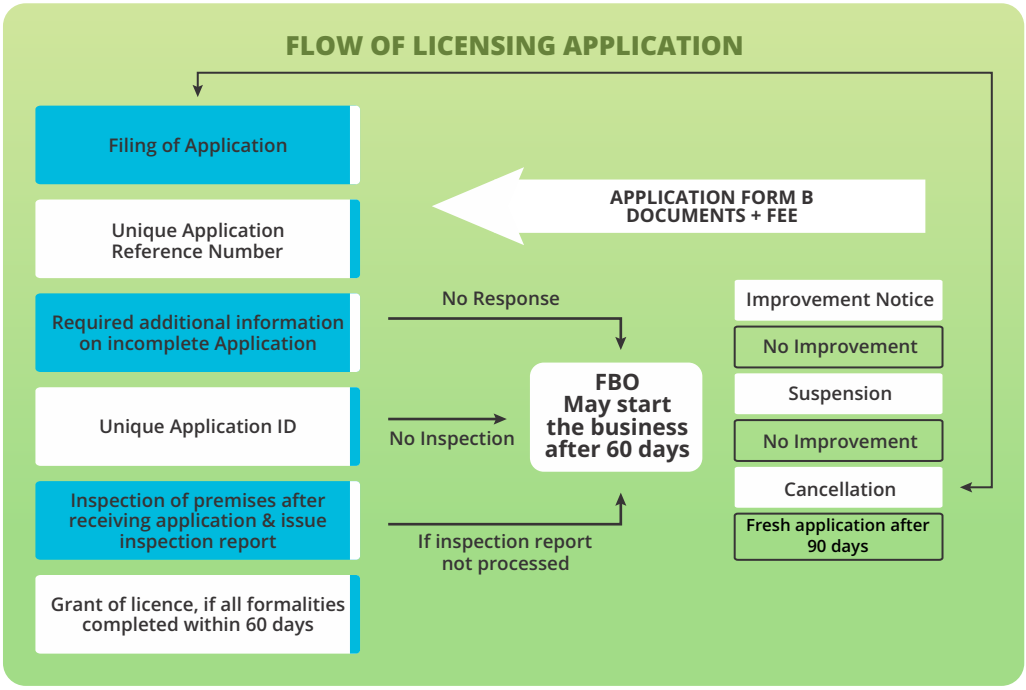
SCHEDULE 1

[See Regulation 2.1.2 (3)]

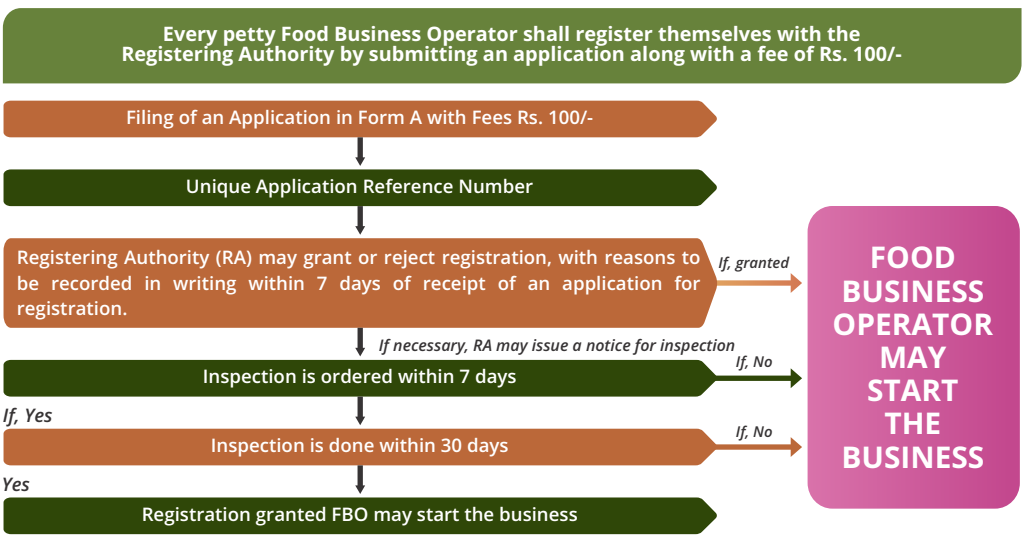
- Dairy units including milk chilling units equipped to handle or process more than 50,000 litres of liquid milk/day or 2500 MT of milk solid per annum.
- Vegetable oil processing units and units producing vegetable oil by the process of solvent extraction and refineries including oil expeller unit having installed capacity more than 2 MT per day.
- All slaughter houses equipped to slaughter more than 50 large animals or 150 or more small animals including sheep and goats or 1000 or more poultry birds per day.
- Meat processing units equipped to handle or process more than 500 kg of meat per day or 150 MT per annum.
- All food processing units other than mentioned under (I) to (IV) including re-labellers and re-packers having installed capacity more than 2 MT/day except grains, cereals and pulses milling units
- 100 % Export Oriented Units.
- All Importers importing food items including food ingredients and additives for commercial use.
- All food business operators manufacture any article of food containing ingredients or substances or using technologies or processes or combination thereof whose safety has not been established through these regulations or which do not have a history of safe use or food containing ingredients which are being introduced for the first time into the country.
- All FBO dealing in manufacturing of Proprietary Food.
- E- commerce kind of business
- Food Business Operator operating in two or more states.
- Food catering services in establishments and units under Central Government Agencies like Railways, Air and Airport, Seaport, Defence etc.

FSSAI license is based on premise and all kinds of food business activities which are being conducted at the same premise can be applied for in a single FSSAI license. FSSAI has launched Food Safety Compliance System called FoSCoS to provide one point stop for all

engagements of an FBO with the department for any regulatory compliance transaction and to facilitate the food business operators in applying for the licenses by minimising the number of documents.



FLOW OF REGISTRATION APPLICATION



SALIENT FEATURES ABOUT LICENSING & REGISTRATION

1. Food Business Operators can start their businesses only after obtaining an FSSAI license / registration.

2. 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; have to register themselves with Registering Authority.

3. There is a unified Licensing/Registration procedures for both Centre and State throughout the country-Single Window Online System through FoSCoS with Completely online submission of documents, and no physical interference is required. FSSAI License/Registration for the premises/units at Airport/Seaport or Railways or Central Govt. Establishments are being issued from the same portal with the same procedures and forms. The online payment gateways are available for making payment of fee for licenses and registrations. The licenses and registrations are being dispatched through e-mode only with embedded QR code. Hence, no signature is required on the license/registration copy. This makes license/registration procedure completely online.

4. Licenses/Registrations are premise based. This means one premise can have only one FSSAI license or registration. Food business involved in multiple Kind of Businesses can endorse it on same license. e.g. Manufacturing, Storage and Retailing of food products, if conducted on same premises, then only one license is required.

5. The timelines for procurement of licenses and registration certificates are specified in the regulations:

a) In case of Registration, after receipt of application, Registering Authority may either grant registration or reject it with reasons to be recorded in writing or issue notice for inspection, within 7 days of receipt of application and in the event if Registering Authority after inspection satisfied with the safety, hygiene and sanitary condition of premises as specified in Part II of Schedule 4, may grant Registration within 30 days. If registration is not granted, or denied, or inspection not ordered within 7 days or no decision is communicated within 30 days after inspection if required, the petty FBO may start his food business, provided that it will be the responsibility of the FBO to comply with any improvement suggested by the FSO in the future.

b) In case of Licenses, the application goes to Designated Officer and FSO has the responsibility of carrying out the inspection of FBO's premises. The FSO has to check for the compliance with the conditions of the license and safety requirements mentioned in Schedule IV under different parts dependent on nature of business, before the DO grants a license to the FBO. DO will either grant or reject the license within 60 days of receipt of completed application or within 30 days from receipt of inspection report.

6. An auto-issuance of license and registration has been implemented by FSSAI, in case of unattended applications by the authorities within stipulated time and auto-rejection of FBO's application on 31st day, if not responded to the queries raised within 30 days. In case of rejection of application, the concerned FBO may request for reactivation of application to DO or CFS, as the case may be within stipulated time through FoSCoS account.

7. Pre license / registration inspection has been waived off by FSSAI, unless there is reasonable ground pertaining to safety of food. Licensing or Registering Authorities shall have to plan or schedule the inspection according to the risk associated with the food businesses but shall not hold / cause undue delay in grant of any license / registration only because of inspection.

REGISTRATION OF FOOD BUSINESS OPERATOR UNDER FSS ACT 2006

REGISTRATION OF PETTY FBO

1. Every petty Food Business Operator will register themselves with the Registering Authority by submitting an application for registration in Form A along with a fee of Rs. 100/- for a year. Registration certificate can be applied maximum for 5 years at a time,

2. The petty food manufacturer has to follow the basic hygiene and safety requirements provided in Part I of Schedule 4 of these Regulations and provide a self- attested declaration of adherence to these requirements with the application in the format provided in Annexure-1.

3. The Registering Authority will consider the application and may either grant registration or reject it with reasons to be recorded in writing or issue notice for inspection, within 7 days of receipt of an application for registration.

4. In the event of an inspection being ordered, the registration will be granted by the Registering Authority after being satisfied with the safety, hygiene and sanitary conditions of the premises as contained in Part I of Schedule 4 within a period of 30 days. If registration is not granted, or denied, or inspection not ordered within 7 days or no decision is communicated within 30 days the petty food manufacturer may start its business, provided that it will be incumbent on the Food Business Operator to comply with any improvement suggested by the Registering Authority even later. The registration can not be refused without giving the applicant an opportunity of being heard and for reasons to be recorded in writing.

5. The Registering Authority will issue a registration certificate and a photo identity card, which has to be displayed at a prominent place at all times within the premises or vehicle or cart or any other place where the person carries on sale/manufacture of food in case of Petty Food Business.

6. The Registering Authority or any officer or agency specifically authorized for this purpose carries out food safety inspection of the registered establishments at least once in a year. Provided that a producer of milk who is a registered member of a dairy Cooperative Society registered under Cooperative Societies Act and supplies or sells the entire milk to the Society shall be exempted from this provision for registration.

EXCEPTIONS FOR FSSAI REGISTRATIONS

Following categories of FBOs have been kept out of the list of FSSAI Registration subject to adherence of conditions by parent entities:-

- Producer of milk who is a registered member of a dairy Cooperative Society registered under Cooperative Societies Act and supplies the entire milk to the Society
- Last mile delivery Persons
- Direct Sellers
- Food Carts/Vendors of a food chain
- Vending Machines/Food ATMs

DOCUMENTS REQUIRED FOR A REGISTRATION CERTIFICATE

Photo of Food Business Operator	**Document for Identity Proof like Ration Card, Voter ID Card, PAN Card, Driving License, Passport, Aadhar Card, Senior Citizen Card, Department Issued ID**	**Proof of Premises of food activity, if premises is different from as mentioned in ID proof**

LICENSE FOR FOOD BUSINESS OPERATOR UNDER FSS ACT 2006

License for commencing or carrying on food business, which falls under **Schedule 1, shall be granted by the Central Licensing Authority,** provided that Food Authority may through notification make such changes or modify the list given in the Schedule I as considered necessary. License for commencing or carrying on food business, which are not covered under Schedule 1, shall be granted by the concerned State/UT's Licensing Authority.

Food Business Operators, excluding the one mentioned in Schedule I (apart from petty food business operators) under the category of license lies under the purview of State Licensing Authority.

APPLICATION FOR LICENSE TO THE LICENSING AUTHORITY

As per Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, an application for grant of License shall be made in Form B of Schedule 2 to the concerned Licensing Authority accompanied by relevant documents as mentioned in Annexure 2 of Schedule 2.

APPLICATION PROCEDURE

The whole process for applying for license to the licensing authority has been digitalised through online system i.e. Food Safety Compliance System (FoSCoS). Submission of Form B has been digitalised. The list of Kind of Business –wise required documents (as approved by Food Authority) has been incorporated in the FoSCoS. The declaration has been embedded within the online application (Form B) in the system.

DOCUMENTATION FOR LICENSE APPLICATION

The KoB-wise proposed list of mandatory documents is divided into two parts i.e. **Documents for Non-Manufacturing KoBs** and **Documents for Manufacturing KoBs.** The KoB-wise mandatory documents are represented below:

A1: List of Documents for non-Manufacturing/Processing Kind of Businesses

Sr. No. 1 to 5 – applicable for all Kind of Businesses	
1	List of Directors/Partners/Proprietor/Executive Members of Society/Trust with full address and contact details*
2	Photo I.D and address proof issued by Government authority of Proprietor/Partner/ Director(s)/Authorised Signatory

3	Proof of possession of premises. (Sale deed/Rent agreement/Electricity bill, etc.)
4	Partnership Deed/Self Declaration for Proprietorship/Memorandum & Articles of Association towards the constitution of the firm/copy of certificate obtained under Coop Act - 1861/Multi State Coop Act - 2002 in case of Cooperatives
5	Form IX: Nomination of Person as per Clause 2.5 of FSS Rules, 2008 (Not applicable in case of Proprietor)*

A2: List of additional specific documents related to type of food business activity

Food Services such as Hotels/ Restaurants, Food Vending Establishments, Club/Canteen or any other prepared food establishment.	Analysis report (Chemical & Bacteriological) of water to be used as ingredient in food from a recognized/public health laboratory to confirm the portability indicating the name of authorized representative of Lab who collected the sample and date of collecting sample **(Not applicable if water is not being used as ingredient)**
Importer	1. Import Export Code (IEC) document issued by DGFT 2. Recall Plan*
Merchant Exporter	1. Import Export Code (IEC) document issued by DGFT 2. Undertaking for not selling the food products (which are not as per FSSAI Standards) in domestic market.*
Head Office/Registered Office/eCommerce	1. Recall Plan*
Transporters	1. List of Vehicle Registration Numbers*

B1: List of Documents for Manufacturers/Processors

Sr. No. 1 to 10 – applicable for all Manufacturing/Processing KoBs	
1	List of Directors/Partners/Proprietor/Executive Members of Society/Trust with full address and contact details*
2	Photo I.D and address proof issued by Government authority of Proprietor/Partner/ Director(s)/Authorised Signatory
3	Proof of possession of premises. (Sale deed/Rent agreement/Electricity bill, etc.)
4	Partnership Deed/Self Declaration for Proprietorship/Memorandum & Articles of Association towards the constitution of the firm/copy of certificate obtained under Coop Act - 1861/Multi State Coop Act - 2002 in case of Cooperatives
5	Form IX: Nomination of Person as per Clause 2.5 of FSS Rules, 2008 (Not applicable in case of Proprietor)*
6	Blueprint/layout plan of the processing unit showing the dimensions in metres/ square metres and operation-wise area allocation *
7	Production unit photographs

8	Name and List of Equipments and Machinery along with the number, installed capacity and horse power used*
9	Analysis report (Chemical & Bacteriological) of water to be used as ingredient in food from a recognized/ public health laboratory to confirm the portability indicating the name of authorized representative of Lab who collected the sample and date of collecting sample. **(Not applicable if water is not being used as ingredient)**
10	Recall Plan*

B2: List of additional specific documents related to type of Manufacturing/ Processing Activity

Dairy Processing	Source or procurement plan for milk*
Meat Processing	1. Source of raw material* 2. NoC from Municipal Corporation/Local Body
Slaughter House	NoC from Municipal Corporation/Local Body
Relabellers and Repackers	1. NOC from Manufacturers 2. Relabellers are not required to submit documents mentioned at Sr. no. 6 to 9 of the above list B1.
Nutraceuticals	Product Specification (ingredients as per applicable Schedule) of each product mentioning the purity criteria adopted for ingredients of Nutraceutical and health supplement products as per the prescribed format*
Proprietary Foods	Composition of the each product as per the prescribed format*
Novel Foods	Product Approval from FSSAI Hq for each product
Packaged Drinking Water	Pesticide residues report of water to be used as ingredient in case of units manufacturing Packaged drinking water, packaged Mineral water and/or carbonated water from a recognised/ public health laboratory indicating the name of authorised representative of Lab who collected the sample and date of collecting sample, including source of raw water and treatment plan.

B3: Additional Documents for Manufacturer – Exporters (in addition to above)

1. Import Export Code (IEC) document issued by DGFT
2. Undertaking of not selling the food products which are not conforming with FSSAI Standards in domestic market*
3. Ministry of Commerce Certificate for 100% EOU (if availing the Scheme)

C: Other Document list irrespective of Kind of Business

1. In case of extraction of ground water, NOC from CGWA as per FSSAI order dated 2nd Jan 2018
2. Any document which is required by the licensing authority to ensure safety of food
3. Any document specified by FSSAI or Commissioner of Food Safety through a public order for any particular Kind of Business activity or in general

D: Documents required for Renewal of License (for all KoBs)

1. FSMS Certificate or plan

E: Documents required for Modification of License (for all KoBs)

1. Supporting Document for the purpose of modification on the letterhead
2. Any document which is required by the licensing authority to ensure safety of food

NOTE:

1. ***All documents shall be self-attested by authorized signatory mandatory prior to uploading the documents on the online system for applying license and registration.***
2. ***All * marked documents in the above proposed KoB-wise list of required documents for licensing to be submitted on the letterhead of the Food Business.***

PAYMENT MECHANISM FOR MAKING APPLICATION FEE FOR LICENSE AND REGISTRATION

The method for making payment for license fee has been made completely online w.e.f. 01st January 2021. No offline payment method is allowed. However, treasury challan method continues for making application fee for registrations in some States/UTs. The applicable fee is prescribed under Schedule 3 of said regulations and same has been implemented in FoSCoS.

PROCESSING OF APPLICATION FOR LICENSE

1. A license shall, subject to the provisions of these Regulations, be issued by the concerned Licensing Authority within a period of 60 days from the date of issue of an application ID number.
2. If, upon scrutiny of the application within 15 days from the date of receipt of the

application, the concerned Licensing Authority requires any additional information with respect to an application or if the application is incomplete, the Licensing Authority shall inform the applicant in writing, to furnish such additional information or complete the application, as the case may be, within 30 days from such notice. In case the applicant fails to furnish the required information within the stipulated time of 30 days, the application for license shall stand rejected.

3. On the receipt of a complete application including the additional information if asked for, the Licensing Authority shall issue an Application ID number.

4. After the issue of Application ID number, the Licensing Authority may direct the Food Safety Officer or another person or agency specially designated for such functions to inspect the premises in the manner prescribed by the Food Safety and Standard Authority of India in accordance with these Regulations. Such Inspecting Officer or person may issue a notice to the applicant, if it deems fit, guiding food business operator on necessary steps to be taken or changes or alteration to be made in the premises in order to ensure general sanitary and hygienic conditions as specified in Schedule 4 of FSS (Licensing and Registration of Food Business) Regulation, 2011. The applicant shall carry out the required steps, changes or alterations and intimate the Licensing Authority within 30 days or such period as may be allowed by the Licensing Authority.

5. Within a period of 30 days from receipt of an inspection report excluding the time taken by the applicant in complying with the advice, if any, given in the inspection report and verification thereof, the concerned Licensing authority shall consider the application and may either grant license or reject the application. Provided that before refusing license an applicant shall be given an opportunity of being heard and the reasons for refusal shall be recorded in writing.

6. The Licensing Authority shall issue a License in Format C under Schedule 2 of FSS (Licensing and Registration of Food Business) Regulation, 2011, a true copy of which shall be displayed at a prominent place at all times within the premises where the Food Business Operator carries on the food business.

PROCEDURE FOR LICENSE IN CERTAIN LOCAL AREAS

A single license may be issued by the Licensing Authority for one or more articles of food and also for different establishments or premises in the same local area including

collection and chilling units run by milk cooperatives or its members.

COMMENCEMENT OF BUSINESS

An applicant may commence his food business and the concerned licensing Authority shall not deny the applicant to commence such business if, from the date of making the completed application, a license is not issued within 60 days or the applicant has not received any intimation

VALIDITY AND RENEWAL

- A Registration or license granted under these Regulations shall be valid and subsisting, unless otherwise specified, for a period of 1 to 5 years as chosen by the Food Business Operator, from the date of issue of registration or license subject to remittance of fee applicable for the period and compliance with all conditions of license.
- Any application for the renewal of a registration or license granted under these Regulations shall be made in Form A or B of Schedule 2 of FSS (Licensing and Registration of Food Business) Regulation, 2011, as the case may be, can be made as early as 180 days prior to the expiry date indicated in the license/registration.
- The Registration or License shall continue to be in force till such time that the orders are passed on the renewal application which in no case shall be beyond 30 days from the date of expiry of registration or license.
- Any renewal application filed beyond the period mentioned but before the expiry date, shall be accompanied by a late fee of Rs. 100 per day for each day of delay.
- Any Registration or license for which renewal has not been applied for within the period mentioned shall expire and the Food Business Operator shall stop all business activity at the premises. The Food Business Operator will have to apply for fresh Registration or license as provided in.

ROLE OF FOOD SAFETY OFFICER IN LICENSING AND REGISTRATION PROCESS

1. The FSO has the responsibility of **carrying out the inspection of the FBO's premises.** This inspection is of the sanitary & hygiene conditions of the premises along with conditions as specified in Annexure 3 of Schedule 2 of FSS (Licensing and

Registration of Food Business) Regulation, 2011. The FBO has to comply with these conditions before the DO grants a license to the FBO.

2. In FOSCOS, FSO has to first **acknowledge the application forwarded by DO** for inspection and then **announce date of inspection to FBO through online system.** The idea here is to ensure that the FBO is as prepared as possible for the inspection thus making the inspection more fruitful. Once at the premises, the FSO should **take detailed notes** and ensure that all sanitary & hygiene conditions of the premises along with conditions as specified in Annexure 3 of Schedule 2 of FSS (Licensing and Registration of Food Business) Regulation, 2011 to be complied with are followed to the maximum extent possible.

3. The FSO should do the inspection as per the checklist available in the online FOSCOS licensing / registration system. This will help ensure that the inspection is objective and systematic. The FSO should immediately record any additional observations made by him during the inspection. FSO can do inspection with manual checklist also and can take the FBO's signature on the checklist for inspection to ensure that the FBO is also aware of the FSO's inspection findings. Preparing these records in such a manner will help with future risk assessment and will also help the FSO provide correct and relevant guidance to each FBO during the licensing process.

4. Once the inspection is complete, the FSO must issue a notice to the FBO pointing out the lack of compliance with the sanitary & hygiene and other conditions, wherever such deficiencies exist either through online FOSCOS system or FSO may issue written notice. In fact, the checklist will help to identify the gaps in compliance, making it easier for the FSO to issue the notice to the FBO.

5. The FSO may also counsel the FBO with the kinds of measures to be undertaken to ensure general hygiene and safety and the expectation of the regulator in terms of on-going compliance. This will be invaluable advice to the FBO and can ensure the FBO's co-operation in the future.

6. The Food Business Operator shall ensure that all conditions of license as provided in Annexure 3 of Form B in Schedule 2 and safety, sanitary and hygienic requirements provided in the Schedule 4 contained under different parts depends on the nature of businesses are fulfilled before applying for a license.

CONDITIONS OF LICENSE – ANNEXURE-3

- Display true copy of License
- Give necessary access to Licensing Authorities to the premises
- Inform authorities about any change or modification of activities
- Employ at least one technical person
- Furnish periodic Annual/Half-yearly Return (Form D-1 / D-2)
- No product other than indicated in License is produced
- Maintain Factory's Sanitary and Hygienic standards. Also workers' hygiene and health check-up as prescribed in Schedule 4 to be done on regular intervals.
- Maintain daily records of production, raw materials utilizations and sales etc.
- Source and standard of raw material used is of optimum quality
- Testing of relevant chemical and/or microbiological contaminants of food products in accordance with these regulations
- Required temperature shall be maintained throughout the supply chain
- Manufacturer/Importer/Distributor shall buy or sell food products only from, or to Licensed/Registered Vendors and should maintain record thereof
- Hotels/Restaurant and other food stalls shall put up a notice board containing separate lists of articles which have been cooked in ghee, edible oil, Vanaspati & other fats for information to purchaser.
- Every manufacturer [including ghani operator] or wholesale dealer in butter, ghee, vanaspati, edible oils, Solvent extracted oil, de oiled meal, edible flour and any other fats shall maintain a register showing the quantity of manufactured, received or sold, nature of oil seed used and quantity of de-oiled meal and edible flour used etc. as applicable and the destination of each consignment of the substances sent out from his factory or place of business, and shall present such register for inspection whenever required to do so by the Licensing Authority.
- 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.

- No Food Business Operator shall sell or distribute or offer for sale or dispatch or deliver to any person for purpose of sale any edible oil which is not packed, marked and labelled in the manner specified in the regulations unless specifically exempted from this condition vide notification in the official Gazette issued in the public interest by Food Safety Commissioners in specific circumstances and for a specific period and for reasons to be recorded in writing.

SUSPENSION OR CANCELLATION OF LICENSE / REGISTRATION CERTIFICATE

Section 32 of the Food safety & Standards Act, 2006 and the Regulations 2.1.8 of Licensing & Registration of Food Businesses, 2011 details the reasons and process to be followed by the Licensing/Registering Authority in suspension or cancellation of a registration certificate.

- The Registering or Licensing Authority in accordance with the provisions of Section 32 of the Act may, after giving the concerned Food Business Operator a reasonable opportunity of being heard, suspend any registration or license in respect of all or any of the activities for which the registration/license has been granted under these Regulations after recording a brief statement of the reasons for such suspension, if there is reason to believe that the Food Business Operator has failed to comply with the conditions within the period mentioned in any Improvement Notice served under Section 32 of the Act. A copy of such statement shall be furnished to the concerned Food Business Operator whose Registration or license has been suspended.

- The registering or Licensing Authority, as the case may be, may direct an inspection of the Food Business Operator's premise(s) within a reasonable period which shall not be less than 14 days from the date of order of suspension.

- In the event that the Registering or Licensing Authority is of the opinion, on a review of the inspection report, that the Food Business Operator has still failed to rectify the defects or omissions or comply with the conditions of the improvement notice causing the suspension, such authority may cancel the license/registration of the Food Business Operator after giving him an opportunity to show cause as provided under Section 32 (3) of the Act.

- Not with standing anything contained in these Regulations, the Registering or Licensing Authority may suspend or cancel any registration or license forthwith in the interest of public health for reasons to be recorded in writing.

- A suspension or cancellation of registration or license under these Regulations shall not entitle the Food Business Operator for any compensation or refund of fee(s) paid in respect of the registration certificate or license or renewal thereof.
- After a period of 3 months from the date of cancellation under Regulation 2.1.8 (3) above the Food Business Operator may make fresh application for Registration or license to the concerned authority if all observations made in the improvement notice have been complied with.

MODIFICATIONS, EXPANSION OR CHANGES IN PREMISE(S) AFTER GRANT OF LICENSE OR REGISTRATION

1. Food Business Operators shall ensure that the Registering or Licensing Authority always has up-to-date information on their food business establishments and shall inform the relevant Authority of any modifications. Provided that any change that alters the information contained in the license certificate shall require an approval or endorsement in license prior to start of business with such changes.
2. The Food Business Operator in the online licensing system have to apply for modification by way of submitting relevant documents alongwith fee. The fee for modification of license is Rs. 1000/-.
3. The licensing Authority may approve and issue an amended license incorporating such changes in activities within 30 days from the date of receipt of such information.
4. While approving the afore mentioned changes the concerned registering or Licensing Authority shall take into account the feasibility of carrying on the business and the legal and other relevant aspects of the desired modifications or additions or changes in activities and, if required, may order an inspection of the premises before granting the approval.

TRANSFER OF REGISTRATION CERTIFICATE OR LICENSE IN CASE OF DEATH

- In the event of death of the holder of a Registration certificate or license, such certificate or license shall subsist for the benefit of the legal representative or any family member of the deceased or until the expiry of: —
    a. The period of 90 days from the date of death of the holder of a Registration certificate or License; or
    b. Such longer period as the Designated Officer may allow, for reasons to be recorded in writing.

- The legal representative or family member of the deceased holder of the registration certificate or license shall apply to the concerned Authority for transfer of such certificate or license in his favour.
- The registering or Licensing Authority, as the case may be, may, after making such enquiry as it may deem fit, either approve the transfer of the Registration certificate or license if satisfied that the applicant is the legal representative, or refuse the request. Provided that the registering or licensing authority shall not refuse the request without giving the applicant an opportunity of being heard and for reasons to be recorded in writing.
- Upon filing of application for transfer and pending the decision of the authority, the registration or license shall continue to be in force.

RETURN

- Every (manufacturer and importer who has been issued a license) shall on or before 31st May of each year, submit a return electronically or in physical form as may be prescribed by the concerned Food Safety Commissioner, in 'Form D-1' provided in Schedule 2 for food handle by him during the course of previous financial year.
- Licensee engaged in manufacturing of milk and/or milk products shall file half yearly returns for the periods 1st April to 30th September and 1st October to 31st March of every financial year in the form D-2, as provided in Schedule-2 of FSS (Licensing and Registration of Food Business) Regulation, 2011. Such returns will be filed within a month from the end of the period.

  Any delay in filing return beyond 31st May of each year shall attract a penalty of Rs 100 per day of delay. 2.1.14 Food Business Operator to be bound by directions or order.

APPEAL

A Food Business Operator aggrieved by an order of the Registering Authority or Licensing Authority can prefer an appeal to the concerned Designated Officer or the Food Safety Commissioner, as per provisions laid down under Section 31(8) and 32 (4) to 32(5) of the Act.

FOOD BUSINESS OPERATOR TO BE BOUND BY DIRECTIONS OR ORDER

- Every Food Business Operator to whom any direction or order is issued in pursuance

of any provisions of this regulation is bound to comply with such directions or regulations and any failure on the part of the Food Business Operator to comply with such direction or order shall be deemed to be contravention of the provisions of these Regulations and will attract legal action under the provisions of the Act.

- Every manufacturer, distributor or dealer selling an article of food to a vendor shall give guarantee either separately or in the bill, cash memo, or label a warranty in FormE.

FOOD SAFETY COMPLIANCE SYSTEM (FoSCoS)

FOOD BUSINESS OPERATORS UNDER PURVIEW OF CENTRAL LICENSING & STATE LICENSING

State Food Safety Officers on the directions of the Designated Officers carry out inspections of State or Central Licensed Food Business Operators in their area of jurisdiction. They also carry out enforcement activities in the area assigned to them, hence it is required that the Food Safety Officers should have information regarding the food licensing.

In the year 2020, FSSAI has launched Food Safety Compliance System (FoSCoS) replacing Food Licensing and Registration System (FLRS) in the phased manner.

FoSCoS is conceptualised to provide one point stop for all engagement of an FBO with the department for any regulatory compliance transaction. It is already integrated with :-

- Online module for submission of Annual Return
- Food Consumer Grievance Module 2.0
- FoSCoRIS 2.0
- Audit Management System
- Hygiene Rating System
- Online module for making request to concerned authorities for reactivation of rejected application.

FoSCoS has been launched with unified flow of applications across pan-India. Kind of Business wise mandatory list of documents, payment mechanism, pdf format of Licenses and Registration including digital Registration ID cards have been standardised through FoSCoS.

Further, FoSCoS has been developed with informative user interfaces such as 'Search Tools' provided on the homepage of FoSCoS for searching Standardised food products and eligibility criteria for food businesses. For manufacturers of standardised food products, listing of food products based approach has been incorporated to ease out the application process for license.

A comprehensive tool for authorities to search food businesses on various parameters has been developed within the FoSCoS. This tool is capable of providing reports to authorities to conduct day to day activities like enforcement, surveillance, organising camps related to particular food sector etc. and thus reducing their dependence on FSSAI Hq for the requirement of data.

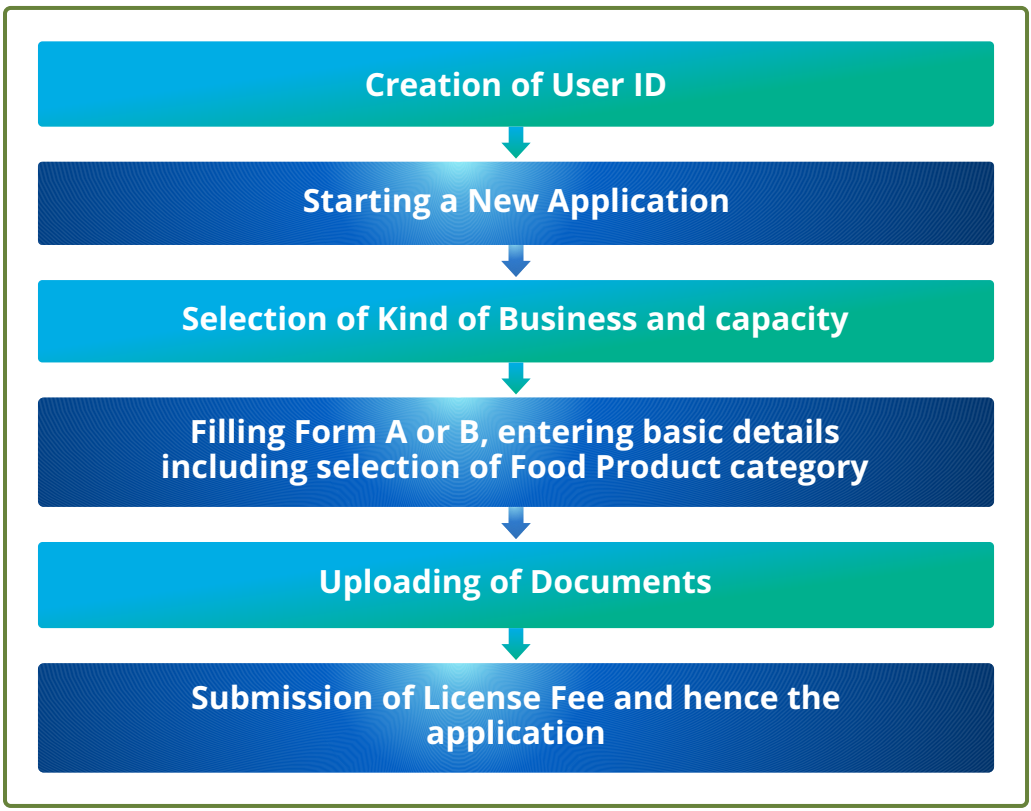
OTHER KEY FEATURES OF FoSCoS

- Informative Home page
- Resource material (Recorded Session of Webinar in English and Hindi, Video Tutorials, Guidance notes, User Manuals on key flows, Flyers, Presentation for Training purpose) is available on https://foscos.fssai.gov.in/user-manual
- Ease of flow (OTP based sign in) for petty/small FBOs to apply for registration certificate.
- Task specific dashboard for FBOs and Authorities.
- Creation of New Kind of Businesses for sensitive foods such as Nutraceuticals, Proprietary Foods and Substances added to food.
- List based approach for Standardised Food Products instead of earlier textbox based approach.
- Capturing of PAN, GST and CIN has been enabled.
- Capturing of Head Office license (if exist).
- Capturing of Food Safety Mitra code (if filing of application by FSM)
- Documentation based on Selected Kind of Businesses in the application.
- Only online payment modes for making License fee to ensure transparency in the process. Payments through Treasury Challan mode are still continue for registration applications in some States/UTs.
- Change of Jurisdiction of application, if required, can be done by Licensing/

Registration authorities.

- Ease of license application processing flow for authorities.
- License and Registration in PDF formats have been standardized across the country.
- Incorporation of Non-Form C annexure (consisting details of Person In-charge of Operations and declared Nominee in Form IX) in the copy of license.
- Incorporation of ID card in the copy of Registration Certificate.

MAJOR STEPS FOR FILING OF APPLICATION BY AN FBO



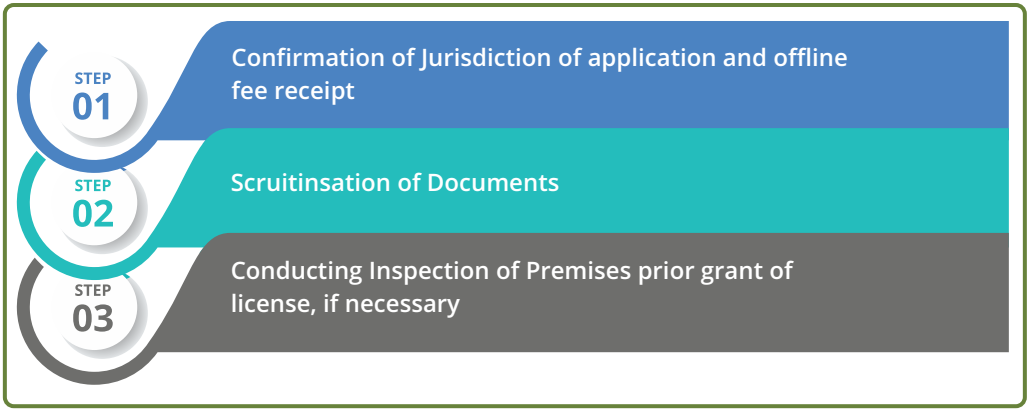
A 17-digit application reference number is generated for future references.

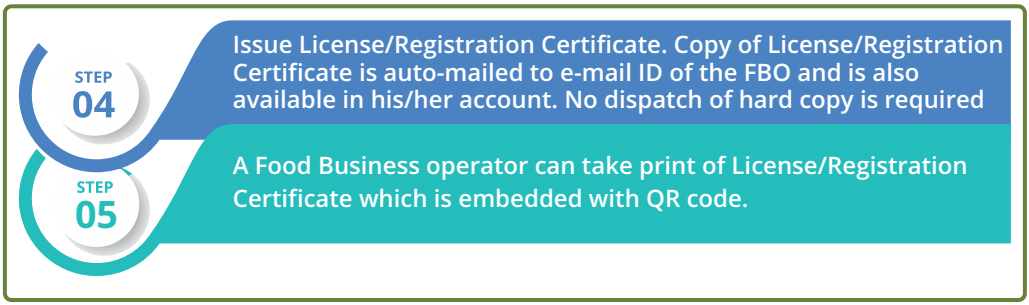
FOOD PRODUCT CATEGORY

01 - Dairy products and analogues, excluding products of food category 2.0
02 - Fats and oils, and fat emulsion

03 - Edible ices, including sherbet and sorbe
04 - Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
05 - Confectionery
06 - Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares of food category 7.0
07 - Bakery products
08 - Meat and meat products including poultry
09 - Fish and fish products, including molluscs, crustaceans, and echinoderms
10 - Eggs and egg products
11 - Sweeteners, including honey
12 - Salts, spices, soups, sauces, salads and protein products
13 - Foodstuffs intended for particular nutritional uses
14 - Beverages, excluding dairy products
15 - Ready-to-eat savouries
16 - Prepared Foods
99 - Substances added to food
100 - Products having specified standards but no additives allowed

PROCESSING OF APPLICATIONS?





Licensing or Registering Authority may raise query at any stage of scrutinization *of application, if he/she finds any anomaly in the application.*

User IDs and Passwords to Authorities are created by FSSAI HQ on the request received from nodal officer of concerned State enclosing the proof of posting / transfer of that officer.

RESPONSIBLE PERSONS AT FOOD UNITS

1. Authorised Signatory/Proprietor
2. Technical Person incharge of Operation having degree as prescribed in Condition of License. (FBOs can have trained Food Safety Supervisors)
3. Person responsible for Complying with Condition of License – Nomination to be filed in Form IX of FSS Rules, 2011. He is responsible for any type of communication with Licensing Authorities.

He is the nodal person for the FBO to handle Consumer Grievances, until or unless FBO designates any other person for this purpose.

Any change in the nominations shall be conveyed to Licensing Authority by way of Non-Form C modification of license.

FoSCoRIS (FOOD SAFETY COMPLIANCE THROUGH REGULAR INSPECTION AND SAMPLING)

Food Safety Compliance through Regular Inspection and Sampling (FoSCoRIS) is a digital tool for recording observations during inspections. FoSCoRIS 1.0 was launched in 2018 and primarily meant for Designated Officers (DO) and Food Safety Officers (FSO). FoSCoRIS 1.0 was a standalone (mobile App and web) system and was not integrated with Food Licensing and Registration System (FLRS) then due to technical limitations for upgrading the FLRS.

FoSCoRIS 2.0 is further enhanced and launched alongwith FoSCoS. FoSCoRIS 2.0 is

fully integrated with FoSCoS that means if a DO allocates an inspection on FoSCoS, it will be visible to the concerned FSO on the FoSCoRIS mobile app. If an FSO conducts inspection through FoSCoRIS mobile app, concerned DO can view it on FoSCoS. After the submission of inspection report, the same is also accessible to the concerned FBO. In case of area of low internet connectivity, FSO can record observations in FoSCoS within 48 hours of conducting inspection. Additional roles for officers specially designated for allocating and conducting inspections have been created in the system.

Further, in FoSCoRIS 2.0, there is also a provision for capturing sample details for samples that have been lifted during the inspection. Provision for conducting inspections on non-licensed/registered food units and capturing details of Samples (without inspection) and Generating Form VA alongwith authentication of FBO, FSO and witness to be provided in future developments of the FoSCoRIS app. An offline version of FoSCoRIS app is also being developed for areas of low internet connectivity.

It has been decided in the 29th meeting of Central Advisory Committee (CAC) held on 05th August 2020, that inspections shall be mandatorily conducted through FoSCoRIS. Mandatory Inspections through FoSCoRIS help in building National level database and to identify hotspots, trends and patterns in food safety to take corrective measures and policy interventions. This will help assess the performance of FSOs and help improve their efficiency.

CEO, FSSAI and Commissioner of Food Safety of States/UTs can access the inspection reports through their FoSCoS logins.

FOOD SAFETY MITRA

Food Safety Mitra is a individual professional certified by FSSAI and performs limited actions on behalf of/for FBOs with respect to the implementation of FSS Act, Rules & Regulation.

JOB ROLE DESCRIPTION

DIGITAL MITRA FOR LICENSING & REGISTRATION

- Filing of new application for License/Registration
- Further online correspondence regarding queries raised by Authorities
- Filing application for modification of License/Registration
- Filing of Annual Returns/Declarations
- Filing applications for approval of Product/ label/ Advertisement Claim
- Filing appeal for revocation of Suspended Licenses/Registration

TRAINER MITRA FOR FOOD SAFETY TRAINING

- Conducting training of food safety supervisors
- Conducting training at Eat Right Campuses
- Conducting training of food safety personnel in businesses on demand

HYGIENE MITRA FOR HYGIENE AUDITING

- To audit the hygiene of FBO outlets as per prescribed guidelines
- To help FBOs with implementation of hygiene guidelines

ELIGIBILITY

DIGITAL MITRA : Candidates between the age of 21 to 60 years, possessing bachelor's degree from a recognised university along with working knowledge of computers, internet etc.are eligible to apply.

TRAINER MITRA : Eligibility criteria for trainers as under FoSTaC scheme will be applicable.

Criteria	Basic Level	Advance Level	Special Courses
Educational Qualification	▸ Minimum graduate in science/food technology/ food science/chemistry/ biology/microbiology or other related subjects.	▸ Minimum graduate in science/food technology/ food science/chemistry/ biology/microbiology subjects.	▸ Minimum graduate in science/food technology/ food science/chemistry/ biology/microbiology subjects.

Criteria	Basic Level	Advance Level	Special Courses
Educational Qualification	▸ If graduate in other streams minimum 5 years experience in relevant food industry (catering, manufacturing, retail, etc.)	▸ If graduate in other streams minimum 7 years work & implementation experience in relevant food industry (catering, manufacturing, retail, etc.)	▸ If graduate in other streams minimum 7 years work & implementation experience in the particular sector of the industry (meat, fish, milk, etc.)
Training Experience as Trainer & Implementation Experience	▸ Minimum 3 years training experience on food safety & hygiene including FSMS, HACCP and other similar food safety systems in the relevant Food Industry.	▸ Minimum 5 years training experience on food safety & hygiene including FSMS, HACCP and other similar food safety systems in the relevant Food Industry.	▸ Minimum 5 years training & implementation experience on food safety & systems regulations in the particular sector of the Industry.
General Training Received	▸ Knowledge of FSS Rules & Regulations	▸ Knowledge of FSS Rules & Regulations	▸ Knowledge of FSS Rules & Regulations
Skills	▸ Should have good communication and motivational skill. ▸ Shall be available for training at Least 20 days in a year.	▸ Should have good communication and motivational skill. ▸ Shall be available for training at Least 20 days in a year.	▸ Should have good communication and motivational skill. ▸ Shall be available for training at Least 20 days in a year.

HYGIENE MITRA* : Candidates between the age of 21 to 60 years, possessing bachelor's degree in Catering Technology/Hotel Management/Food/Dairy/Fisheries/Oil Technology/ Bio Technology/Agricultural Sciences/Veterinary Sciences/Biochemistry/Microbiology from a recognised university are eligible to apply.

Additionally, such candidates must possess the knowledge of the FSSAI Act and the Rules and Regulations there under. Sector specific knowledge of hygienic and sanitary practices, processing techniques, hazards identification, knowledge/analysis/control of contaminants & allergens is a plus.

**Tentative*

CODE OF CONDUCT OF FSM

INTEGRITY

As individuals responsible for helping FBOs with compliance, the first norm for a FSM is integrity at all times. This may include:-

- Due diligence at all times - filing applications, conducting hygiene audit
- Advising FBOs correctly about processes, regulatory requirements & liabilities
- Advising FBOs to correct mis-declarations and non-compliance
- Charging only prescribed fees from clients, against receipt.

TRANSPARENCY

As they are the human face of FSS Act for FBOs, it is essential that FSMs maintain transparency about their services.

- Applications filed by them on behalf of FBOs - they must quote their unique identification number whenever a service is offered by them to the FBOs
- Service charges should be transparently communicated to FBOs. All receipts & acknowledgements must be shared with FBOs
- FSM will not represent themselves as officers of FSSAI or use its name or logo without authorisation.

QUALITY

- Whether it is training, audit or filing of applications, FSMs will maintain a highest quality standard
- Apart from the work itself, FSMs will ensure quality service level by being knowledgeable, friendly and available to their client FBOs.

NOTES

NOTES

CHAPTER-5

AUDIT & INSPECTION OF FBO

5 AUDIT & INSPECTION OF FBO

CONCEPTS AND APPROACH TO INSPECTIONS AND AUDITS UNDER FSS ACT 2006

The inspection and audits are the main activities for enforcing the Food Safety Act Rules and regulations, to ensure the food safety compliance. In the times of PFA Act 1954, the inspection activities were focused on sampling and testing of end products to determine their compliance with standards and regulations. Under the FSS ACT 2006, it is considered more efficient to focus inspection activities on ensuring compliance of systems for food safety management (FSMS) that can minimise the occurrence of food safety problems. **This shift from a "reactive" towards a "preventive" approach to food safety risks is subject to a general international consensus.**

GENERAL INSPECTION AND AUDIT PROCEDURES

The Food Safety Officers are empowered by law and regulation to conduct inspections, so it is necessary for the Food Safety Officers to have a thorough knowledge about these laws and regulations and about the scope of the authority vested on him/her. They should have copies of all the pertinent law(s) and regulations for consultation in case of any disagreement. In absence of laws and regulations to allow an FSO to implement a risk based approach to food inspection, areas for improvement identified during the inspection can be raised as recommendation instead of noncompliance while legislation is reviewed.

- *Thorough knowledge of food law(s) and pertinent regulations.*
- *Background information on the field of safety and quality.*
- *Prerequisite sanitation, hygiene and pest control practices.*
- *HACCP principles.*
- *Inspection techniques.*
- *Sampling techniques for product testing*
- *Compliance verification skills.*
- *Skill of creating awareness about food safety and quality among food producers and processors for compliance verification.*
- *Dissemination of concept of continuous improvement of the quality and safety management system.*
- *Recognition of organization or agency for food safety audit (Section 44).*

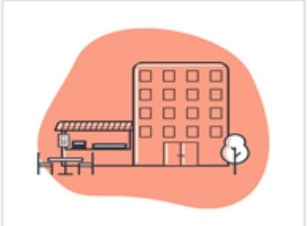
PRINCIPLES FOR INSPECTION

- During the inspection, inspecting officer should behave professionally and demonstrate proper sanitary practices.
- The output of inspection should be based on evidences and inspector should not be prejudiced.

- The inspecting officer should inform the Designated Officer, if they perceive any impartiality with the establishment to be inspected
- Inspection should be conducted in a planned manner and as per schedule only after approval by the Designated Officer.
- Improvement notices as per provisions of the act should be issued in place of penal measures wherever possible.
- Electronic reporting of findings of inspection should be submitted by the Food Safety Officer within 24 hours to the supervisory officer and Food Safety Commissioner.
- Confidentiality of outcome of inspection should be maintained by the officer unless required in public interest.
- Food safety officers are prohibited from demanding/receiving any compensation directly or indirectly from food business operator or any other part. Avoid gifts and lunches outside the premises.
- **Final decision and action** shall be decided by supervisory officers within stipulated time.
- Monitoring of inspection findings should be done in the steering committee meetings at the state level.

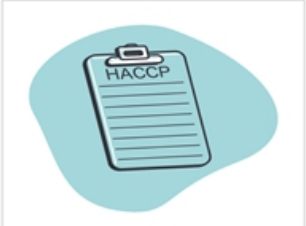
Hygienic food handling

The preparation and cooking of food and how it is subsequently reheated and cooled. Storage of food is also considered in this part of the inspection.



Physical condition of the premises & facilities

Whether it has an appropriate layout, adequate lighting, a high standard of cleanliness, suitable ventilation & pest control.

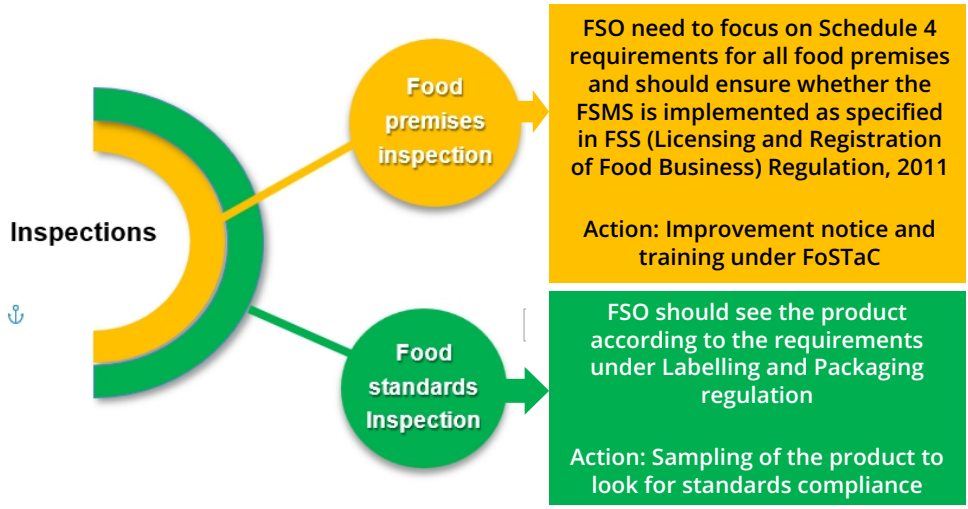


Food safety management

Evidence that the business is taking suitable precautions to keep food safe. This can include HACCP systems, staff training records and logs of relevant checks.

PLANNING OF INSPECTION

Food Safety Officer should have a planned inspections or interventions for all food premises and there can be two important concepts for planned inspections as depicted in the flow diagram below:



FOOD PREMISES INSPECTION

Food premises inspections are routinely carried out and is an integral part of inspections and evaluation of food premises. The focus of the inspection should be on the Schedule 4 requirements as specified in FSS (Licensing and Registration of Food Business) Regulation, 2011 and at the end of the inspection, a copy of the inspection report (in the form of a checklist) should be provided to the scoring as developed to evaluate the food premises. The FSO recommend to the Designated Officer to issue an improvement notice and which can include recommendations for training of the food handlers under FoSTaC if required.

TYPES OF FOOD PREMISES INSPECTIONS

Either for License/Registration, for information basis, on complaint basis, for routine basis- Risk based inspection and Inspection Plan

License/ Registration	Information Basis	Complaint Basis	Routine Basis- Risk Based Inspection	Inspection Plan

Examination of food, food preparation, serving area, personnel, equipments, vessels, premises to assure wholesome and clean products, free from unsafe microbes or chemical, physical contamination, natural or added deleterious substances and decomposition during raw materials and ingredient receiving, cleaning, production, processing, packaging & delivery with an objective of providing safe, right and wholesome food to all consumers.

CODE OF ETHICS OF FSO

- All Inspections shall be done in a planned manner and the inspection shall be approved by the designated officer
- Improvement notices shall be issued in place of penal measures wherever possible.
- Electronic reporting of findings shall be submitted by FSO within 24 hours of inspection to the designated officer and food safety commissioner.
- Confidentiality of inspection shall be maintained by the officer unless required in public interest.
- FSOs are prohibited from demanding/receiving any compensation directly or indirectly from any FBO.
- Final decision on actions/outcome shall be decided by the superior officer within the stipulated time frame.
- Monitoring of inspection findings must be done in the steering committee meetings at the state level.

Grievance redressal mechanism should be available at the offices of the designated officers and the food safety commissioner's level.

PRE-REGISTRATION INSPECTION

Informed inspection of the petty food business operator premises as a part of issue of registration–When a petty Food Business Operator submits the application for registration, then an inspection may be ordered within 7 days. If the safety, hygiene and sanitary conditions are satisfactory as contained in Part II of Schedule IV of FSS (Licensing and Registration of Food Business) Regulation, 2011, then the registration is granted. If any deviations are there, it is informed to FBO for rectification and upon completion of deviations satisfactorily, the registration certificate is issued. This inspection is a pre-informed one.

PRE-LICENSE INSPECTION

Informed inspection of the food business operator premises as a part of issuance of license–Based on the license application, the designated officer in the specified area may order an inspection of the premises to FSO. If the conditions are satisfactory based on the provisions of the FSSAI Regulations in the premise, at the time of inspection, then the license is granted. If any deviations are there, then FSO shall report to designated officer. The deviations will be reported to FBO with a time frame and upon satisfactory completion license is issued.

This inspection is a pre-informed one.

➢ ROUTINE INSPECTION

The food safety inspections of the registered food safety establishments at least once in a year by the registering authority/designated officer-The licensed FBOs shall be inspected at least once in a year by FSOs. The FBO's food safety, hygiene and sanitary conditions have to be satisfactory as contained in Part II of Schedule IV of FSS (Licensing and Registration of Food Business) Regulation, 2011 under different parts, depending on the nature of business all times. To achieve this licensing authority/designated officer shall ensure periodical food safety audit and inspection of the licensed establishments through the food safety officers. The food safety officer will inspect the food establishments as frequently noted by the food safety officer. If the food safety officer satisfies the implementation them he/she will submit the report to the designated officer.

If he/she finds that the food establishment is laid down and is working as per the provisions of the act & various regulations as under, will submit a report to the designated officer. If the food safety officer observes that the food establishment is not laid down or functioning as per the provisions of the act and regulations made under, he/she recommends the designated officer to issue an improvement notice to the food business operator to comply with the conditions of the license within the prescribed limit.

This inspection is routine inspection where a food safety officer has to check whether the unit is following all the provisions of the law in the perfect way.

➢ FOLLOW UP INSPECTION

The food safety officer undertakes follow up inspection of the premise of a petty food business operator to ensure and satisfy himself/herself that the food business operator has fulfilled all the improvement suggestions provided by the Food Safety Officer either during pre-registration inspection or routine inspection.

The food safety officer on the direction of the designated officer undertakes follow up inspection of the food establishment of an FBO to ensure that the food business operator has complied with all the suggestions mentioned in the improvement notice issued by the designated officer at the time of pre-license Inspection or routine Inspection. This inspection is done as a follow up inspection to see whether the FBO has complied with the suggestion mentioned in the Improvement Notice.

➢ INSPECTION BEFORE RENEWAL OF LICENSE

The Food Safety Officer may inspect a food establishment of a petty food business

operator before renewal of a registration certificate, if considered necessary for reasons to be recorded in writing. A designated officer may order an inspection before renewal of a license if considered for reasons to be recorded in writing. This is normally done in the case where the Designated Officer feels that there is a necessary of doing it in the interest of public health at large.

➢ INSPECTION FOR INVESTIGATION OF COMPLAINT

The Food Safety Officer should investigate any complaint which is made to him in writing in respect of any contravention of the provisions of the Act or Rules & Regulations made there under.

➢ INSPECTION FOR FOOD SAFETY AUDITS (THIRD PARTY AUDIT)

In order to cultivate and foster the growth of compliance culture, FSSAI is enabling compliance through private recognized audit agencies. Food Safety Audits will reduce the burden of regulatory inspections done by Central or State Licensing Authorities. Satisfactory audits will lead to less frequent regulatory inspections by Central or State Licensing Authority except the regulatory sampling. This will strengthen food safety surveillance system and encourage self-compliance while at the same time assuring safe food to the consumers.

➢ INSPECTION FOR HYGIENE RATING SCORE SCHEME

To promote a culture of self-compliance amongst food businesses by encouraging them to understand the gaps and further improve their hygiene standards and thus reduce the incidence of food borne illness FSSAI has introduced Hygiene Rating Scheme. The display of score certificates will also help consumers in making informed choices. Higher hygiene rating audits may be linked with risk based inspection system to finalize the frequency of audits of those FBOs awarded 4/5 hygiene rating.

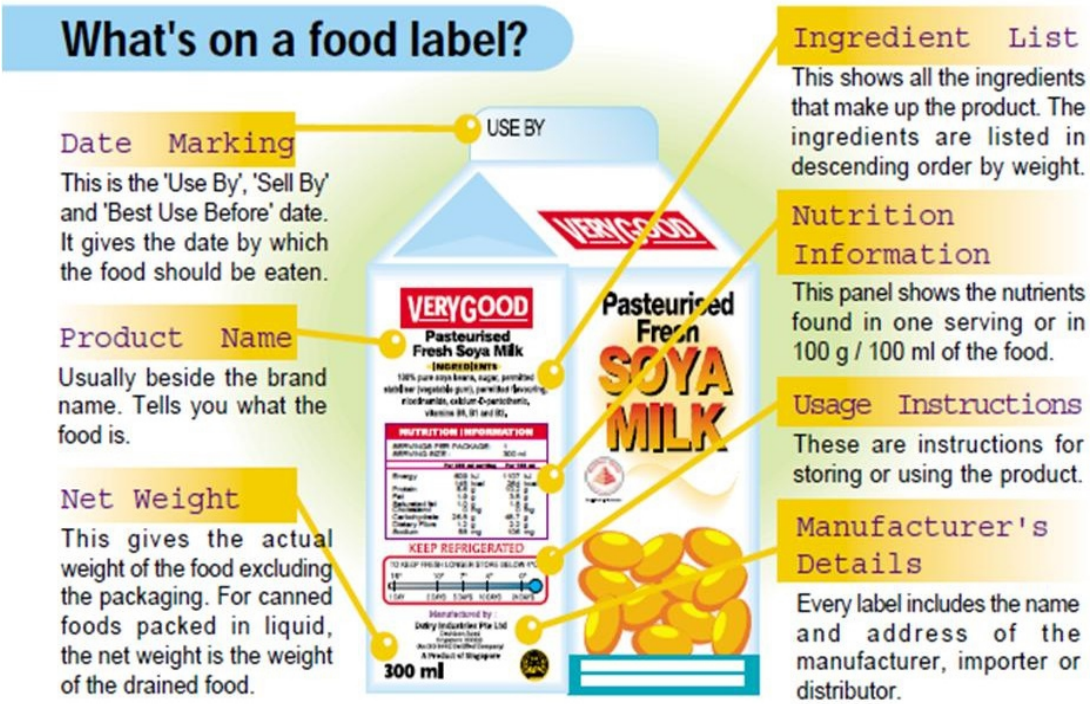
➢ FOOD STANDARDS INSPECTIONS

The FSO will check the product by visual inspection before going for sampling. The FSO can very easily notice the defect in labelling through visual inspection provided he/she has through knowledge about the Act and relevant regulations. There may be no need for sending a sample for analysis to identify the labeling defects. If the food product is not labeled in accordance to the regulations or it does not provide the required complete information or the food product is promoted for sale with false, misleading or deceptive claims then it is considered as misbranded food and attracts the penalties as per Law. If during inspection the FSO notices any labelling defect that creates doubt in the mind of the FSO about the quality of

the food product also, then invariably the sample of such food product is taken and sent for analysis check its quality. On analysis if the sample is found non-complying to the standards then the food product is declared as substandard besides misbranding and adjudication is launched for substandard and also for misbranding i.e. labelling defect. And if the sample is found confirming to standards on analysis but shows the label contravention only then the adjudication is launched for misbranding only.

WHAT ALL THE FSO HAS TO CHECK ON VISUAL INSPECTION OF THE PRODUCT

FSSAI is working to transform the food ecosystem from Inspection Raj to Self-Compliance, so the focus needs to be changed from product testing to compliance. However, to verify the regulatory compliance for labelling and packaging the product is checked by visual inspection by the Food Safety Officer and other inspecting officers. The FSO can very easily notice the defect in labelling through visual inspection provided he/she has through knowledge about the Act and relevant regulations. There may be no need for sending a sample for analysis to identify the labelling defects. If the food product is not labelled in accordance to the regulations or it does not provide the required complete information or the food product is promoted for sale with false, misleading or deceptive claims then it is considered as misbranded food and attracts the penalties as per Law.



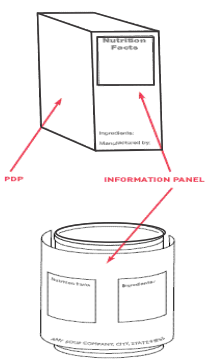
- ✓ *The name of Food*
- ✓ *List of Ingredients,*
- ✓ *Nutritional Information,*
- ✓ *Declaration regarding Veg or Non-Veg,*
- ✓ *Declaration regarding Food Additives,*
- ✓ *Name and complete address of the manufacturer or packer*
- ✓ *FSSAI License Number on principal display panel*
- ✓ *Net Quantity,*
- ✓ *Code No. /Lot No./Batch No.,*
- ✓ *Date marking (Date of manufacture or packing/Best Before and Use by Date)*
- ✓ *Labelling of imported food*
- ✓ *Country of Origin for imported food and*
- ✓ *Instructions for use*
- ✓ *Declaration regarding Food Allergen*

PRINCIPAL DISPLAY PANEL OF THE FOOD PRODUCT

Principal Display Panel (PDP) means that part of the container or package that the customers will first read if it is on display in a shop or which they will pick up to read and examine if they want to purchase that commodity. The principal display is what the salesperson will show to the customer if the customer has asked to buy that particular packaged product.

According to regulations the Principal Display Panel normally gives the identity of the food like, Jam, Pickle in a specific way, where the letters have to be of specific height. It also mentions the net quantity or amount of the product in the specific container of package, the numerals for which have to be of specific height as mentioned in regulations. The information on the Principal Display Panel has to be clear, easily readable and cannot be obscured by design, vignettes or crowding. For the packages of the same size the quantity of the contents need to be in uniform size as directed by regulations.

In case the container is rectangular then the space occupied by the Principal Display Panel must be in 40% of the available space when height is multiplied by width of the package in the area where the package is the broadest.



In case the container is cylindrical or nearly cylindrical, round or nearly round, oval or nearly oval container then the Principal Display Panel must be on 20% of the available space when the height of the container is multiplied by the average circumference.

In case the container/package is of any other shape then 20% of the total surface area will contain the Principal Display Panel but only if there is no label affixed securely to the container. If a label has been affixed, then the surface area of the label that works as the PDP must not be less than 10% of the total surface area of the container. Principal Display Panel can be must be tape or card affixed to the package or container if it has the capacity of only 5 cubic centimeters and must bear all the required information according to regulations.

SPECIFIC LABELLING REQUIREMENTS FOR FOOD CATEGORIES

Food category	Labelling requirement
Infant milk substitutes and infant foods	Prior approval of the food and the label form the Authority, label shall contain "**IMPORTANT NOTICE**" for statements namely: **MOTHERS MILK IS BEST FOR YOUR BABY**" • Infant food only used on the advice of a health worker. • Infant food or infant substitute is not the sole source of nourishment of an infant. • Warnings and captions about the use and storage of these foods. • Label on infant milk substitutes or infant food shall have **NO** picture of infant or women or both. • The label shall indicate the additional information if recommended as **PREMATURE BABY, LOW BIRTH WEIGHT and TO BE TAKEN UNDER MEDICAL ADVICE** in capital letters. • Infant milk substitutes or infant food for lactose intolerant infant the label shall indicate "**LACTOSE FREE or SUCROSE FREE** statements. • Infant milk substitutes or infant food for infants allergic to cows/ buffalo milk or soy protein shall have label with statement" **HYPOALLERGENIC FORMULA, composition of Nutrients /100gms as well as ISI mark.**
Edible Oils and Fat	• Label shall not use the expressions which are an exaggeration of the quality of the product (Extra refined, Ultra refined , Anti-Cholesterol etc.)
Permitted food colours	• Label shall state the word **" Food Colours**" with complete chemical and the common name and colour index of the dye stuff.
Irradiated foods	• The label shall have bear the declaration "PROCESSED BY IRRADIATION METHODE , DATE OF IRRADIATION and the Logo License Number of Irradiation Unit and purpose of Irradiation.

Exemptions from Labelling Requirements (Sub-Section 2.6.1) of Packaging and Labelling Regulation 2011

Under Sub-Section 2.6.1 of FSS (Packaging and Labelling) Regulations, certain cases where one or more of the mandatory information required to be given on the labels such as list of ingredients, Lot Number or Batch Number or Code Number, nutritional information, the 'date of manufacture' or 'best before date' or 'expiry date' and instructions for use, need not be given on the labels. Such cases are as given below :

Label declaration exemptions

Food category	Label declaration exemptions
If the surface area of the package is not more than 100 square centimeters.	List of ingredients, Lot Number or Batch Number or Code Number, Nutritional information and Instructions for use, need not be given on the labels, but this information shall be given on the wholesale packages or multi piece packages, as the case may be.
If the surface area of the package is less than 30 square centimeters.	List of ingredients, Lot Number or Batch Number or Code Number, Nutritional information the 'date of manufacture' or 'best before date' or 'expiry date' and Instructions for use, need not be given on the labels, but these information shall be given on the wholesale packages or multi-piece packages, as the case may be.
In case of liquid products marketed in bottles and the bottle is intended to be reused for refilling.	List of ingredients need not be given on the label. If the glass bottles have been manufactured after March 19, 2009,then the list of ingredients and nutritional information are required to be given on the bottle.
In case of food with shelf-life of not more than seven days.	The 'date of manufacture'; need not to be mentioned on the label of packaged food articles, but the 'use by date' is required to be mentioned on the label by the manufacturer or packer.
On the wholesale packages (Multi piece Packages)	List of ingredients. Date of manufacture/ packing, Best before or expiry date Labelling of irradiated food and, Vegetarian logo/non-vegetarian logo, need not to be specified.

PRODUCT RECALL INSPECTION

The Food Safety Officer should investigate the product recall incident. This shall be based on the information received from the Designated Officer on product recall. If any product recall is there, the procedure of product recall handling shall be followed by the FSO. The Food Authority's main role in a recall is to monitor the progress of the recall and assess the adequacy of the action taken by the FBO in this regard. After a recall is completed, the Food Authority will make sure that the product is destroyed or suitably improved. Where the recall is related to serious defects in the manufacturing process, the concerned authority may review the license of the FBO concerned. The Food Authority will publicize the recall when it is of the opinion that the public need to be alerted about a health hazard or that clarification of the situation needs to be made to allay public worries.

The recall will be terminated when FSO/Designated Officer determines that all reasonable efforts have been made in accordance with the recall strategy and it is reasonable to assume that the food product subject to the recall has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled food product. Written notification that a recall is terminated will be issued by the Food Authority to the company. In case of unsatisfactory reports, the concerned Food Safety Officer may consider further action like stepped-up inspection, seizure or any other legal action.

Action to be taken by an FSO following an Inspection :

Inspections	Action to be taken by FSO	Remark
Pre license/ Registration – New premises, and type of food establishments	➢ Report for issuing License by Designated Officer ➢ Issue Registration Certificate	Depending on the kind of business the inspection is required for issuance of license / registration and the focus of inspection should be on the structural requirements and documentations of the food premises as per Schedule 4 of the Regulations.
Routine Unannounced as a part of planned inspection programme	If required issue hygiene Improvement notice and revisit to ensure the compliance Seizure and Sampling	Recommendation for improvement and training of food handlers under FoSTaC. Seizure and sampling will depend on the condition of the premises at the time of inspection.

Hygiene Rating Score inspection Requested by the FBO	Audits and Hygiene Rating	Audits can be requested by FBOs through a third party agencies notified by FSSAI. FBOs after self-assessment can request for Hygiene Rating Score. Request for rescores in case of lower scores in HRS.
Following a complaint	▸ Improvement Notice can be issued if required and revisit to ensure the compliance ▸ Sampling of the food product ▸ Food Recall procedure	After verifying the complaint, the FSO can initiate the action. If FBO has been careless in that case the action as per the law can be initiated.
Following a confirmed food poisoning report from the local health agency	▸ Inspections of premises along with sampling of the suspected food product if available. ▸ If not, sampling of ingredients used in the preparation of the suspected foods. ▸ Emergency prohibition order for the production and closure of premises. ▸ Coordination with environmental health.	Depending on the circumstances the actions could vary. The FSO can sample the food products / ingredients and request the DO / CFS for issuing an emergency prohibition order in case it is evident that the food poisoning is as a result of food being served in the particular food premises.
Food Standards inspection	▸ Inspection of the food ingredient / product in compliance with the labelling and packaging regulation. ▸ Sampling of the product to endure compliance to standards (Vertical & Horizontal standards).	FSO will do a visual inspection of the label and packaging of the product Sampling and analysing to see if the product complied with the standards laid down for the products under FSSR, 2016.

RISK BASED INSPECTION SYSTEM (RBIS)

Section 31(1) of FSS Act, 2006 provides that no person shall commence or carry on any Food Business except under a License. With limited number of officials, it is practically impossible for FSOs to inspect all food businesses. So far, inspections for Enforcement and Surveillance are undertaken as per the plans developed by each State / UTs as per their respective perceptions of risk. A comprehensive Risk Based Inspection System (RBIS) is required to increase transparency and ensure that scarce Government resources are focused on products and businesses with greater risk to human health. RBIS seek to target Food Business Operators (FBOs) as per the risk matrices therefore optimizing inspection tools and output.

OBJECTIVES

- Prevent release of un-safe food in the domestic market, in order to protect consumers in India.
- To draw a food inspection system from a product-based process to a risk-based process that can be used by food inspectors in their inspection across the food sector, regardless of the specific product(s) handled or manufactured by the inspected establishment.
- Linking "Risk Grade" with Licensing & Registration System.

The risk-based inspection system has two main components:

- Scheduling regular inspections based on a risk classification (using a risk grade) of food establishments (*implemented at FSSAI and State FDA levels*),
- Conducting inspections following a risk-based process control approach and using appropriate inspection grids (*implemented by officers at local level*).

Rules for inspection scheduling in the risk-based inspection system

- Defining grading rules for risk classification of FBOs

  "N" = risk grade = an "Inspection Priority Score", calculated by considering selected risk factors to classify food businesses into risk categories.
- Linking « risk grade N » with the existing computerized licensing & registration system
- Defining Rules to determinate risk categories and inspection frequencies
  - "N" = risk grade.
  - N = Ri x Pri x V x M

- Risk factors to calculate N:
  - Ri = Theoretical risk by type of Establishment
  - Pri=Product Risk Rank
  - V = Production Volume
  - M = Compliance Profile = Score of last Inspection Report
- Risk grade N defines risk categories:
  - Number of risk categories: 3 or 4
  - Low inspection priority to top priority
  - Adaptation of inspection frequency
- Risk grade N = Ri x Prix V x M
- Factor Ri= 'Theoricalrisk' of establishment, depending on:
  - Kind of food facility, and
  - Food type handled or processed in the facility.

In Indian FLRS, classification by "kind of businesses", depending on food type (e.g. meat, milk) and type of activity (slaughter, processing, catering, retail, storage...).

- Two Ri categories are suggested:
  - Ri = 1 : all estab. Handling only food of plant origin / retail
  - Ri = 4 : estab. Processing food of animal origin : milk and dairy products and meat/fish/poultry/eggs + central catering services.

THE PRODUCT RISK RANKING FOR EACH FOOD CATEGORY : PRODUCT RISK RANKING

Product	Flag	Category	Risk Rank
01 - Dairy products and analogues, excluding products of food category 2.0	Y	High	0.75
02 - Fats and oils, and fat emulsion	Y	Low	0.1
03 - Edible ices, including sherbet and sorbe	Y	Low	0.1
04 - Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	Y	Low	0.1

Product	Flag	Category	Risk Rank
05 – Confectionery	Y	Low	0.1
06 - Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares of food category 7.0	Y	Low	0.1
07 - Bakery products	Y	Low	0.1
08 - Meat and meat products including poultry	Y	High	0.75
09 - Fish and fish products, including molluscs, crustaceans, and echinoderms	Y	High	0.75
10 - Eggs and egg products	Y	High	0.75
11 - Sweeteners, including honey	Y	Medium	0.25
12 - Salts, spices, soups, sauces, salads and protein products	Y	Medium	0.25
13 - Foodstuffs intended for particular nutritional uses	Y	Medium	0.25
14 - Beverages, excluding dairy products	Y	Medium	0.25
15 - Ready-to-eat savouries	Y	High	0.75
16 - Prepared Foods	Y	High	0.75
99 - Substances added to food	Y	Low	0.1

PROCEDURES TO BE FOLLOWED FOR AN INSPECTION

Some general guiding principles to follow during inspections are also set out below:

- Announce the approximate time for inspection unless inspection is to check for a specific violation.
- Prepare for inspection in terms of preparing all required documents, identity of FSO, copies of past inspection records if relevant etc. and review all relevant documentation related to the FBO
- During inspection explain the applicable regulations, the FBO's rights during and after the inspection and the purpose of the inspection.
- Inform the FBO that the result of the inspection will remain confidential.
- Request and encourage co-operation from the FBO and its management.

- Review the facility's quality, critical control points and safety management system with a focus on the risk factors and provisions made in the safety management system for these risk factors.
- Verify that these provisions are adequate and appropriate.
- Other factors to check storage / transportation of finished products, packaging and labelling, verifying processing control measures, verifying that critical limits are observed, facility assessment, equipment assessment, employee / staff health, hygiene and training provisions, facilities for employees, raw material and additives reception / storage, general facility sanitation and pest control, surrounding environment assessment.
- At the time of closing of inspection, advice FBO on appropriate measures and caution and counsel FBO if FSO has found any non-compliance, potential non-compliance or any objectionable or questionable practices.

The FSO and FBO must communicate freely and the FSO must provide guidance to the FBO to ensure compliance rather than use the threat of penalty. The FSO should discuss his observations and findings with the FBO and they should agree on the time line for corrective action.

- The FSO must provide a signed copy of the inspection report to the DO and keep a copy for his own records. The FSO has to give a copy of the inspection report to the FBO.

LOGISTIC PREPARATION

Forms and checklists* Inspection Checklists to be referred and carried in the software as per the nature of FBO ***Sample Checklist is attached as Annexure to this Mannual.***	☞ General Manufacturing ☞ Milk Processing ☞ Meat Processing ☞ Slaughter Houses ☞ Catering ☞ Retail ☞ Transport ☞ Storage & Warehouse ☞ Water based beverages ☞ Alcoholic beverages ☞ Vegetable oils and fats ☞ Bakery products

List of documents related to FBO to be verified	1. Medical Fitness Certificate 2. Form E-Form of Guarantee 3. Foreign matter source control record 4. Incoming material evaluation record 5. Personnel hygiene checklist 6. Vehicle inspection 7. Operation log sheet 8. Employee muster 9. NC product control 10. Product evaluation record 11. Product traceability 12. Product recall 13. Calibration 14. Equipment maintenance records 15. Complaint monitoring record
Sampling kit for sampling the food product / ingredient. A sampling kit based on the nature of sample and the purpose of sampling. Below enlisted are the basic requirements that are to be fulfilled	1. White coats 2. White hats 3. Chill packs 4. Lockable or secure freezer (-18 0C) 5. Insulated boxes 6. Adequate supply of hard frozen ice blocks 7. Food grade sampling bags 8. Sample Labels 9. Seals 10. Hair nets 11. Disposable paper towels 12. Measuring jug(s) 13. Funnel(s) 14. Scissors 15. Knives 16. Spoons 17. Can Opener 18. Sample containers (various sizes) 19. Glass bottles 20. Thermometer (Calibrated) 21. Disinfectant wipes 22. Sterile sample jars (various sizes) 23. Sterile knives and spoons as necessary 24. Swabbing equipment

Sampling kit for sampling the food product / ingredient. A sampling kit based on the nature of sample and the purpose of sampling. Below enlisted are the basic requirements that are to be fulfilled	☞ Water sampling bottles ☞ Latex gloves ☞ Isopropanol (70%)

REQUIREMENTS FOR INSPECTION OF ALL FOOD BUSINESSES

The food establishment wherein the food is being handled, processed, manufactured, packed, stored and distributed by the food business operator and the personnel handling them should conform to the sanitary and hygienic requirement, food safety measures and other standards as specified in the regulations and it should also be deemed to be the responsibility of the food business operator to ensure adherence to necessary requirements. In addition to the requirements specified in regulations, the FBO shall identify steps in the activities of food businesses, which are critical to ensuring food safety.

GENERAL FOOD SAFETY SYSTEM REQUIREMENTS

Pre Requisite Programmes (PRPs) are *code of good practices* that comprises the fundamental principles, procedures and means needed for safe food production. PRPs are defined as basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption.

Good Agricultural Practices (GAP) and Good Hygienic Practices (GHP) are these essential preconditions and are together called pre requisite program(PRPs) in Food Safety System.

PRE REQUISITE PROGRAMME (PRPS)

Schedule 4 requirements of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011

- Location and surrounding
- Layout and design of food establishment
- Equipment

- Facilities
  - Water supply (potable / non-potable water)
  - Drainage and waste disposal
  - Personal hygiene
  - Air quality and ventilation
  - Lighting
- Food operations and Controls
  - Procurement of raw materials
  - Storage of raw materials and final products
  - Food processing / preparation, packaging and distribution / services
  - Time and temperature controls
  - Food packaging
  - Food distribution/ services
- Management and supervision
- Food testing facilities
- Audits, documentations and records
- Sanitation and maintenance of establishment
  - Cleaning and maintenance
  - Pest control system
- Health and Personal Hygiene
- Product information and consumer awareness

GOOD MANUFACTURING PRACTICES (GMP) AND HACCP

In any food operation, food safety management is achieved through the application of HACCP. Prior to implementation of HACCP, food processors must operate in accordance with Good Hygiene Practices (GHP) and Good Manufacturing Practices (GMP). HACCP principles are not mandatory under the present regulation, but are strongly recommended and should be incorporated in the Food Safety Plan developed by the Food Safety Officer. The prerequisites are important as they can often be used to reduce or eliminate a food safety

hazard.

Good Manufacturing Practices (GMP) is a process of food control wherby the requirements for mainataing the quality and safety of products are written down in a GMP mannual which becomes a key reference for the operation of a food manufacturing buisness. HACCP may form part of GMP requirements but, where HACCP focuses on product and their manufacturing processes, GMP takes a wider perspective and covers all aspects of the buisness which may impinge on food quality and safety.

KEY ASPECTS OF GMP

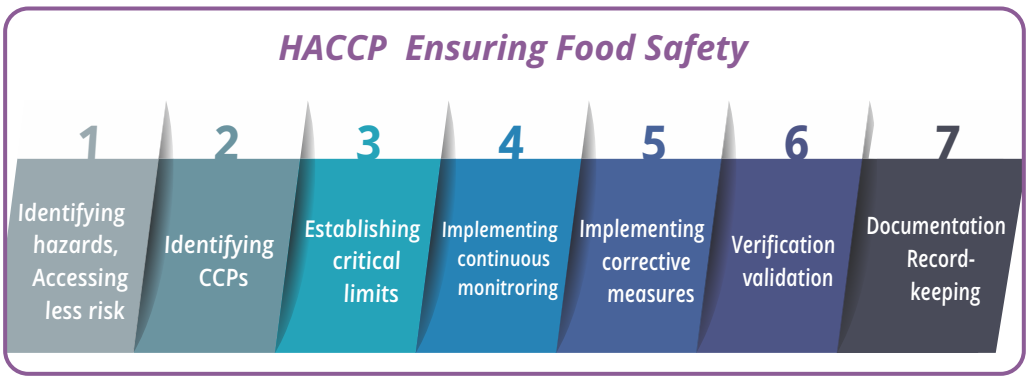
- Consideration of requirements for the premises and maintenance of their suitability for food manufacturing operations.
- The facilities and their adequacy for involvement in food manufacturing.
- The manufacturing, storage and distribution operations and their appropriateness for the manufacture and supply of food safety management,

  Requirements for hygiene and food safety management.
- Management responsibility for the quality and safety of foods including the maintenance of good manufacturing practices.

HACCP (HAZARD ANALYSIS AND CRITICAL CONTROL POINT)

HACCP system for food safety control was initially developed for the US Space Programme. HACCP provides a means of ensuring that food eaten by astronauts was safe and did not contain any food poisoning organisms which may have added to the difficulties of space mission. The FSS Act 2006 also encourages all food services establishments, industry to follow HACCP principles to ensure food safety.

There are seven HACCP principles that will be a part of your food safety plan. Principles one to five are required and principles six and seven are highly recommended:



TYPE OF SAMPLES

- Legal sample – Legal samples are those samples, where after analysis, if an adverse result is received legal action shall be initiated along with relevant enforcement action for quick relief.
- Surveillance & monitoring sample – The sample drawn for purposes of surveillance is to be monitor the safety and quality of food manufactured, sold or imported in the country.

CIRCUMSTANCES OF DRAWING A SAMPLE

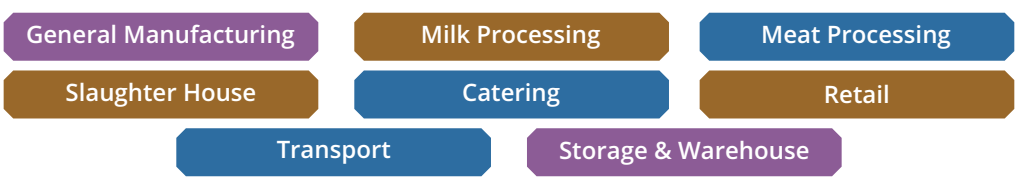
When a Food Safety Officer has reason to believe that a food article being manufactured, stocked or sold or exhibited for sale in contravention of the provisions of the act or rules and regulations framed there under:

- Consumer complaints
- Food hazard warnings and food suspected of contamination generally
- Changing local concerns
- Additional national surveillance programs
- New businesses
- New products or manufacturing practices in existing businesses
- Observation during the factory inspections

INSPECTION MATRICES

FOOD SAFETY INSPECTION CHECKLISTS

Food Safety & Standards Authority of India (FSSAI) has developed inspection checklist for facilitating Food Safety Officers to efficiently inspect the Food Business Operators (FBOs). The inspection checklists are used to identify the level of compliance with each requirement that is set out in the regulation. These inspection checklists are based on Schedule 4 of Food Safety & Standards (Licensing & Registration of Food Businesses) Regulation, 2011 and have been developed for following sectors



MARKING & GRADING SYSTEM

The inspection checklist includes food safety observations which will be given marks by the Food Safety Officers. Based on the marking, the FBOs will be graded as A+, A etc. A marking and grading scheme has been developed to facilitate the Food Safety Officers in doing the inspection.

The inspection checklist has been divided into five major sections namely:-

- Design & facilities
- Control of Operation
- Maintenance & sanitation
- Personal Hygiene
- Training & complaint handling

The Food Safety Officer will inspect the facility of the FBO according to the requirements as laid down in the inspection checklist and accordingly will mark the finding as compliance (C), non-compliance (NC), partial compliance (PC) & Not applicable/Not observed (NA). All the requirements are allotted 2 marks and there are few requirements which are asterisk marked (*) which are allotted 4 marks. Non-observance to any of the asterisk marked (*) finding will lead to Non-Compliance (NC), as they are critical to food safety. Each finding will be awarded marks as mentioned below:-

Compliance - Yes, the requirement is fully documented and implemented. Adherence with the requirement with no major or minor conformance is observed.

Non-compliance - No, the requirement is not documented and implemented. Non-adherence with the requirement with major non - conformance is observed.

Partial compliance - Requirement is partially implemented but not documented or partially documented but not implemented. A non-conformity that, based on the judgement and experience of the FSO, is not likely to result in the failure of the food safety management system or reduce its ability to assure controlled processes or products. It may be either a failure in some part to a specified requirement or a single observed lapse. Partial Compliance is not applicable to asterisk marked (*) requirements as they are critical to food safety.

Not Applicable/Not observed (NA) - Requirements are not applicable to FBO & hence cannot be observed.

Sub-sequentially awarding the marks as per the finding against the requirements, total marks

are calculated & based on the final marks, grading of the FBOs is done. The grading has been divided into 4 levels, i.e.

Grade	Status	Marks Required
A+	Compliance – Exemplar	90 & above
A	Compliance – Satisfactory	80-89
B	Needs Improvement	50-79
No grade	Non-Compliance	Below 50

Mapping of Inspection Checklist with Kind of Business

The inspection checklist has been developed for major business activities such as manufacturing, retail etc. and there are specific kind of businesses in Food Licensing and Registration System. Thus, to facilitate the Food Safety Officers and Food Business Operators in selecting the inspection checklists according to their kind of business, a mapping of inspection checklists & kind of business has been done.

S. No.	Kind of Business	Inspection checklist
1	**Manufacturer**	
i	Dairy units including milk chilling units equipped to handle or process	Milk processing
ii	Vegetable oil processing units and units producing vegetable oil by the process of solvent extraction and refineries including oil expeller unit	General manufacturing
iii	Slaughtering units	Slaughter house
iv	Meat processing units	Meat processing
v	All food processing units including labellers and repackers	General manufacturing
vi	Food business operators manufacturing any article of food containing ingredients or substances or using technologies or processes or combination thereof whose safety has not been established through these regulations or which do not have a history of safe use or food containing ingredients which are being introduced for the first time into the country.(They need to apply for product approval at FSSAI(HQ) separately before applying for license)	General manufacturing

2	Other Businesses	
i	Storage (Except Controlled Atmosphere and Cold)	Storage
ii	Storage (Cold/ Refrigerated)	Storage
iii	Storage (Controlled Atmosphere + Cold)	Storage
iv	Wholesaler	Depending on the activity they are performing; the relevant inspection checklist would be applicable (Transport, retail, storage etc.)
v	Retailer	Retail
vi	Distributor	Depending on the activity they are performing; the relevant inspection checklist would be applicable (Transport, retail, storage etc.)
vii	Food Vending Agencies	Retail
viii	Supplier	
ix	Caterer	Catering
x	Dhaba, Boarding houses serving food , Banquet halls with food catering arrangements, Home Based Canteens / Dabba Wallas, Permanent / Temporary stall Holder, Food stalls/ Arrangements in religious gatherings / fairs etc., Fish / Meat / Poultry shop / seller or any other food vending establishment.	Catering
xi	Club / Canteen	Catering
xii	Hotel	Catering
xiii	Restaurant	Catering
xiv	Transporter (having a number of specialised vehicles like insulated refrigerated van / wagon, milk tankers etc.)	Transport

xv	Marketer	Depending on the activity they are performing; the relevant inspection checklist would be applicable (Transport, retail, storage etc.)
xvi	Petty retailer of snacks / tea shops	Retail
3	**Premises at Central Govt. Agencies**	
I	Food Catering / Canteen Services in Central Government Agencies	Catering
ii	Storage (Except Controlled Atmosphere and Cold)	Storage
iii	Storage (Cold / Refrigerated)	Storage
iv	Storage (Controlled Atmosphere + Cold)	Storage
v	Wholesaler	Depending on the activity they are performing; the relevant inspection checklist would be applicable (Transport, retail, storage etc.)
vi	Retailer	Retail
vii	Distributor	Depending on the activity they are performing; the relevant inspection checklist would be applicable (Transport, retail, storage etc.)
4	**Mid- Day meal**	
I	Caterer	Catering
ii	Canteen	Catering

STEPS FOR INSPECTION

Inspection is an important component of our food safety system.

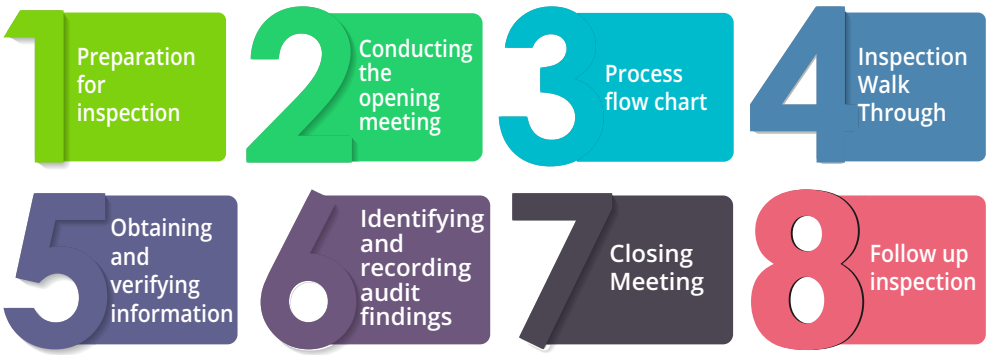
The Food Safety Officer have the right to enter and inspect premises at all reasonable hours - normal opening hours for the food business. Visits are generally made without any warning so that the Officers can get a true picture of how the business usually operates. The Food Safety Officer has to visit alone.

Food Safety & Standards (Licensing & Registration of Food Businesses) Regulations,

2011, provides details for procedure of inspections of various food establishments.

It is the responsibility of the Food Safety Officers to ensure food safety and quality within the area assigned to him. In other words, the major part of enforcement of the Act and various Regulations on food lies with them.

An inspection is a careful, critical, official examination of a facility to determine its compliance with the laws and regulations administered by FSSAI. Inspections may be used to collect evidence to document compliance and violations and to support regulatory action, when appropriate. It is now considered more efficient to focus inspection activities on ensuring compliance of systems for food safety management (implementation of the general principles for food hygiene and HACCP based approaches that can minimise the occurrence of food safety problems.



PRE INSPECTION ACTIVITIES

1. Preparation for inspection

It is always important to prepare yourself prior to the start of any inspection or investigation. We may need to follow number of activities to prepare our self for inspection. These will differ based on whether this is an inspection or an investigation.

(i) Plan and preparations for Inspection- Pre-announcement (Except if inspection in response to compliant / violation)

(ii) Review inherent risk factors / products

(iv) Schedule opening meeting

(v) Examine Records / study Schedule IV / GHP / GMP requirements and documents required to be maintained by the FBO.

(vi) Foresee food borne disease risk factors

(vii) Review facility's quality and safety management system/ (documents)

The Food Business Operator may be informed about the inspection schedule of inspection few days prior to the inspection to be commenced (except if the inspection is in response to a complaint or any violation of the FSS Act, 2006 & Rules & Regulations made there under). The inherent risk factors of the process of manufacturing or ingredients or product should be reviewed. Before visiting the premise all the records and documents pertaining to the file of the FBO is to be studied

Review establishment's history, e.g. previous inspection reports if any, complaints, recalls information from website.

It is also important to ensure or review what kind of personal safety requirements to be ensured before visiting the establishment i.e. any health hazard, requirements for climbing, inspection needs to enter walk-in chillers etc.

Please identify if you need any technical expert along with you for inspection of the establishment. The need for technical expert may arise in case of some new technology or new risk associated with the establishment.

Prior to initiating any inspection, you should become familiar with the reporting requirements for the specific assignment.

As soon as FSO reach the establishment he/she should introduce himself/herself to the available top management along with the team member if any. If, possible FSO should show his Government official ID card.

Be clear about your purpose of visit and confirm if they need to invite more employees before you start with your inspection process.

DURING THE INSPECTION

The Food Safety Officer will introduce himself, produce identification and explain why the inspection is being made. This could be due to a complaint or it could be just a routine inspection. During the Inspection, inspector should behave professionally and demonstrate proper sanitary practices. Planning of inspection shall be such that at the time of inspection the inspected facility shall be in operation for key processes and inspection activity shall cover important aspect like shift/plant change over unless otherwise required.

The Officer will usually ask to speak with the food business operator, but if he is not available, whoever is responsible in the unit should be referred. If the FBO is not found present in the unit then FSO should try to communicate with him and convey about his visit to

him and should further communicate that he is doing the inspection of the premises in the presence of responsible person present in the unit.

During the visit, the Officers may do the following:

- look at the condition and layout of all of the areas within and outside the premises
- watch how food is being processed / prepared,
- ask questions of staff or the food business operator relating to food handling practices and procedures.

A general procedure may be followed by the Food Safety Officer for carrying out inspections of a food establishment,

A process flow chart of the kind of business and product should be prepared in advance. Food Safety Officer should schedule an open meeting with the FBO and the management.

2. Conducting the opening meeting

A formal opening meeting, shall be held with the top management and, where appropriate, those responsible for the functions or processes to be inspected and legal nominee. The purpose of the opening meeting, usually conducted by the Officer, is to provide a short explanation of how the inspection activities will be undertaken. The degree of detail shall be consistent with the familiarity of the establishment with the audit process and shall consider the following:

a) Introduction of the participants, including an outline of their roles;

b) Confirmation of the scope and purpose of Inspection;

c) Confirmation of the Inspection Plan (including type and scope of inspection, objectives and criteria) any changes, and other relevant arrangements with the establishment, such as the date and time for the closing meeting.

d) Explain regulations and philosophy

e) Confirmation of formal communication channels between the Inspector and establishment;

f) Confirmation that the resources and facilities needed by the Inspector are available;

g) Confirmation of matters relating to confidentiality;

h) Confirmation of relevant work safety, emergency and security procedures for the

Inspector; Please follow the establishment procedure and rules for work safety.

i) Confirmation of the availability, roles and identities of any guides and observers;

j) The method of reporting, including any grading of inspection findings;

k) Information about the conditions under which the inspection may be prematurely terminated

l) Confirmation of the status of findings of the previous review or Inspection, if applicable;

m) Methods and procedures to be used to conduct the Inspection based on sampling;

n) Confirmation of the language to be used during the Inspection.

o) Request management collaboration

p) Opportunity for the establishment to ask questions.

The Food Safety Officer shall inspect a FBO premise. The Food Safety Officer should put on neat and clean dress and if possible carry aprons, head gears and gloves at the time of visit of FBO premise. FSO should carry inspection check lists, relevant forms for sampling, seizure and detention forms and all other relevant documents along with all tools required for sampling. During the meeting the FSO shall make the FBO & his management aware about the FSS Act, Rules & Regulations and the duties of a FBO. The FSO should encourage FBO to cooperate in the inspection.

All the documents required to be maintained by the FBO as per the concerned Regulations is inspected by the FSO. The FSO may seek various information from the food handlers.

3. Process flow chart

(i) Obtain/ prepare operation flow chart

(ii) Method of monitoring & validation

(iii) Anticipate CCPs

(iv) Focus on risk factors

(v) Check CCP critical limits

The FSO may ask for a process flow chart of the products being manufactured in the premise, methods of monitoring and validation. FSO may anticipate CCPs and focus on risk

factors. FSO may also check CCP critical limits.

4. Inspection Walk Through

A walk through inspection of the premises should be conducted as early as possible to become familiar with the operation and to plan the inspection strategy. A walk through visual inspection of the manufacturing site is helpful in establishing the depth of the inspection, learning about products and processes, identifying sources of manufacturing records and identifying potential areas of concern. The size of the facility, the number of employees, employee practices, environmental conditions inside and outside the plant, raw materials, manual and automated processes, sources of contamination, manufacturing flow, method of data collection including computer terminals, are some of the areas to be taken into consideration in establishing the depth of the inspection. A visual inspection of a manufacturing site should also be used to check obvious potential problem areas such as: general housekeeping, state of operation for processes and processing equipment, and people dependent operations. Visual inspections of areas used for failure investigation, product sampling and testing, product reworks, return goods and product quarantine areas should be inspected for obvious potential product problems. Depending on the product being inspected, some of the general inspectional equipment an investigator should have available, may include, eye and ear protection, boots and protective clothing.

Where the available inspection evidence indicates that the inspection objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the Inspector shall report this to the establishment/firm in charge and if possible, to the office to determine appropriate action. Such action may include reconfirmation or modification of the Inspection Plan, changes to the Inspection scope or termination of the Inspection. Alert the firm's person in charge when an immediate corrective action is necessary.

5. Obtaining and verifying information

During the inspection, information relevant to the scope and criteria (including information relating to interfaces between functions, activities and processes) shall be obtained by appropriate sampling and verified to become inspection evidence.

Use suitable methods to obtain information and may include, but are not limited to:

a) Interviews;

b) Observation of processes and activities;

c) Review of documentation and records. Review and evaluate the appropriate records

and procedures for the establishment's operation and effectively apply the information obtained from this review [during the inspection].

Collect adequate evidence and documentation to support inspection observations in accordance with State program procedures

6. Identifying and recording audit findings

Inspection findings summarizing conformity and detailing nonconformity shall be identified, classified if needed and recorded to enable an informed outcome to be made or the licence to be maintained. Opportunities for improvement may be identified and recorded, unless prohibited by the regulator.

Any non-compliance shall be recorded against a specific requirement and shall contain a clear statement of the noncompliance, identifying in detail the objective evidence on which the noncompliance is based. Noncompliance shall be discussed with the establishment/firm to ensure that the evidence is accurate and that the noncompliance/s are understood. The Inspector however shall refrain from suggesting the cause of noncompliance or their solution. Inspection should be carried out from least contaminated area to most contaminated area i.e. from Finished Goods to Processing and then to Raw materials storage/preparation area (fruits, vegetables, milk, fish, meat etc.) to avoid contamination

(i) Storage / transportation of finished products, Packaging and Labelling

(ii) Product characteristics / labelling / sampling

(iii) Processing- verify control measures

(iv) Verify that critical limits are observed

(v) Facility assessment

(vi) Equipment assessment

(vii) Employee / staff health, hygiene & Training

(viii) Sick employee policy / hand washing

(ix) Examine employee facilities

(x) Check raw material reception/ storage

(xi) Additives and non-food chemicals

xii) Packaging material specifications / storage

(xiii) Sanitation and pest control

(xiv) Site & surrounding environment assessment

(xv) Inspect laboratory facility wherever necessary and check the proper functioning of the various equipments.

During inspection the FSO should make inspection as per Schedule IV of FSS (Licensing & Registration of Food Businesses) Regulations, 2011applicable for the particular kind of business and product. FSO should review the critical control points and safety management systems with a focus on risk factors and provisions made in the food safety management system for these risk factors. Accordingly, he should cover all the points mentioned in the Schedule IV and inspection checklist. All the areas provided in the premise should be inspected. If any area is locked the FSO should make sure that the room/ area is unlocked for inspection.

7. Closing Meeting

(i) Discuss finding (especially non-compliance & Violation)

(ii) Agree on time line for corrective action

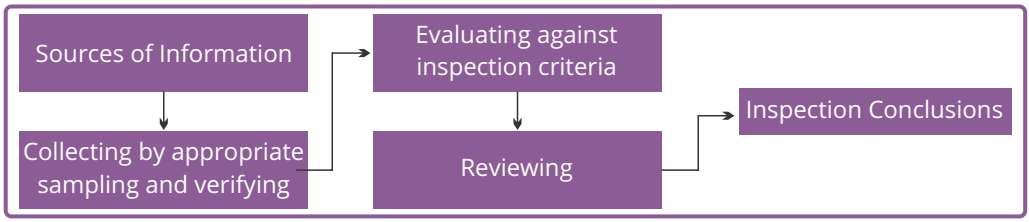
(iii) Sign report, get it signed by the FBO and handover a copy to the FBO and retain one copy of the inspection report which is to be submitted to the Designated Officer for issuing a Improvement Notice to the FBO.

(iv) Discuss possible improvements and prepare the draft of improvement notice.

(v) Schedule follow-up inspection.

After the physical inspection of the food establishment is over, the Food Safety Officer will note down all the observations as an inspection report in the inspection checklist. He will discuss the findings and possible improvements with the FBO and the management (especially in case of noncompliance & violation of law) and also timeline for corrective action. The FSO & FBO should interact freely and FSO should advice the FBO to comply with the provisions of the Act, Rules & Regulations made there in to avoid any kind of penalty. FSO will then sign the report, get it signed by the FBO and handover a copy to the FBO and retain one copy of the inspection report which is to be submitted to the Designated Officer for issuing a Improvement Notice to the FBO. Confidentiality of outcome of inspection should be maintained by the officer unless required in public interest.

INSPECTION FLOW



Process overview from collecting information to reaching Inspection conclusions

When in doubt, start at the beginning. Follow the process flow from receiving to shipping. However, this may not make the best sense if you handle raw and cooked products or pasteurized and unpasteurized products. In those cases, to protect finished product, a better plan of action would be to start in the finished product areas and work backward through the process. This will reduce the risk of pathogenic bacteria being transferred from the raw- to the cooked-product side of the facility.

PREPARING INSPECTION CONCLUSIONS

Prior to the final conclusion or the closing meeting, the inspector shall:

a) Review the inspection findings, and any other appropriate information obtained during the inspection, against the inspection objectives and inspection criteria and identify the non-compliance) agree upon the Inspection finding,

b) Taking into account the uncertainty inherent in the Inspection process;

c) Agree any necessary follow-up actions.

CONDUCTING THE CLOSING MEETING

An inspector should able to distinguish between significant and insignificant observations, and isolated incidents versus trends. A formal closing meeting, shall be held with the client's management and where appropriate, those responsible for the functions or processes inspected. The purpose of the closing meeting, usually conducted, is to present the Inspection findings and outcome.

Inspector shall explain findings clearly and adequately throughout the inspection. He should answer questions and provide information in an appropriate manner and write findings accurately, clearly, and concisely on the format and provide a copy to the firm's person in charge

The closing meeting if conducted should also include the following elements

a) The method and timeframe of responses.

b) The regulators process for handling non-compliances including any consequences relating to the status of the client's licence or registration.

c) The authority's post inspection activities.

d) Information about the complaint and appeal handling processes.

e) The establishment shall be given opportunity for questions.

Any diverging opinions regarding the inspection findings or conclusions between the inspector and the firm shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to the authority.

DOCUMENTATION - INSPECTION REPORT

The Inspector should provide a written report for each inspection. The inspector may identify opportunities for improvement but shall not recommend specific solutions. Ownership of the report shall be maintained by the authority.

The Inspector shall ensure that the inspection report is prepared and shall be responsible for its content. The inspection report shall provide an accurate, concise and clear record of the finding and shall include or refer to the following:

a) Identification of the Name of the inspector or inspecting team;

b) The name and address of the establishment and the establishment's representative

c) The type of Inspection (e.g. initial, routine, follow-up or special inspection)

d) The inspection criteria including the year

e) The scope, particularly identification of the organizational or functional units or processes inspected and the time of the inspection

f) Information on evidences positive and negative both

g) Information, where sampling has been exercised.

h) The dates and places where the inspection activities (on site or offsite, permanent or temporary sites) were conducted

i) Inspection non-compliances

The FSO may also schedule a follow up inspection in case of registration but in case of a licensed unit the schedule will be finalized by the Designated Officer and then assigned to the FSO.

8. Follow Up Inspection

(i) Schedule inspection after the prescribed time period of corrective action by FBO is over in case of registered unit. However, in case of licensed units the same will be scheduled by the Designated Officer and assigned to the Food Safety Officer.

(ii) Follow up inspection is carried out to verify whether the suggestions for improvement have been carried out by the FBO within the prescribed time limit. This may be surprise after prior information.

Note : Inspection of Various Food Establishments as per Schedule IV, GHP/GMP {Refer to FSS (Licensing & Registration of Food Businesses Regulation, 2011)}. For Inspection Checklists of various Food Establishments (fssai.gov.in/cms/inspection-matrices.php)

Documents to be inspected during inspections of various Food Manufacturing Units and Food Service Establishments

- Blueprint/layout plan of the processing unit showing the dimensions in metres/square metres and operation wise area allocation.
- Name and List of Equipment and Machinery along with the number, installed capacity and horse power used.
- Analysis report {Chemical & Bacteriological) of water to be used as ingredient in food from a recognized / public health laboratory to confirm the portability indicating the name of authorized representative of Lab who collected the sample and date of collecting sample
- Proof of possession of premises. (Sale deed / Rent agreement / Electricity bill, etc.)
- Partnership Deed/Affidavit/Memorandum & Articles of Association towards the constitution of the firm. Copy of certificate obtained under Coop Act - 1861/Multi State Coop Act - 2002 in case of Cooperatives.
- NOC from manufacturer in case of Re-labellers & Re-packers
- Food Safety Management System plan or certificate if any,
- Source of milk or procurement plan for milk including location of milk collection canters etc in case of Milk and Milk Products processing units.
- Source of raw material for meat and meat processing plants.
- Pesticide residues report of water to be used as ingredient in case of units

manufacturing Packaged Drinking Water, Packaged Mineral Water and/or Carbonated Water from a recognized/public health laboratory indicating the name of authorized representative of Lab who collected the sample and date of collecting sample, including source of raw water and treatment plan.

- Recall plan wherever applicable, with details on whom the product is distributed.
- NOCs from Municipality or local body and from State Pollution Control Board except in case of notified industrial area.
- List of workers with their Medical fitness as per the Medical Fitness Performa by the Food Authority.
- Pest Control document along with day to day records of treatments.
- Documents related to transportation of raw materials and finished goods. If food is transported under controlled conditions the records of temperature controls.
- Cleaning and sanitation programme of the premise along with day to day maintenance records of the same.
- Records of source and standards of raw material used are of optimum quality as per the Regulations and Standards.
- Test Reports from NABL accredited/FSSAI notified laboratories regarding microbiological contaminants in food.
- Records of daily production, raw material utilized and sales.
- Records of sale and purchase that the food product is sold to registered/licensed vendor and raw material purchased from registered/licensed supplier.
- Records for periodic audit of the whole system according to Standard Operating Procedure conducted regarding GHP / GMP system.
- Appropriate records of food processing/preparations, food quality, laboratory test results, pest control, etc. for a period of one year or the shelf life of the product, whichever is more.
- Training records of food production personnel and production floor managers/ supervisors on food hygiene.
- Food labels for requisite information as per the FSS (Packaging & Labelling) Regulation, 2011.

- Form no. IX (Form of Nomination-Refer rule 2.5.1) nomination of persons by a company.

Procedure of taking extracts of documents and matters connected therewith

Rule 2.2 of the Food Safety & Standards Rule, 2011, details the manner in which the extracts from any books of accounts and other relevant documents are taken by a Food Safety Officer.

(a) When a Food Safety Officer has seized any books of account and other relevant documents in exercise of powers conferred upon him under Sub-Section (6) of Section 38 of the Act, he has to return the same to the person from whom they were seized within a period not exceeding thirty days from the date of such seizure.

(b) Before returning the books of account and other documents, the Food Safety Officer can take for copies thereof or extracts therefrom, as the case may be.

(c) When a communication has been received from the Food Safety Officer, the person from whom the books of account and documents were seized has to provide the copies or extracts as the case may be, duly authenticated by the Food Business Operator.

(d) The extracts can be taken by the Food Safety Officer or by any person authorized by him.

(e) The person making the extracts cannot in any manner cause dislocation, mutilation, tampering or damage to the records in the course of making extracts.

(f) The person making extracts cannot make any marking on any record or paper.

(g) The extracts or the copies above, has to be initialled on each page of such extracts or copies by the person from whom the books of account and other documents were seized and such authenticated extracts or copies is to be provided to the Food Safety Officer and the same has to be accompanied by an Affidavit in Form I of the person from whom the books of account and other documents were seized, certifying the authenticity of such extracts or copies.

Samples, including "Factory Food Samples" (in-lines) and packaged finished products collected during inspections provide the necessary key to establish routes of contamination and/or actual product adulteration. They also document the character of products packed prior to the inspection. Collect samples for laboratory examination only when they contribute to confirming the suspected violation. Be selective since negative reports of analysis of food

samples are required under the act to be furnished to the firm and might give management a false picture of the firm's operation. When possible collect duplicate subsamples to provide for the portion of the sample.

Impressive exhibits are extremely effective and important forms of evidence to establish existence of violative conditions or products. They should relate to insanitary conditions contributing or likely to contribute, filth to the finished product, or to practices likely to render the product injurious or otherwise violative. Diagrams of the establishment, floor plans, flow charts, and schematics are useful in preparing a clear concise report and in later presentation of testimony. A small compass is useful in describing exact locations of objectionable conditions in the plant, in your diagrams and locations from which samples were taken, etc. Submit as an sample exhibits (except photographs) collected during an inspection or investigation. Describe each subsample and assign a unique subsample number to each exhibit. Group similar subsamples on one collection report. Examples of exhibits include:

- Live and dead insects, insectfrass, webbing, and insect chewed materials; nesting material of rodents and/or other animals; and other behavioral evidence of the presence of insects, rodents and other animals.
- Components and finished dosage forms.
- Samples of in-process ingredients, in-process materials and unpackaged finished products. (“Factory Food Samples” or “in-lines.”) Note: Samples of packaged finished products and ingredients are official samples.
- Manufacturing and control devices or aids.
- Physical samples if possible and practical or photographs with descriptions of scoops, stop-gap expediencies, other unorthodox manufacturing equipment or makeshift procedures.

DOCUMENTATION - PHOTOGRAPHS

Photos taken during inspections are not investigational samples. They are exhibits. Photos are not attached to collection reports unless the photos are part of an Official Sample. Only use a Government issued camera to take photographs. Since photographs are one of the most effective and useful forms of evidence, every photo should be taken with a purpose. Photographs should only be taken for evidentiary purposes, e.g., to document violations and environmental surface subsample sites. Photographs should be related to insanitary conditions contributing or likely to contribute filth to the finished product, or to practices likely

to render it injurious or otherwise violative.

CAUTION : Evaluate the area where flash photography is contemplated. Do not use flash where there is a potentially explosive condition; e.g. very dusty areas or possible presence of explosive or flammable vapors. In these situations, use extremely fast film and/or long exposure time instead of flash. Examples of conditions or practices effectively documented by photographs include:

- Evidence of rodents or insect infestation and faulty construction or maintenance, which contributes to these conditions.
- Routes of, as well as, actual contamination of raw materials or finished products.
- Condition of raw materials or finished products.
- Employee practices contributing to contamination or to violate conditions.
- Manufacturing processes.
- Manufacturing and various control records showing errors, substitutions, penciled changes in procedure, faulty practices, deviations from GMP's, altered or inadequate assays or other control procedures and any variation from stated procedure.
- Effluent contamination of water systems.

When photographing labels, make sure your picture will result in a legible label with printing large enough to be read by an unaided eye. Photograph whited out documents by holding a flashlight against the whited outer side and taking a close up photo of the reverse using high speed film. This will produce a photo with a mirror image of the whited outer side. If you use a Polaroid camera or color slide film, explain the facts in your inspection report to alert reviewers that there are no negatives.

Don't request permission from FBO to take photographs during an inspection because taking photographs is part of the Agency's authority to conduct inspections. If management objects to taking photographs, explain that photos are an integral part of an inspection and present an accurate picture of firm conditions.

SEIZURE / SEALING OF BOOKS OF ACCOUNTS OR OTHER DOCUMENTS

The Food Safety Officer shall, in exercising the powers of entry upon, and inspection of any place under this section, follow, as far as may be, the provisions of the Code of Criminal Procedure, 1973 (2 of 1974) relating to the search or inspection of a place by a police officer executing a search warrant issued under that Code.

The Food Safety Officer may seize any article of food which appears to the Food Safety Officer to be in contravention of this Act or the regulations made thereunder; and keep it in the safe custody of the food business operator such article of food after taking a sample; and in both cases send the same for analysis to a Food Analyst for the local area within which such sample has been taken.

Provided the Food Safety Officer keeps such article in the safe custody of the food business operator, he may require the food business operator to execute a bond for a sum of money equal to the value of such article with one or more sureties as the Food Safety Officer deems fit and the food business operator shall execute the bond accordingly.

Where any article of food seized is of a perishable nature and the Food Safety Officer is satisfied that such article of food is so deteriorated that it is unfit for human consumption, the Food Safety Officer may, after giving notice in writing to the food business operator, cause the same to be destroyed.

Any adulterant found in the possession of a manufacturer or distributor of, or dealer in, any article of food or in any of the premises occupied by him as such and for the possession of which he is unable to account to the satisfaction of the Food Safety Officer and any books of account or other documents found in his possession or control and which would be useful for, or relevant to, any investigation or proceeding under this Act, may be seized by the Food Safety Officer and a sample of such adulterant submitted for analysis to a Food Analyst.

POST - INSPECTION STEPS

Once the Officer has completed the inspection, he will discuss the findings of the inspection with a suitably responsible person. The Officer will make clear which issues are contraventions (these must be sorted out) and which are recommendations (these are suggestions for good hygiene practice). He will agree time scales within which the work should be completed. He will leave a summary report at the time of the inspection and a more comprehensive report will be sent later detailing all legal requirements and recommendations for good practice.

Sometimes it may be necessary to serve an improvement notices for significant contraventions or imminent risks to health. These might be left following the visit or they may be sent at a later date. Failure to comply with the notice may result in more formal action such as prosecution.

A follow up visit may be necessary to check that any matters requiring attention have been suitably resolved. The food business operator should always contact the Inspecting

Officer before the time elapses if he feels the work cannot be completed within the time period.

All documentation arising from the inspection will be kept in the premises file and will be available for inspection by the public.

FOLLOW-UP OF INSPECTION (INCLUDING DOCUMENTATION)

Improvement Notice

The Act provided power to Designated Officer to issue improvement notice towards corrective action if he has reasonable ground to believe that the FBO has failed to comply with the regulation. Usually before the issuance or grant of license or grant of registration, the Licensing Authority is required to inspect the unit or the establishment to check the compliance of the applicable conditions if not satisfied, an Improvement Notice may be issued in accordance to Section 32 of the Act.

Role of Food Safety Officer in issuance of Improvement Notice

Food Safety officer after inspection can recommend Designated Officer to issue improvement notices to the Food Business Operators whenever necessary.

The FBO shall take the required measures, or measures which are at least equivalent to them, within a reasonable period (not being less than 14 days) as may be specified in the notice. As it is clear that improvement notices should depict the areas for the FBOs to quickly close the non-compliance's (which also involve explanation or clarifications) which were identified during the FSSAI inspection. It is also important for the FBO to adequately respond within the timelines specified by the Authority failing which the results can be detrimental for the business (like suspension of license, show cause notice followed by cancellation of license).

How do food businesses respond to Improvement Notices?

As is evident that improvement notices has to be addressed carefully by gathering, analysing data from internal departments, vendors and other stakeholders of the business. Corrective actions post third party (or internal) audits are seen as analogy to improvement notice responses. Below are the critical steps that can be adapted by the parties in articulating the responses

- **Comprehend the notice :** Upon the receipt of notice, the senior management should comprehend the document and understand the risks to the business. Also, they

should nominate a competent person to complete the initial draft along with necessary approvals to expedite the closure prior to the deadline. This will enable the management to vet the draft and tweak the content

- **Assembling a team :** The senior management (or its representative) should engage a team comprising of individuals from quality, internal audit, legal & compliance, supply chain, procurement and any other as applicable and relevant to the nonconformities. Also, external consultants (or SMEs) would bring industry experience and aid the internal team for a quick closure of draft.

- **Root-cause analysis :** Basis the observations, the team should perform a root cause analysis and come with corrective & even preventive action plan considering the risk and impact. Subsequently, the team should prioritize the tasks based on the time take for completion and initiate the corrective action.

- **Gathering evidence :** Upon completion of the corrective actions, it is important to demonstrate the compliance to the nonconformities observed. Hence, capturing images of these actions would be helpful for the authorities to gain confidence on the FBO. Evidences include registers, destroying raw materials, segregation of raw materials, pest activity, laboratory reports and so on.

- **Collation of responses & final review :** its time for collating the explanations, clarifications and evidences to make a final draft with assurance to Authority on the organization commitment to food safety. It is often recommended to get the final draft reviewed by a consultant (who can bring in a neutral view) before dispatch. Obtain the postal acknowledgment receipt upon dispatching the dossiers to FSSAI.

- **Course correction :** To err is human; therefore, being in food business it is important to develop a course correction plan post such incidents. The senior management has to assemble and draw a strategy to mitigate such risks and product the brand equity. Few corrections like training, increased internal audits, random safety testing, supply chain audits etc. are most prevailing practices in the industry.

In conclusion, food businesses should shift towards being self-compliant in the light of unscheduled inspections from the Authority. This attitude will keep the FBO prepared of the regulatory audits and help themselves attain a good compliance score. Also, FBOs as a best practice should retain records & documents for at least one year to demonstrate the food safety compliance. Further, it is recommended that food businesses should adapt the inspection checklist introduced by FSSAI for various businesses.

SUSPENSION AND CANCELLATION OF LICENSES

Suspension or cancellation of license may happen only after the Improvement Notice has not been complied with by the FBO. After issuance of the Improvement Notice, during inspection, if it is proved that the FBO has not taken the corrective action as expected form him, his License / registration may be suspended till the time he corrects the condition. Before taking the action of suspension the reasonable opportunity of hearing must be given to the FBO and during the course of hearing, if FBO has submitted that he has complied with the contravention recorded in the improvement notice then again re-inspection should be done to verify the fact. If it is found that the FBO has complied with the contravention as mentioned under the improvement notice then no further action should be taken in that regard and If on re-inspection it is found that the FBO has not complied with the contravention showed in the improvement notice then there is a need of issuing show cause notice. The show cause notice will demonstrate details of contravention and in the notice ,the authority should ask the FBO as to why his licence not suspended in this circumstances?. The reply giving time for show cause notice will be there in the said notice. Now if the reply is received or not received in the given time the authority has to take the final decision of suspension of licence. By following the above procedure of giving all the opportunity of improvement to the FBO, the authority will successful even if the appeal is made by the FBO in front of CFS. It means each and every opportunity must be given to the FBO for doing compliance/improvements and if it is found that after giving all the opportunities of improvement the FBO does want to respond to it and is not willing to comply with the contravention then the action of suspension will be proper. After the suspension of licence the FBO still failed to rectify the defects or omissions or comply with the condition of improvement notice causing suspension then authority may cancel the licence after giving the opportunity to show cause. So note that there is requirement of show cause notice is there in the Act to provide FBO all the opportunities to improve on the aspects of contravention.

ROLE OF FOOD SAFETY OFFICER IN SUSPENSION OR CANCELLATION OF LICENSE/REGISTRATION

FSO can recommend to the Designated Officer giving specific grounds, suitable action in regard to licenses issued to any Food Business Operator, if on Inspection the Food Safety Officer finds that the Food Business Operator has violated the conditions for grant of license.

APPEAL

A FBO aggrieved by an order of the Registering Authority or Licensing Authority, as

the case may be, under these regulations may prefer an appeal to the concerned Designated Officer or the Food Safety Commissioner, as per provisions laid down under Section 31(8) and 32(4)-(5) of the Act.

Section 31(8) provides for Appeal against the order of grant of License before the commissioner of Food Safety.

Section32(4) deals with appeal before the Food Safety Commissioner against an Improvement Notice served on the FBO or refusal to issue a certificate as to improvement or cancellation or suspension or revocation of license.

Section 32(5) sets the time limit for appeal within 15 days of receiving the order. In case the order is issued by the Designated Officer for many noncompliance or failure by the FBO then the time frame is mentioned in that order (if Any) or 15 days, whichever is earlier.

PROCEDURE OF TAKING EXTRACTS OF DOCUMENTS AND MATTERS CONNECTED THEREWITH

MANNER OF TAKING EXTRACTS

- Where the Food Safety Officer has seized any books of account and other relevant documents in exercise of powers conferred upon him under Sub-Section (6) of Section 38 of the Act, he shall return the same to the person from whom they were seized within a period not exceeding thirty days from the date of such seizure. Provided that before returning the books of account and other documents, the Food Safety Officer shall be entitled for copies thereof or extracts there from, as the case may be.
- On receipt of such communication from the Food Safety Officer, the person from whom the books of account and documents were seized shall provide the copies or extracts as the case may be, duly authenticated by the Food Business Operator.
- The extracts shall be taken by the Food Safety Officer or by any person authorized by him.
- The person making the extracts shall not in any manner cause dislocation, mutilation, tampering or damage to the records in the course of making extracts.
- The person making extracts shall not make any marking on any record or paper.

AFFIDAVIT

- The extracts or the copies referred to in Rule 2.2.1 above, shall be initiated on each

page of such extracts or copies by the person from whom the books of account and other documents were seized and such extracts or copies so authenticated shall be provided to the Food Safety Officer, accompanied by an Affidavit in Form I of the person from whom the books of account and other documents were seized, certifying the authenticity of such extracts or copies.

SEIZURE OF ARTICLES OF FOOD BY THE FOOD SAFETY OFFICER AND MATTERS CONNECTED THEREWITH

2.3.1. Form of receipt for article of food seized by a Food Safety Officer : For every article of food seized under clause (b) of Sub-Section 1 of Section 38 of the Act, a receipt in Form II shall be given by the Food Safety Officer to the person from whom the article of food was seized.

2.3.2. Form of order/bond not to dispose of the stock : Where the Food Safety Officer keeps any article of food in the safe custody of the Food Business Operator under clause (c) of Sub-Section (1) of Section 38 of the Act.

- He shall, after affixing the seal, on the article of food, make an order to the Food Business Operator in Form III and the Food Business Operator shall comply with such an order, and
- He may require the Food Business Operator to execute a bond in Form IV.

FOOD SAFETY AUDITS OF FBOS

WHAT IS A FOOD SAFETY AUDIT?

Before covering the specific character and nature of a food safety audit, let us first look at what an audit is in general. An audit is usually defined as a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. An audit is a process where an authorised auditor visits a facility to assess food safety compliance. During the audit the auditor carries out an inspection of the facility, observes the food handling practices, and reviews food safety documentation (including the food safety program and monitoring).

Food Safety Audit means a systematic and functionally independent examination of sanitary & hygiene compliances as per Schedule IV of FSS (Licensing and Registration of Food Business) Regulation, 2011, food safety measures (based on HACCP) and other standards (e.g. product standards) adopted by FBO to meet the regulatory requirements.

According to the FSS Act, 2006, a Food Safety Audit means, a systematic and functionally independent examination of food safety measures adopted by manufacturing units to determine whether such measures and related results meet with the objectives of food safety and the claims made in that behalf.

Audits on licensed food business will be carried out by the auditors of agencies recognised under the Food Safety and Standards (Food Safety Auditing) Regulation 2018.

FOOD SAFETY AUDIT STRUCTURE

Audits can be classified in 3 ways based on the auditor/auditee relationship:

- **First Party :** This type of audit is a self-assessment, to internally verify that procedures and management strategies reflect the requirements of a standard and reflect business objectives.
- **Second Party :** Also known as proprietary audits, a primary organization evaluates the performance of a supplier or contractor.
- **Third Party :** Independent auditors from outside the organization conduct audits, often for purposes of certification.

THIRD PARTY AUDIT

To strengthen the food safety surveillance system, FSSAI has envisaged audits of Food Business Operators through Private Auditing Agencies. In order to cultivate and foster the growth of compliance culture, FSSAI is enabling compliance through private recognized Auditing Agencies.

The Food Safety Audits reduce the regulatory Food Safety Inspections conducted by Central or State Licensing Authorities. Satisfactory Audits will lead to less frequent regulatory inspections by Central or State Licensing Authority except the regulatory sampling. This will strengthen food safety surveillance system and encourage self-compliance while at the same time assuring safe food to the consumers.

Section 44 of the Food Safety and Standards Act, 2006 provides the power to Food Authority to recognize an organization or an agency for carrying out food safety audit and checking compliance with the Food Safety Management Systems.

Section 16(2)(c) of the Food Safety and Standards Act, 2006 specifies Food Authority may specify the mechanisms and guidelines for accreditation of certification bodies engaged in certification of Food Safety Management Systems (FSMS) for food businesses; Food Safety

and Standards (Food Safety Auditing) Regulations, 2018, have been notified for the same.

FOOD SAFETY AND STANDARDS (FOOD SAFETY AUDITING) REGULATIONS, 2018

FSS Act, 2006 defines FSMS or "Food Safety Management System" as the adoption Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business." The establishment in which food is handled, processed & packed, by the FBO and the persons handling them should conform to the sanitary and hygienic requirement (as described in Schedule IV), Food Safety measures (based on HACCP Principles) and other standards (including FSSAI product standards). It shall also be deemed to be the responsibility of FBO to ensure adherence to necessary requirements.

Food Safety (FSMS) audits will reduce the regulatory inspections conducted by Central or State Licensing Authorities. Food Businesses classified by Food Authority for mandatory Third Party Audits are liable to get their businesses timely audited by recognised Auditing Agencies. FSSAI may from time to time specify the kinds of businesses to be mandatorily audited. It shall be the responsibility of the FBO to get their businesses timely audited. Food businesses which are not subject to mandatory Third-party auditing can also conform to Auditing of their businesses.

I. FOOD SAFETY AUDIT PROCESS

THE FOOD SAFETY AUDIT PROCESS	
FBO will select the audit agency	The shortlisted Audit agency will collect all the information on FBO, Scope, Number of production lines / product group, consultancy / training details , number of food handlers, area for storage (in case of storage & distribution)
	FBO will finalise the audit date with the agency and decide upon the Audit fee to be paid by the FBO.

The Audit agency fills in the audit intake form in FSSAI Audit management system web page	The Audit Agency will log in FSSAI audit portal using their credentials and fill in the details of scheduled audit in Audit Intake Form (Annex 2).
	Audit date, auditor details, audit man-days will be mentioned in the audit intake form. Once the form is filled, the information cannot be changed. Once filled, the details of the audit scheduled are visible to the Food Authority, concerned Agency and FBO.
	The agency will communicate the Audit Plan to FBO at least 8 days in advance.
FBO will get their businesses audited as per the audit plan on the scheduled date.	Auditor / audit agency will execute the audit as per inspection checklist and communicate the audit score and the draft audit report shall be submitted before leaving the FBO facility. All the findings shall be agreed by FBO. The FBO can represent to the Food Authority in case of disagreements, if any.
	In case of major non-conformity, the food authority will be informed through the web portal within 24 hours (also email / phone). Information about the same should also reach Director (RCD), Central Licensing Authority and Commissioner of Food Safety of concerned State / UT through web portal / mail / other means.
	In case of minor non-conformities, audit agency will close the findings within 15 days including its rectification and follow up. FBO has to close the findings and take corrective actions. In case of delay by FBO, concerned CLA or SLA shall be intimated by the agency through web portal / mail / other means for necessary action at their end.
	The final audit report shall be uploaded on the FSSAI Audit management web page within 15 days from the date of audit.

II. MANDATORY VS VOLUNTARY AUDITS AND ITS FREQUENCY

The Food Authority shall, from time to time specify the category or type of food businesses which shall be subject to mandatory food safety auditing, primarily based on their risk classification. The classification of food business shall be done after consideration of the major risk factors like food type, intended customer use, nature of activity of the business, volume of the business, method of processing and or any other factors that the Food Authority may specify in this behalf. Such food businesses shall get their business audited by the recognized auditing agency as per the frequency specified by the Food Authority. Food businesses which are not mandatorily subject to food safety auditing but are desirous of getting audited by the recognized auditing agency, can opt for the same.

Food businesses in which food safety audits have been satisfactorily conducted may be subject to less frequent inspections by the Central or the State licensing authorities except for regulatory purpose. Provided that in case of any complaints against the food businesses or when it comes to the knowledge of the Food Authority that the public health and safety is at risk, the Food Authority shall have the discretion to undertake more frequent inspections.

The audit process involved for assessing the food safety management system of a Food Business Operator shall be based on IS/ISO 19011:2011 (Guidelines for auditing management systems).

III. AUDIT FREQUENCY

The Audit Frequency recommended by the Food Authority for FBOs to conduct the mandatory food safety audits is as per table below:

Note : The original scope for recognised agencies is as per the declaration submitted by them as per Annex 1. The Kind of Business and product categories as per the existing FLRS are as indicated below:

Product ID	Product	Audit Score Range	Audit Frequency
1	Dairy products and analogues, excluding products of food category 2.0	Score : 81-100%	Once in 12 months
		Score : 51- 80 %	Once in 09 months
		Score : < 50 %	Once in 06 months
2	Fats and oils, and fat emulsion	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months
3	Edible ices, including sherbet and sorbe	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months

Product ID	Product	Audit Score Range	Audit Frequency
4	Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months
5	Confectionery	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months
6	Cereals and cereal products, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares of food category 7.0	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months
7	Bakery products	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months
8	Meat and meat products including poultry	Score : 81-100%	Once in 12 months
		Score : 51- 80 %	Once in 09 months
		Score : < 50 %	Once in 06 months
9	Fish and fish products, including molluscs, crustaceans, and echinoderms	Score : 81-100%	Once in 12 months
		Score : 51- 80 %	Once in 09 months
		Score : < 50 %	Once in 06 months
10	Eggs and egg products	Score : 81-100%	Once in 12 months
		Score : 51- 80 %	Once in 09 months
		Score : < 50 %	Once in 06 months
11	Sweeteners, including honey	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months
12	Salts, spices, soups, sauces, salads and protein products	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months
13	Foodstuffs intended for particular nutritional uses (eg. Food for infant nutrition etc)	Score : 81-100%	Once in 12 months
		Score : 51- 80 %	Once in 09 months
		Score : < 50 %	Once in 06 months
14	Beverages, excluding dairy products	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months

Product ID	Product	Audit Score Range	Audit Frequency
15	Ready-to-eat savouries	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months
16	Prepared Foods (catering etc)	Score : 81-100%	Once in 12 months
		Score : 51- 80 %	Once in 09 months
		Score : < 50 %	Once in 06 months
99	Substances added to food	Score : 81-100%	Once in 18 months
		Score : 51- 80 %	Once in 12 months
		Score : < 50 %	Once in 06 months

List of agencies recognised by FSSAI as Food Safety Auditing Agencies under the Food Safety and Standards (Food Safety Auditing) Regulations, 2018 are mentioned in the officials' website of FSSAI.

Inspection checklist will be same as regulatory check list discussed under "preparation of an inspection" point 2 – logistic preparation.

FOOD HYGIENE RATING SCHEME

Hygiene Rating Scheme is a certification system for the food service and retails establishments providing food directly to the consumers. The food businesses are rated based on food hygiene and safety conditions observed at the time of audit/inspection. The hygiene rating certificate will be displayed prominently in the food service area to create demand of high levels of food hygiene standards.

Purpose of the scheme is to:

- Encourage food businesses to ensure high hygiene standards and continue maintaining them and showcase the same to their consumers.
- Motivate other food businesses having lower hygiene standards to improve.
- Allow consumers to make an informed food choice about where to eat and cultivate responsible eating habits.

Hygiene Rating will score FBO based on self-assessment checklist for compliance with food hygiene and safety procedures and structural requirements followed by the verification of the hygiene rating by physical inspection and validation by the Hygiene Rating Auditor, Hygiene Mitra or state FDAs. The Hygiene Rating will be in the form of smileys (1 up to 5) as per the level of compliance.

TYPE OF FOOD BUSINESSES INCLUDED IN HYGIENE RATING SCHEME

The food establishments falling under this scheme includes food service establishments (which include hotels, restaurants, cafeteria, dhabas, etc.), meat retail shops and sweet shops (Mithai Shop).

THE KEY REQUIREMENTS TO GET HYGIENE RATING

Food Hygiene Rating Scheme will be implemented online through Hygiene Rating Portal (www.fssai.gov.in/hygieneRating). But prior to enrolling for this scheme FBOs or agency should ensure that the FBOs fulfil the following conditions:

1. FBOs should have FSSAI License / Registration and follow Schedule 4 requirements

This is to provide for adequate measures that are to be adopted to ensure that food being served to the consumers is of good quality and safe to eat.

2. FBOs should have certified Food Safety Supervisors and trained food handlers

A Food Safety Supervisor is a trained professional to be appointed by a FBO in his/her restaurant to supervise and maintain food hygiene practices and train other food handlers working in the premises. There should be one FSS per 25 food handlers.

3. Must have Food Safety Display Boards (FSDBs) prominently displayed in the premises (Optional)

- Food Safety Display Board (FSDB) with the information to consumers and food handlers about important food safety and hygiene requirements.

- FSDB must provide options to consumers for sending feedback through WhatsApp, SMS or give feedback on FSSAI App.
- All FSDB must have the FSSAI registration/license number on it for consumers to verify.

4. Get food samples tested periodically from any FSSAI approved Lab

- Water samples: to be tested biannually for organoleptic and physiochemical parameters as mentioned in Food Safety and Standards Regulations 2011
- Food samples: to be tested bi-annually for safety parameters (contaminants and microbiological parameters)

Ensure following preliminary information is available:

- FSSAI License Number of the food service establishment.
- Name of Organisation (as in FLRS)
- Name of Food outlet
- Location of the food outlet
- Validity of FSSAI License
- Name of FoSTaC trained Food Safety Supervisor(s) working in the food outlet. Also, note their details of FoSTaC Certificate such as Unique Certificate Number and Course Name and Course Code.

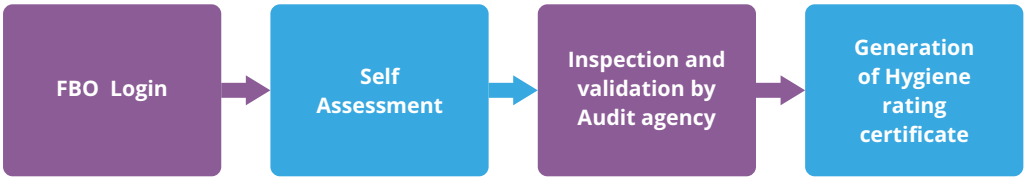
HOW FBOS CAN ENROLL FOR HYGIENE RATINGS SCHEME?

For State and Central Licensed FBOs

Once FBO have fulfilled all the set requirements they can follow the steps given below to enroll in hygiene rating scheme. Log in using your FLRS credentials at:

- Log on to www.fssai.gov.in/hygieneRating
- Follow guidelines to implement key requirements, provide details of food establishment and complete self-assessment process.
- Generate "hygiene rating".
- If the rating on self-assessment is 4 or 5 and the score is validated by the Hygiene Audit agency, the FBO may enroll for Eat Right Score.

- Inspection/Verification of ratings will be done by Hygiene Rating Audit Agency (HRAA)/ Third Party Audit (TPA) Agency /Food Safety Officer (FSO, either using online checklist (on FoSCoRiS or Serve Safe Portal) or physical checklist.
- After Inspection / verification is done, FBO can generate the verified (signed) hygiene rating certificate.
- FBOs can enroll for "Eat Right Score" if above ratings score is 4 (Good) or 5 (Very Good).



FOR FBOS WITH REGISTRATION

For petty food businesses who wish to enrol for hygiene rating scheme , the self is not required . For this category of businesses there will be direct verification of the hygiene requirements as per the HR checklist by the auditors.

1. What is the Assessment and Scoring Process?

- Hygiene Rating assessment checklist is based on the food hygiene and safety requirement stated in Schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011. This food hygiene and safety requirement in this checklist is aligned with inspection checklist of regulatory staff of food safety department.
- There is a score awarded for compliance of each requirement mentioned in this checklist.
- The total score attained is converted into a percentage against which Hygiene Rating is awarded.

2. How to interpret score?

- Indicated marks for each question marked as yes, will be added to arrive at the total score.
- Questions marked with "Asterisk" are critical and which can impact food safety. Failure to comply with these will lead to non-issuance of hygiene ratings.

- Score achieved is converted to percentage by the formula:

Total Score value * Score Obtained during assessment / Total Score of checklist.

The score of the checklist is converted in per cent and numerical score (between 1-5). The table below provides detail of percent score wise rating

3. What is the validity of Hygiene Rating awarded?

The ratings awarded under Hygiene Rating Scheme will be valid for two years. However, inspecting officer/agency may schedule an audit during this period in case any complaints are received.

4. How to improve Hygiene Ratings / Scores?

- Post audit, the auditor will share the report and suggest suitable practices to fill the gaps identified during the audit. FBO can check for non-compliant food hygiene and safety practices as per the checklist. Take clear, concrete steps to ensure and demonstrate compliance for each of these issues.
- FBO will redo self-assessment, but only 3 months after the previous inspection, then FBO can get the scores/ rating revalidated and print the certificate.
- In case the FBO will again attains low score, then auditor shall inform the food safety department about the same and the State FDA may issue improvement notice to the FBO.
- FBO can request for re-inspection/revisit for re-verification of hygiene ratings, and the time will be 3 months from the date of last assessment done by Hygiene Rating Audit.

Hyg. Rating	Category	% Score
5	Excellent	81 to 100
4	Very Good	61 to 80
3	Good	41 to 60
2	Needs Improvement	21 to 40
1	Urgent Improvement	20 or below

PROCESS FLOW FOR RECEIVING HYGIENE RATING

FSSAI's License Registration & Schedule 4 of FSS Regulation

No → Log on to https://foscos.fssai.gov.in/ apply for license & comply with Schedule 4 requirements

Yes ↓

Appoint Certified Food Safety Supervisor in the premise & Train all Food Handlers and a Trained

No → Log on to https://fostac.fssai.gov.in to get training and get certified

Yes ↓

Food Safety Display Board (FSDB) install in the premises

No → Download FSDB by logging on to fssai.gov.in safe food products FSDB's install FSDB in premises

Yes ↓

Periodic Food & Water sample testing as per FSSAI's requirement → Login the website for information regarding List of FSSAI approved labs and get the food samples tested

Yes ↓

Enroll for Hygiene Rating at www.fssai.gov.in/servesafe

»FBO login with FoSCoS login ID & Password
»Self Assessment follow guidelines
»Inspection by FSO within 30 days
»Rating available to print

» Licensed FBOs will login using FoSCoS ID Passwordand Self Assessment
» Inspection by HRAA
» Generate Hygiene Rating

VERIFICATION AGENCIES

WHO CAN DO VERIFICATION FOR HYGIENE RATING?

Hygiene Rating Audit Agencies (HRAA)

FSAAI has recognized Hygiene Rating Audit Agencies (HRAA) for the purpose of verification of hygiene ratings after self-assessment scores. The trained auditors of HRAA/ TPA audit agencies will register on hygiene rating portal and can validate the scores. Apart from audit agencies, the regulatory staff as FSO of state food safety department may also conduct Hygiene Rating Audits (this is only proposed till the pool of Hygiene Auditors are generated in sufficient numbers).

Verification process

- Within 45 days of online submission of self-assessment report by state and central FBOs, they will undergo a final verification for getting the certificate. While the petty food businesses will directly undergo assessment by HRAA.
- For final verification, FBO can choose the verification body from the portal itself. Hygiene Rating Auditor (HRA) deputed by HRAA will verify the hygiene rating and submit the report to their designated HRAA. Once the HRAA verifies the audit report, hygiene rating can be generated by the FBO. FBO will download the certificate and display it at prominent location in the food premise. The hygiene rating of FBO can also be displayed on e-commerce platforms.
- Once the inspection process is complete, a PDF of the inspection report and Hygiene Rating Certificate can be generated by HRA and provided to the FBO. The FBO can also directly generate hygiene rating certificate from its dashboard.
- A dashboard for HRAA/HRA/FBO and state Food Safety Department has been created on Hygiene Rating Portal. The FSO/DO/FBO can login to Hygiene Rating Portal using FLRS credential while HRAA and auditors may create their login on Hygiene Rating Portal.
- After the verification process is completed, FBO can download the 'Verified Hygiene Rating.

Details with all annexures for the hygiene rating scheme can be accessed through https://www.fssai.gov.in/hygieneRating/home

HYGIENE RATING CHECKLIST FOOD SERVICE ESTABLISHMENTS / BAKERY

Date | **FSSAI Licence No.**

Name of Organisation | **Outlet Name**

Outlet Location | **FSS Name**

FSS Certificate Code | **Course Code**

S. No.	Audit Check List for Retail Meat Shop	Score
1	The FSSAI Registration or licence certificate obtained for meat shop. NOC from municipality or local body.	2
2	Food Establishment have FoSTaC certified FSS as per mandate	2
I	**Design and Facilities**	
3	The retail meat shop should be located away from environmental polluted area like dust, dirt, fumes, smoke and other contaminants.	2
4	The premises should be of appropriate size with adequate working space having size of minimum 3 meters.	2
5	The layout of the premises shall be such that there is a unidirectional flow of men and material to avoid cross contamination which could be achieved by operation timings.	2
6	Internal structure & fittings are made of non-toxic, cleanable, impermeable materials which prevent the entry of dirt, dust & pests.	2
7	Floors are impervious, non-slippery, easy to clean / washable without possibility of stagnation.	2
8	Walls are paved with imperious glazed tiles at least 5 feet height.	2
9	Windows & other openings are free from accumulated dirt; those which when open are fitted with insect-proof screen.	2
10	Doors are smooth, non-absorbent surface, close fitted & Self-closing (where appropriate) with tinted glass.	2
11	Premises is well ventilated and properly lighted. Premises have sufficient lighting of at least 220 lux in dressing or work area.	2
12*	In case of poultry meat shop, adequate space for the handling, slaughter / dressing of poultry birds at the rear portion which is tiled, well lit and ventilated. The working and storage space should be separate.	4
13	The chopping block should be made of food grade synthetic material or a hard wooden block without chipping at the surface, to be kept neat & clean all the times.	2
14	Facility of hot and cold water for cleaning / sanitation and sterilization of equipment and premises.	2
15*	The premise is well equipped with chilling / freezing equipment for keeping of the meat/ carcasses and not to be kept in open and / or wrapped in a wet cloth. In addition, the cooling / freezing cabinets shall be provided to keep the processed meat (fresh / frozen or packaged) or value added /marinated meat products with temperature measuring or recording devices.	4

II	Control of Operations	
16*	The duly stamped meat / carcasses or live poultry birds shall be procured from a Govt. authorised or Municipal Corporation slaughter house and poultry market respectively. If the meat is outsourced, it should be from an FSSAI licensed / registered supplier or vendor.	4
17	The live poultry birds or carcasses should be transported in an appropriate temperature controlled vehicle without inflicting cruelty to the birds or preventing contamination. The birds should be kept in the cages avoiding overcrowding with provision of feed & water.	2
18	The temperature of the premises for dressing / minor processing is controlled & held suitably low particularly if the height of the meat shop is less than 2.5 meter.	2
19	Area used for preparing, packing or other handling of meat is equipped with adequate facilities for cleaning / disinfecting the implements such as knives, steel, cleavers, saws etc.	2
20	Containers used for storing inedible parts, cleaning chemicals & other hazardous substance are clearly identified; kept separately from meat or its products.	2
21	Knives and sharpeners (mushtala) are made of stainless steel or corrosion resistant metal and sanitized and sterilized before use.	2
22	The meat shall be packed / dispensed using food grade materials in a hygienic manner.	2
III	**Maintenance and Sanitation**	
23*	Clean potable water as well as supply of hot water is available in dressing / slaughter area.	4
24	Cleaning / sterilization of equipment e.g. butcher's knife/cleaver, hooks etc. and of premises with hot water not less than 82 degree Celsius is done daily.	2
25	Floorings are washed daily with disinfectant. Lime washing, colour washing or paint washing is done at least once in 12 months.	2
26	Preventive and breakdown maintenance of equipment and machinery is carried out regularly.	2
27	Effective pest control management be there.	2
28	The entry of animals like dog, cats or mongoose into the premises should be prohibited.	2
29	There is an efficient drainage system and all drains and gutters are properly installed / fitted with traps and screens.	2
30	Liquid waste like waste water should be drained immediately into drains or sewers and not allowed to accumulate	2
31	Covered garbage bins with foot operated pedals should be used for waste disposal. Waste is removed from meat handling area at regular intervals & the receptacles are cleaned & disinfected immediately after use.	2

32*	There shall be proper arrangement for disposal of feathers, skin, offal or waste tissues / trimmings of the carcasses arising from the dressing of poultry birds / meat preparation through the concerned agency/ local authority/ Municipality / corporation as per solid waste management laws or rules in force from time to time .	4
IV	**Personal Hygiene**	
33*	A medical health certificate on yearly basis for the butcher / meat handlers from a Registered Medical Practitioner to ensure they are free from any infectious / contagious disease with regular updation of health cards. The persons suffering from any infectious disease shall not be permitted to work. Inoculation of butcher/ meat handlers against the enteric group of diseases as per recommended schedule of the vaccine is done.	4
34	The meat handlers should maintain personal hygiene like regularly trimming their nails, hairs and shave properly.	2
35	The food handlers should wear clean protective clothing, beard / hair net (cap) during cutting / handling of meat. The meat handlers should not wear personal effects e.g. watch, rings, chains, other loose jewellery during the work.	2
36	No person with open wounds or burns or skin infection is involved in handling of meat or materials which come in contact with meat. Any behaviour which can potentially contaminate the meat such as eating, use of tobacco, chewing, spitting, shall be prohibited in any part of the registered unit.	2
37	Hand washing facility be fitted in the premises. Hands should be washed thoroughly before start of the work, after use of toilet, after handling chemicals / disinfectants or after touching unclean surfaces.	2
V	**Training and Record Keeping**	
38	The personnel engaged (butcher, meat handlers) in the meat shop shall undergo training for basic hygiene.	2
39	Appropriate documentation and records are maintained.	2

Total points ...../114

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance

ANNEXURE 2B

HYGIENE RATING CHECKLIST FOR SWEET SHOP

Date

Name of Organisation

Outlet Location

FSS Certificate Code

FSSAI Licence No.

Outlet Name

FSS Name

Course Code

S. No.	Audit Question	Score
A	**General Requirement**	
1	Food establishment has an updated FSSAI license and is displayed at a prominent location.	2
2	Food Establishment have FoSTaC certified FSS as per mandate.	2
B	**Basic food Safety & hygiene**	
I	**Design & facilities**	
3	The mithai / sweet shop should be located in hygienic environment. The design of sweet / halwai shop provides adequate working space; permit maintenance & cleaning to prevent the entry of dirt, dust & pests.	2
4	The internal structure & fittings are made of non-toxic and impermeable material.	2
5	Walls, ceilings & doors are free from flaking paint or plaster, condensation & shedding particles.	2
6	Floors are non-absorbent, non-slippery & sloped appropriately.	2
7	Windows are kept closed & fitted with insect proof screen when opening to external environment.	2
8	Doors are smooth and non-absorbent. Suitable precautions have been taken prevent entry of pests.	2
9*	Potable water (meeting standards of IS: 10500 & tested semi-annually with records maintained thereof) is used as product ingredient or in contact with food or food contact surface.	4
10	Equipment and containers are made of non-toxic, impervious, non- corrosive material which is easy to clean & disinfect.	2
11	Adequate facilities for heating, cooking, cooling, refrigeration and freezing food & facilitate monitoring of temperature.	2
12	Premise has sufficient lighting. Lighting fixtures are protected to prevent contamination on breakage.	2
13	Adequate ventilation is provided within the premises.	2
14	An adequate storage facility for food both hot and cold, packaging materials, chemicals, personnel items etc. is available.	2
15	Personnel hygiene facilities are available including adequate number of hand washing facilities, toilets, and changing rooms for employees.	2
16	Raw and finished product to be tested periodically, Check records.	2

II	Control of operation	
17*	Incoming material like colour, flavour, raw material like milk, oil etc. is procured as per internally laid down specification from approved vendors. Check for records (like certificate of analysis, Form E, specifications, name and address of the supplier, batch no., mfg., use by/expiry date, quantity procured etc.). Only permitted colours and flavours to be used.	4
18	Raw materials are inspected at the time of receiving for food safety hazards. (Farm produce like flour, milk etc. must be checked for spoilage and accepted only in good condition). Ensure raw and finished products are free from visible adulteration.	2
19	Incoming material, semi or final products are stored according to their temperature requirement in a hygienic environment to avoid deterioration and protect from contamination. FIFO & FEFO is practiced.	2
20	All raw materials is cleaned thoroughly before food preparation.	2
21	Proper segregation of raw , semi processed and finished food is done.	2
22	All the equipment is adequately cleaned and sanitized before and after food preparation.	2
23	Cutting, portioning, slicing etc. of sweet is not done directly on floor.	2
24	Cooking done minimum at appropriate temperature, 60°C for 10 minutes or 65°C for 2 minutes core food temperature.	2
25	Hot food intended for consumption is held at 65°C. Cold foods are maintained at 5°C or below and frozen products are held at -18o C or below.	2
26	Prepared food intended for refrigeration is cooled appropriately to prevent from spoilage.	2
27*	Oil being used is suitable for cooking/frying purposes. Visual inspection of fat and oil by checking the color, the flavour, rancidity and floated elements is being done.	4
28*	Sweets are properly covered during the entire process and not kept exposed Display of sweets in required temperature conditions according to the nature of sweets.	4
29	Food and non-food products transported at same time in the same vehicle are separated adequately to avoid any risk to food.	2
30	Vehicle intended for food transportation are kept clean and maintained in good repair & are maintain required temperature.	2
31	Packaging, wrapping and serving material coming in contact with food is clean and of food grade quality. Avoid use of newspaper.	2
32	Labelling should be as per the FSSAI norms. Shelf life indicated properly.	2
III	**Maintenance & sanitation**	
33	Cleaning of equipment, food premises is done as per cleaning schedule & cleaning programme. There should be no stagnation of water in food zones.	2
34	Preventive maintenance of equipment and machinery are carried out regularly as per the instructions of the manufacturer. Check for records.	2
35	Measuring & monitoring devices are calibrated periodically.	2
36	Pest control program is available & pest control activities are carried out by trained and experienced personnel. Check for records.	2

37*	No signs of pest activity or infestation in premises (eggs, flies, larvae, faeces etc.)	4
38	Drains are designed to meet expected flow loads and equipped with grease and cockroach traps to capture contaminants and pests.	2
39	Food waste and other refuse are removed periodically from food handling areas to avoid accumulation.	2
IV	**Personal Hygiene**	
40	Annual medical examination & inoculation of food handlers against the enteric group of diseases as per recommended schedule of the vaccine is done. Check for records.	2
41	No person suffering from a disease or illness or with open wounds or burns is involved in handling of food or materials which come in contact with food.	2
42*	Food handlers maintain personal cleanliness (clean clothes, trimmed nails & water proof bandage etc.) and personal behaviour (hand washing, no loose jewellery, no smoking, no spitting etc.)	4
43	Food handlers are equipped with suitable aprons, gloves, headgear, etc.; wherever necessary.	2
V	**Training & records keeping**	
44	Internal / External audit of the system is done periodically. Check for records.	2
45	Food Business has an effective consumer complaints redressal mechanism.	2
46	Food handlers have the necessary knowledge and skills & trained to handle food safely. Check for training records.	2
47*	Appropriate documentation & records are available and retained for a period of one year, whichever is more.	4

Total points ...../108

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance

ANNEXURE 2C

HYGIENE RATING CHECKLIST FOR MEAT RETAIL

Date **FSSAI Licence No.**

Name of Organisation **Outlet Name**

Outlet Location **FSS Name**

FSS Certificate Code **Course Code**

S. No.	Audit Check List for Retail Meat Shop	Score
1	The FSSAI Registration or license certificate obtained for meat shop. NOC from municipality or local body.	2
2	Food Establishment have FoSTaC certified FSS as per mandate.	2
I	**Design and Facilities**	
3	The retail meat shop should be located away from environmental polluted area like dust, dirt, fumes, smoke and other contaminants.	2
4	The premises should be of appropriate size with adequate working space having size of minimum 3 meters.	2
5	The layout of the premises shall be such that there is a unidirectional flow of men and material to avoid cross contamination which could be achieved by operation timings.	2
6	Internal structure & fittings are made of non-toxic, cleanable, impermeable materials which prevent the entry of dirt, dust & pests.	2
7	Floors are impervious, non-slippery, easy to clean / washable without possibility of stagnation.	2
8	Walls are paved with imperious glazed tiles at least 5 feet height.	2
9	Windows & other openings are free from accumulated dirt; those which when open are fitted with insect-proof screen.	2
10	Doors are smooth, non-absorbent surface, close fitted & Self-closing (where appropriate) with tinted glass.	2
11	Premises is well ventilated and properly lighted. Premises have sufficient lighting of at least 220 lux in dressing or work area.	2
12*	In case of poultry meat shop, adequate space for the handling, slaughter / dressing of poultry birds at the rear portion which is tiled, well lit and ventilated. The working and storage space should be separate.	4
13	The chopping block should be made of food grade synthetic material or a hard wooden block without chipping at the surface, to be kept neat & clean all the times.	2
14	Facility of hot and cold water for cleaning / sanitation and sterilization of equipment and premises.	2
15*	The premise is well equipped with chilling / freezing equipment for keeping of the meat/ carcasses and not to be kept in open and / or wrapped in a wet cloth. In addition, the cooling / freezing cabinets shall be provided to keep the processed meat (fresh / frozen or packaged) or value added /marinated meat products with temperature measuring or recording devices.	4

II	Control of Operations	
16*	The duly stamped meat / carcasses or live poultry birds shall be procured from a Govt. authorised or Municipal Corporation slaughter house and poultry market respectively. If the meat is outsourced, it should be from an FSSAI licensed / registered supplier or vendor.	4
17	The live poultry birds or carcasses should be transported in an appropriate temperature controlled vehicle without inflicting cruelty to the birds or preventing contamination. The birds should be kept in the cages avoiding overcrowding with provision of feed & water.	2
18	The temperature of the premises for dressing / minor processing is controlled & held suitably low particularly if the height of the meat shop is less than 2.5 meter.	2
19	Area used for preparing, packing or other handling of meat is equipped with adequate facilities for cleaning / disinfecting the implements such as knives, steel, cleavers, saws etc.	2
20	Containers used for storing inedible parts, cleaning chemicals & other hazardous substance are clearly identified; kept separately from meat or its products.	2
21	Knives and sharpeners (mushtala) are made of stainless steel or corrosion resistant metal and sanitized and sterilized before use.	2
22	The meat shall be packed / dispensed using food grade materials in a hygienic manner.	2
III	**Maintenance and Sanitation**	
23*	Clean potable water as well as supply of hot water is available in dressing / slaughter area.	4
24	Cleaning / sterilization of equipment e.g. butcher's knife/cleaver, hooks etc. and of premises with hot water not less than 82 degree Celsius is done daily.	2
25	Floorings are washed daily with disinfectant. Lime washing, colour washing or paint washing is done at least once in 12 months.	2
26	Preventive and breakdown maintenance of equipment and machinery is carried out regularly.	2
27	Effective pest control management be there.	2
28	The entry of animals like dog, cats or mongoose into the premises should be prohibited.	2
29	There is an efficient drainage system and all drains and gutters are properly installed / fitted with traps and screens.	2
30	Liquid waste like waste water should be drained immediately into drains or sewers and not allowed to accumulate.	2
31	Covered garbage bins with foot operated pedals should be used for waste disposal. Waste is removed from meat handling area at regular intervals & the receptacles are cleaned & disinfected immediately after use.	2

32*	There shall be proper arrangement for disposal of feathers, skin, offal or waste tissues / trimmings of the carcasses arising from the dressing of poultry birds / meat preparation through the concerned agency/ local authority/ Municipality / corporation as per solid waste management laws or rules in force from time to time .	4
IV	**Personal Hygiene**	
33*	A medical health certificate on yearly basis for the butcher / meat handlers from a Registered Medical Practitioner to ensure they are free from any infectious / contagious disease with regular updation of health cards. The persons suffering from any infectious disease shall not be permitted to work. Inoculation of butcher/ meat handlers against the enteric group of diseases as per recommended schedule of the vaccine is done.	4
34	The meat handlers should maintain personal hygiene like regularly trimming their nails, hairs and shave properly.	2
35	The food handlers should wear clean protective clothing, beard / hair net (cap) during cutting / handling of meat. The meat handlers should not wear personal effects e.g. watch, rings, chains, other loose jewellery during the work.	2
36	No person with open wounds or burns or skin infection is involved in handling of meat or materials which come in contact with meat. Any behaviour which can potentially contaminate the meat such as eating, use of tobacco, chewing, spitting, shall be prohibited in any part of the registered unit.	2
37	Hand washing facility be fitted in the premises. Hands should be washed thoroughly before start of the work, after use of toilet, after handling chemicals / disinfectants or after touching unclean surfaces.	2
V	**Training and Record Keeping**	
38	The personnel engaged (butcher, meat handlers) in the meat shop shall undergo training for basic hygiene.	2
39	Appropriate documentation and records are maintained.	2

Total points ...../90

Asterisk mark (*) questions may significantly impact food safety & therefore must be addressed as a priority. Failure in any of the asterisk mark questions, will lead to Non-compliance

NOTES

CHAPTER-6

SAMPLING & FOOD TESTING ECOSYSTEM

6 SAMPLING & FOOD TESTING ECOSYSTEM

INTRODUCTION

Food Analysis is at the heart of safety and quality monitoring. Sampling and analysis of food may be conducted for various purposes, such as surveillance, data collection, monitoring for enforcement, quality control/process monitoring, research, public information / survey.

Different types of samples are collected and submitted to the laboratory for analysis. Some are sample units from lots or consignments of foods or ingredients. This chapter briefly describes some of the major factors that should be considered when collecting sample units, shipping them to a laboratory, preparing them for analysis, and analysing them. The broad objectives of testing articles of food / ingredients are:

a) **Protecting Public Health -** The most important objective of food testing is to protect public health. Detection of naturally occurring toxins, contaminants, use of unsuitable ingredients, addition of food-additives more than permitted level and failure of declaration of allergic ingredients will all contribute to this objective.

b) **Detecting fraudulent activities -** This is particularly true for imported food where inspection of the manufacturing process establishment is not an option.

c) **Providing customers with information to make informed choices -** Product labelling plays a very important role to help consumers make informed choices about what products to buy. Labelling information ranges from details that may provide guidance on the quality of the food (e.g. Nutritional Facts) to information on the presence or otherwise of substances (e.g allergens, gluten, added sugar) that a consumer may wish to avoid, for ethical or health reasons. Sampling followed by analysis is a vital tool to help check the veracity and accuracy of the labelling information.

d) **Ensuring compliance to the National Food Standards** - Sampling and analysis is an essential tool to evaluate whether foods meet the compliance to National standards. Enforcement alerts industry that products are being monitored for the purpose of consumer protection and legal compliance

e) **Surveillance and Enforcement -** Sampling and analysis aid inspection activities either as part of, or associated with, visits to establishments and identify food sector

or products where enforcement attention is required. Sampling and analysis are also of use during the investigation of complaints, break outs of food borne illnesses, and follow-up purposes.

f) **Providing advice on food safety and quality to Food Business Operator (FBO) -** Informing food producers or retailers of sampling and analytical results highlight issues that they were not aware of, thus allowing them to take prompt action.

g) **Promoting fair trade and deterring bad practice -** Businesses and consumers alike need to know where they stand. It is, therefore, important that food law is effective and is enforced efficiently and consistently. Fair and effective enforcement helps honest and diligent food businesses and is supported by industry.

LEGAL PROVISIONS RELATED TO SAMPLING AND ANALYSIS

The following provisions provided in the Food Safety and Standards Act (2006) and Food Safety and Standards Rules and Regulations, 2011 are related to sampling and analysis of food and functioning of laboratories

i. Food Safety and Standards Act (FSSAI), 2006 - Section 43, 45, 46, 47 of FSS Act, 2006;

ii. Food Safety and Standards (FSS) Rules, 2011 - Rules 2.4.1 and 2.4.2

iii. Food Safety and Standards (Laboratory and Sample Analysis) Regulation, 2011

iv. Food Safety and Standards (Recognition and Notification of Laboratories) Regulation, 2018

As per Section 3(zs) of FSSAI, 2006 "sample" means a sample of any article of food taken under the provisions of this Act or any rules and regulations made there under for.

Compliance to FSSAI : These samples are taken under formal enforcement and regulatory compliance activities.

Compliance testing is a regulatory control measure to prevent the marketing or remove from market a product known to be contaminated or adulterated. It can be directed at specific samples suspected of not complying with specific regulations and guidelines governing the sale and distribution of food and for also for evaluation in case of certain concerns and / or issues.

The sample integrity, homogeneity and representativeness are vital for a fair and meaningful inference and subsequent actions. Hence, such samples have to be purchased or procured by the Food Safety Officer (FSO) /Authorized Officer before

sending for analysis and the products are usually seized or kept in the custody until the test results indicate the proper disposition. In this type of sampling, the chain of custody has to be maintained. Such samples hold a legal entity and are challengeable in the court of law. The reports of these analyses are filed for legal actions.

Monitoring sampling : monitoring sampling is conducted to assess human dietary exposure, perform risk assessments, monitor trends, identify potential problems and at-risk population groups, set standards and guidelines, and evaluate the effectiveness of programs. It is an **'unbiased'** sampling, and the purpose is the processing and analysis of samples to provide information on the occurrence and/or levels of chemical residues / contaminants, food additives, microbiological organisms and nutritional components in pre-defined sample populations. Monitoring information is normally obtained through random sampling. The sampled lots are not held and are usually available to consumers before the results are known.

Surveillance/survey sampling: this type of sampling is for information gathering studies. They are usually limited in scope and duration. The surveys may be used to gather information about the occurrence of chemical residues, food additives, microbiological organisms and nutritional value. Special surveys also include pilot surveys, where information is gathered primarily to help improve larger, future collections (i.e. information for testing and refining: feasibility, collection methods, operational aspects, time/cost/sample size estimates). Sample taken for monitoring/ surveillance purposes does not hold any legal entity and are not challengeable in the court of law.

RELEVANT DEFINITIONS USED IN SAMPLING PROTOCOLS

Lot (or Population) : A defined quantity of a commodity that has been produced or manufactured under the same basic conditions on the same day, at the same establishment, and identified under the same batch number or the entire production for a certain period of time from which samples are to be taken. In other words, it is the stated portion of the consignment which needs to be assessed (e.g a truck or ship load of grain; oil packages in the store). The lot may be homogenous or heterogenous.

Lot size : It is the number of units of the product in a lot e.g (100 metric tonnes of wheat or 500 L of milk or 200 packets of biscuits).

Consignment : The quantity of grain/oilseeds/milled/first transformation products/ prepackaged foods dispatched or received at one time and covered by a particular contract or shipping document. It may be composed of one or more lots or parts of a lot.

Sample : A portion of a material selected from a larger quantity of material. The word "sample" should only be used with a modifier described below.

- **Primary sample (or increment) :** A small quantity of grain/oilseeds/milled/first transformation products taken at one time from a single position from a stationary lot. A series of primary samples is taken from different parts of the stationary lot, so that when they are bulked, they are representative of the lot/container. if collected from a lot of prepacked products it will normally be in the form of a unit.
- **Composite (Bulk) Sample :** Quantity of commodity (grain / oilseeds / milled / first transformation product) obtained by combining and mixing the increments taken from a specific lot. The sample comprises all of the sample units drawn for examination or testing purposes from a particular lot.
- **Laboratory Sample :** Representative quantity of commodity (grain/oilseeds/milled/ first transformation product/packages) obtained by division of the bulk sample and intended for analysis finally submitted to the laboratory for analysis.
- **Official (Legal) Sample :** Sample taken in a manner so that it can serve as the basis for enforcement and/or legal action and handled in a manner that preserves integrity as evidence including identity, ownership, traceability and a clear record of chain of custody.
- **Investigation Sample :** Taken during a food safety inspection to document inspector observations, support regulatory actions or provide other information.
- **Surveillance Sample :** Taken as part of routine inspections or surveys to identify any lack of compliance with state, federal or other laws and regulations.
- **Representative (Random) sample :** A sample in which the characteristics of the lot from which it is drawn are maintained. It is in particular the case of a simple random sample where each of the items or increments of the lot has been given the same probability of entering the sample i.e. all elements in the lot have an equal and independent chance of being included in the sample.

Unit : Each of the discrete, identifiable units of food that are suitable for removal from the lot (population) as samples and that can be individually described, analyzed or combined. These units form the basis of most food analysis work (e.g. an apple, a bunch of bananas, a can of fruit, a packet of biscuits, a package of oil).

Unit size : The particular food portion or container selected as a sample and from which one or more units will be taken for analysis.

Sampling plan : predetermined procedure for the selection, withdrawal, preservation, transportation and preparation of the portions to be removed from a lot as a sample.

Sampling procedure (or protocol) : operational requirements and / or instructions relating to the use of a particular sampling plan (i.e., the instructions for the implementation of the plan).

Note : The terms "individual" and "item" are synonymous with "unit".

ACCEPTANCE SAMPLING

Acceptance sampling is one of the main areas of statistical quality control and is an inspection procedure. For food safety and quality, acceptance sampling techniques are a commonly used procedure used to determine whether to accept or reject a specific quantity of food lot. Sampling inspection plans are used to assess safety of the food for human consumption and the "fitness for use" of batches of products. The steps involved are

1. A random sample is taken from a large quantity of items and tested or measured relative to the quality and / or safety characteristic of interest.
2. If the sample passes the test, the entire quantity of items is accepted.
3. If the sample fails the test, either **(a)** the entire quantity of items is subjected to 100 percent inspection and all defective items repaired or replaced or **(b)** the entire quantity is returned to the supplier.

This provides protection not only to the consumers but also motivates producers to make quality product following good hygienic practises. They may be used for evaluation of attributes or variables or both. Acceptance sampling involves the application of a predetermined plan to decide whether a lot of goods meet defined criteria for acceptance. The risks of accepting "bad" or rejecting "good" lots are stated in conjunction with one or more parameters, for example, quality indices of the plan. Statistical plans can be designed to regulate the probabilities of rejecting good lots or accepting bad lots. They are applicable to Stationary lots and moving as in a production stream (Figure 1):-

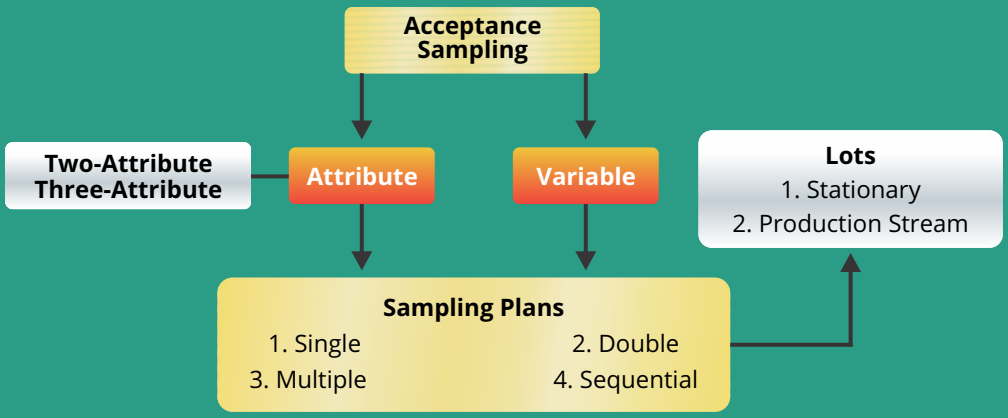


Figure 1 Types of Acceptance sampling and sampling plans

Acceptance sampling is employed in food testing when one or several of the following hold:

1. Testing is destructive.
2. The cost of 100% inspection is very high.
3. 100% inspection takes too long.

The presence of a well-designed plan is important as it provides a consistent model to guide samplers, and serves as a reminder of the important elements of the overall sample analysis program. The precise definition of an acceptance sampling procedure will require the setting or selection of:

1. The characteristic to be measured
2. Lot size
3. An attribute or variables sampling plan
4. The Limiting Quality (LQ) level for isolated lots; or the AQL (Acceptable Quality Level), for a continuous series of lots
5. The level of inspection
6. The size of the sample
7. The criteria for acceptance or rejection of the lot
8. The procedures to be adopted in cases of dispute

THE CHARACTERISTIC

A characteristic is a property, which helps to identify, or differentiate between, items within a given lot. The characteristic may be either quantitative (a specific measured amount) or qualitative (meets or does not meet a specification). Three types of characteristic associated with inspection of food items are listed in Table 1.

Table 1 Characteristics of food associated with inspection

Type of Characteristic	Type of Sampling plan
Commodity defects : characteristics that may be expressed by two excluding situations as passed/not passed, yes/not, integer/not integer, spoiled/not spoiled (e.g. as applied to visual defects such as loss of colour, mis-grading, extraneous matter, insect infestation etc)	Attribute
Compositional characteristics : characteristics that may be expressed by continuous variables. They may be normally distributed (e.g. most analytically determined compositional characteristics such as moisture content) or they may be non-normally distributed.	Variables with unknown standard deviation' for normally distributed characteristics and 'attributes' for characteristics whose distributions deviate significantly from normal
Health-related properties (e.g. in the assessment of microbial spoilage, microbial hazards, irregularly occurring chemical contaminants etc)	Quantitative Specified sampling plans to be proposed appropriate to each individual situation (e.g. for microbiological control)
Source : *General Guidelines on Sampling (CAC/GL 50-2004)*	

LOT SIZE

A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc. Where the size or boundary of each lot in a large consignment is not readily established, each one of a series of wagons, lorries, ship's bays, etc., may be considered to be a separate lot. There is no mathematical relationship between sample size (n) and lot size (N). However, to reduce the risk of making an incorrect decision for larger lots. The ratio f = n/N influences the sampling error only when the lot size is small. Moreover, in an objective of consumer protection (in particular health), it is recommended, to choose samples of larger sizes when the lot sizes are large.

ATTRIBUTE AND VARIABLE PLANS IN ACCEPTANCE SAMPLING

Acceptance sampling is "the middle of the road" approach between no inspection and 100% inspection. There are two major classifications of acceptance plans: by attributes (accept or reject) and by variables. The properties of foods can usually be classified as either attributes or variables.

An attribute is something that a product either does or does not have, e.g., it does or does not contain a piece of glass, or it is or is not spoilt. On the other hand, a variable is some property that can be measured on a continuous scale, such as the mass, fat content or moisture content of a material. The attribute case is the most common for acceptance sampling.

The major sampling plans used in food analysis are:

1. Attribute sampling plan
2. Variable sampling plan

ATTRIBUTE SAMPLING PLAN

In attribute sampling plan, sampling is done to decide the acceptability of a lot based on the number of unacceptable items in the sample. The acceptability of an item depends on the presence or absence of a characteristic.

In the case of canned fruit, each can that weighs 1 kg or more is accepted, and each unit that weighs less than 1 kg is rejected. If the number of rejected units exceeds a predetermined number, the lot is rejected. If the number of rejected units is less than the predetermined number, the lot is accepted. This plan is based on the binomial or Poisson distribution. There are two types of attribute sampling plan viz., two-class attribute sampling and three-class attribute sampling, which are often used when assessing microbiological contamination of foods.

Two-class attribute sampling : The two-class plan is essentially defined by two numbers and two attributes. The first one 'n', determines the number of sample units that are to be drawn independently and randomly from the lot and tested. The second number c, is the maximum allowable number of defective sample units, which separates acceptable from non acceptable or defective quality. The value c is usually set to zero for pathogens.

For example, if *Clostridium botulinum* is just present in a sample of canned food, then the lot is rejected. This means that out of the 'n' samples tested, not even one sample should test positive for pathogens. For canned infant food for *Salmonella* (acceptance is absent in 25g)

n is set at 60, and c=0 which means that out of the 60 samples tested not even one sample should test positive.

Acceptability decisions with two-class plans may be based on a single sampling plan, a double plan, or a multiple plan. A single sampling plan specifies a sample size and an acceptability criterion. A typical single sampling plan might be n = 15, c = 2. This means that the food analyst takes a sample of 15 items and accepts the lot or lots if 2 or fewer do not conform to the specifications for safety. If three or more do not conform, reject the lot (Figure 1). A double plan that has approximately the same properties and specifies sample sizes n1 = 8, n2 = 8; acceptance numbers c1 = 0, c2 = 3. This means the that in the first set of 8 samples; the lot is accepted if there are no nonconforming items and rejected if there are 3 or more. If there are 1 or 2 nonconforming items, the second set of 8 samples is taken. If from the entire 16 items, there are 3 or fewer nonconforming items, the lot is accepted; otherwise, it is not.

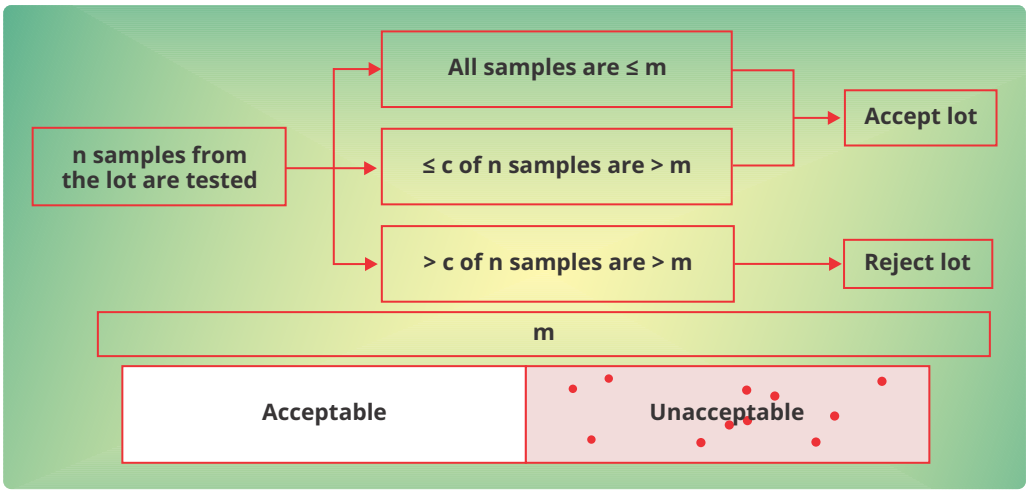


Figure 2: Schematic of a single 2-Class Attribute plan.

Three-class attribute sampling : In this case, 'n' is the number of samples selected at random from the lot, the numerical value 'm' represents acceptable level and 'M' unacceptable concentrations / counts, and 'c' is the maximum allowable number of marginally acceptable sample units such that if this number is exceeded, the lot is considered as un-acceptable. While 'm' separates sample units of acceptable quality from those of marginally acceptable quality, 'M' separates sample units of marginally acceptable quality from those of defective quality. In short, lot is accepted if the number of marginally defective items (i.e. those items with a concentration of micro-organisms between m and M) ≤ c. Lot is rejected if the concentration of the microorganisms in any item is > M and / or the number of marginally defective items > c (Figure 3). For e.g. in frozen vegetables, while testing for Staphylococcus

aureus, n=5, c=1, m=20 cfu /g, M=1 x 10^2 cfu/g. In 5 samples taken for testing, the lot is acceptable if only one sample has a concentration of >20 cfu/g and <1 x10^2/g. If 2 or more samples have counts >20 cfu/g it is unacceptable. It is also unacceptable even if one sample has a concentration of ≥ 1 x 10^2 cfu/g.

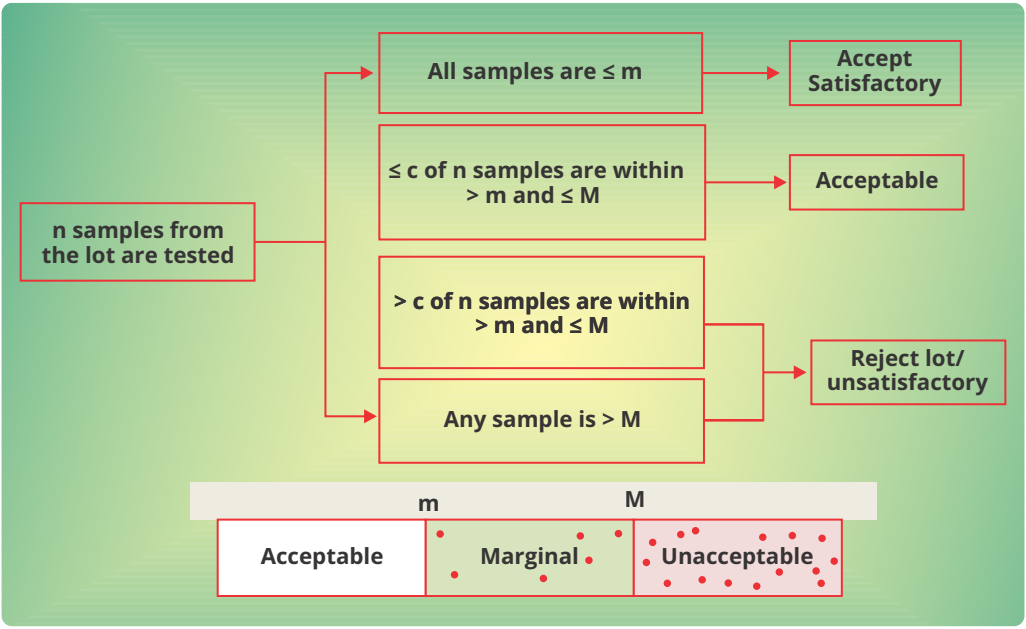


Figure 3: Schematic of a 3-Class Attribute plan

VARIABLE SAMPLING PLAN

When actual quantitative information can be measured on sampled items, rather than simply classifying them as acceptable or unacceptable, variables sampling plans can be used. Variable plans are those for which a quality characteristic is measured quantitatively on each item inspected. The average measurement is compared with the standard and used for the acceptability decision. For e.g. salt content, moisture. This type of sampling usually produces data that have a normal distribution such as in the per cent fill of a container and total solids of a food sample. To achieve the same operating characteristic as an attribute plan, a variable sampling plan requires fewer samples than an attribute plan since more information is available in the measurements. When a lot is rejected, the measurements in relation to the specification limits give additional information helps to prevent rejected lots in the future. Such sampling plans have a much greater ability to distinguish between good and bad lots. However, only a single characteristic may be measured with each sampling plan. Also, some characteristics are not measurable on a continuous scale, such as appearance, texture of meat, colour, or odour. This plan is usually based on normal distribution.

SINGLE, DOUBLE, MULTIPLE AND SEQUENTIAL PLANS IN ACCEPTANCE SAMPLING

These variable and attribute plans of acceptance sampling may be single, double, multiple, or sequential plans.

Single-sampling plan : The single-sampling plan is a decision rule to accept or reject a lot based on the results of one random sample from the lot. The procedure is to take a random sample of size (n) and inspect each item. If the number of defects does not exceed a specified acceptance number (c), the consumer accepts the entire lot. Any defect found in the sample are either repaired or returned to the producer. If the number of defects in the sample is greater than c, the consumer subjects the entire lot to 100 %inspection or rejects the entire lot and returns it to the producer. The single-sampling plan is easy to use but usually results in a larger average number of items inspected than the other plans. This is the most common sampling inspection procedure

Double-sampling plan : In a double-sampling plan, two sample sizes (n_1 and n_2) and two acceptance numbers (c_1 and c_2) are specified and $c_2 > c_1$. If the quality of the lot is very good or very bad, the consumer (the regulatory body is considered as the consumer) can make a decision to accept or reject the lot on the basis of the first sample, which is smaller than in the single-sampling plan. To use the plan, the consumer takes a random sample of size n_1. If the number of defects is less than or equal to c_1, the consumer accepts the lot. If the number of defects is greater than c_1, the consumer rejects the lot. If the number of defects is between c_1 and c_2, the consumer takes a second sample of size n_2. If the combined number of defects in the two samples is less than or equal to c_2, the consumer accepts the lot. Otherwise, it is rejected. A double-sampling plan can significantly reduce the cost of inspection relative to a single-sampling plan for lots with a very low or very high proportion defective because a decision can be made after taking the first sample. However, if the decision requires two samples, the sampling costs can be greater than those for the single-sampling plan.

Multiple-sampling : It is an extension of the double-sampling concept in that more than two samples may be required in order to reach a decision regarding the disposition of the lot. A lot is accepted or rejected based upon the results obtained from several samples drawn from the lot. A multiple-sampling plan involves smaller first samples than single or double sampling plans. A multiple sampling plan is comparatively difficult to design and explain, and expensive to administer

Sequential-sampling : It is a further refinement of the double-sampling plan. In sequential-sampling plan, the samples are randomly selected from the lot and the analyst inspects them one by one. Each time an item is inspected, a decision is made to (1) reject the

lot, (2) accept the lot, or (3) continue sampling, based on the cumulative results so far. The analyst plots the total number of defectives against the cumulative sample size, and if the number of defectives is less than a certain acceptance number (c_1), the consumer accepts the lot. If the number is greater than another acceptance number (c_2), the consumer rejects the lot. If the number is somewhere between the two, another item is inspected. In sequential sampling plan, a sample is taken and after analysis a decision of accepting, rejecting, or taking another sample is made. Therefore, the number of total samples to be taken depends exclusively on the sampling process.

DEFECTS (NONCONFORMITIES) AND CRITICAL NONCONFORMITIES

A defect (nonconformity) can be described as when one or more, quality characteristic does not meet its established quality specification. A defective item contains one or more defects (e.g having a concentration in microorganisms greater than M, a milk sample having fat content below prescribed limit, food sample having a pesticide limit greater than the prescribed limit). Lot quality may be judged in terms of the acceptable percentage of defective items or the maximum number of defects (nonconformities) per hundred items, in respect of any type of defects.

Most acceptance sampling involves the evaluation of more than one quality characteristic, which may differ in importance with respect to quality and safety. Defects (nonconformities) are classified as follows, according to their degree of seriousness

Class A : Those considered to be of the highest concern in terms of the quality and / or safety of the product (such as health / safety-related properties see Table 2);

Class B : Those nonconformities considered to be less important than the Class A nonconformities (such as commodity defects or compositional characteristics, see Table 2).

THE ACCEPTABLE QUALITY LEVEL (AQL) AND LIMITING QUALITY (LQ) LEVEL

The inspection of a lot using either an attributes or variables sampling plan will allow a decision to be made on the quality of the lot.

The Acceptable Quality Level (AQL) for a given sampling plan is the rate of non-conforming items at which a lot will be rejected with a low probability, usually 5 %. AQL is used as an indexing criterion applied to a continuous series of lots which corresponds to a maximum rate of acceptable defective items in lots (or the maximum number of defective items per hundred items). This is a quality goal fixed by the profession.

Any value for AQL should be realistic in practice and be economically viable. If

necessary, the value of AQL should take into account safety aspects. The selection of a value for the AQL depends on the specific characteristic considered and of its relevance (safety or economic) for the standard in its whole. A risk analysis is generally undertaken to assess the possibility and severity of negative impacts on public health caused, for example, by the presence of additives, contaminants, residues, toxins or pathogenic micro-organisms in food products

The characteristics which may be linked to critical defects (for example to sanitary / hygiene risks, microbiological parameters) will have low AQL (i.e. 0,1 % to 0,65 %) whereas the compositional characteristics such as the fat, protein or water content can have higher AQL (e.g., 2,5 % or 6,5 % are values often used for milk products).

The Limiting Quality (LQ) for a given sampling plan is the rate of non-conforming items at which a lot will be accepted with a low probability, usually 10%. The LQ is applied when a lot is considered in isolation. It is a quality level (expressed, for example, as percentage nonconforming items in the lot) which corresponds to a specified and relatively low probability of acceptance of a lot having a rate of defective items of LQ. It is recommended that the LQ is set at least three times the desired AQL, in order to ensure that lots of acceptable quality have a reasonable probability of acceptance. The LQ is generally very low when the plans aim at the control of food safety criteria. It is often higher when the plans aim at the control of quality criteria, e.g. a low AQL (e.g. 0.65 %) being allocated to Class A nonconformities (e.g. pesticide content in follow-up milk), and a higher AQL (e.g. 6,5%) being allocated to Class B nonconformities (e.g. protein content in follow-up milk). If four samples must be collected, they can be taken simultaneously for practical reasons.

OPERATING CHARACTERISTIC CURVE (OC) : A MEASURE OF THE ACCEPTANCE SAMPLING PLAN

An important measure of the performance of the acceptance sampling plan is the OC curve. This curve plots the probability of accepting the lot versus the lot fraction that is defective. The OC curves are used extensively to determine acceptance or not. The OC curve shows the relationship between the quality and the per cent of lots expected to be acceptable for the quality characteristic inspected. In other words, the OC curve describes how well a sampling plan discriminates between good and bad lots. It is a plot of number of lot defectives against the probability that the sampling plan will accept the lot.

One possible single-sampling plan shown in Figure 5 is for sample size of 50 (n=50) and reject the lot if three or more nonconforming items are found. If two or less are found non-conforming it is accepted.

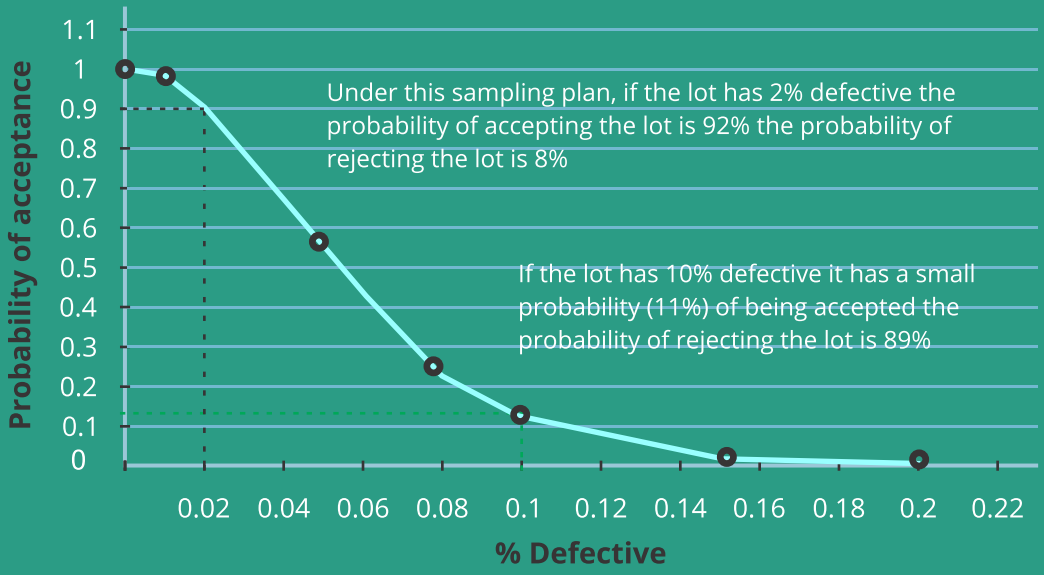


Figure 5 : Operation curve for a single-sampling plan where n=50 and c=2

CHOICE OF ACCEPTANCE SAMPLING PLAN

Selection of the right type of sampling plan is very important. The type of property measured also determines the seriousness of the outcome if the properties of the laboratory sample do not represent those of the lot. For example, if the property measured is the presence of a harmful substance (such as bacteria, glass or toxic chemicals), then the seriousness of the outcome if a mistake is made in the sampling is much greater than if the property measured is a quality parameter (such as fat, moisture color or texture). Therefore, the sampling plan has to be very rigorous for detection of potentially harmful substances than for quantification of quality parameters.

Attribute sampling plan can be used when evaluating isolated lots. Variable sampling plan can be used if a smaller number of parameters is to be assessed. Microbial assessment uses either two or three class attribute sampling plans. Lots for international trade are usually sampled by attributes. Various factors that must be considered for a systematic approach for the selection of a sampling plan based on the qualitative or quantitative characteristics of the sample (Table 1).

Selection of a recommended sampling plans for homogeneous bulk lots based on the characteristics of the sample (Table 1). The recommended sampling plans for commodity

defects and compositional characteristic are listed in Table 2. The sampling plan used for safety related characteristics (e.g. in the assessment of microbial spoilage, microbial hazards, irregularly occurring chemical contaminants, etc.) is shown in the flow chart (Figure 6). Essential points that should be considered when choosing sampling plans based on CODEX guidelines is show in Box 1.

Table 2: Recommended sampling plans for Qualitative and Quantitative characteristics

Qualitative Characteristics (e.g. commodity defects)		
Inspection Lot	Characteristic example	Sampling Plan
Isolated Lot	Aspects of a piece of fruit, or of a can for defects	Attribute sampling plan for isolated lots
Continuous series (Production stream)	Aspects of a piece of fruit, or of a can	Attribute sampling plans for continuous lots
Quantitative characteristics (e.g. Compositional characteristics)		
Isolated (Bulk lot)	fat content of milk in a tank	Variable sampling plans for an isolated lot.
Isolated (Items)	Sodium content of a dietary cheese	Attribute sampling plan for isolated lots
Continuous series (Bulk lot)	Fat content of milk in a tank.	Variable sampling plans for continuous lots
Continuous series (Items)	Sodium content of a dietary cheese	Attribute sampling plans for a continuous series
Adapted from General Guidelines on Sampling (CAC/GL 50-2004)		

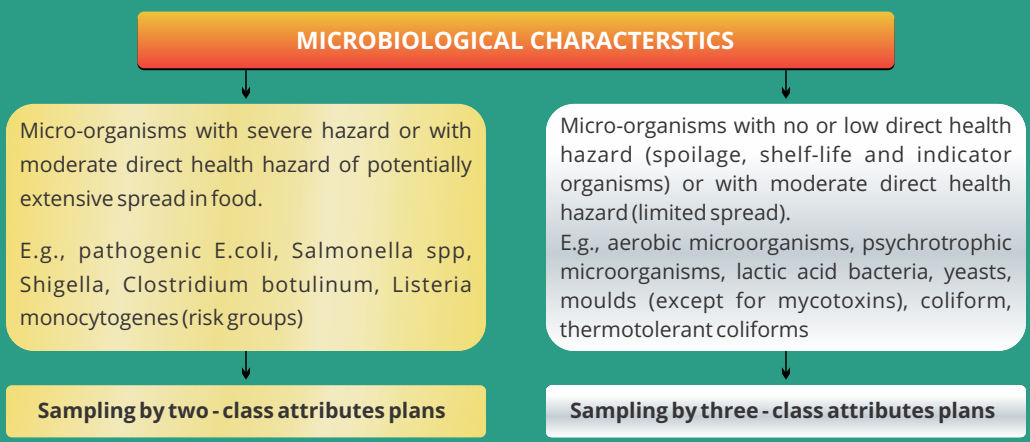


Figure 6 Flow diagram showing the recommended sampling plans used for microbiological analysis of foods

Box 1 : Recommendations for the selection of sampling plans

Essential points that should be considered for the selection of appropriate sampling plans

1. Existence (or not) of international reference documents on sampling of the considered products.
2. Nature of the control item of the lot;
    a. Characteristics applicable to each item of the lot
    b. Characteristics applicable to the whole lot (statistical approach).
3. Nature of characteristic to control
    I. Qualitative characteristic (characteristic measured on pass/failed or similar basis measured on a pass/failed or similar basis, i.e. presence of pathogen micro-organism);
    II. Quantitative characteristic (characteristic measured on a continuous scale, for example a compositional characteristic).
4. Choice of the quality level (AQL or LQ)
    I. In accordance with the principles laid down in the CODEX Manual of Procedures and with the type of risk: critical/non-critical non-conformities.
5. Nature of the lot
    I. Bulk of pre-packed commodities
    II. Size, homogeneity and distribution of the concerning the characteristic;
6. Control
    I. Composition of the sample
    II. Sample composed of single sampling unit
    III. Sample composed of more than one unit (including the composite sample).
7. Choice of the type of sampling plan

    Acceptance sampling for statistical quality control;
    a. For the control of the average of the characteristic;
    b. For the control of per cent non-conforming items in the lot
    c. Definition and enumeration of nonconforming items in the sample (attribute plans)
    d. "Comparison of the mean value of the items forming the sample with regards to an algebraic formula (variable plans)

Adapted from Methods of Analysis and Sampling

Source : The CODEX General Guidelines on Sampling-CAV/GL 50-2004 (FAO/WHO, 2004)

GENERAL PRINCIPLES FOR COLLECTING SAMPLE FOR LEGAL CONFORMANCE AND SURVEILLANCE

GENERAL PRINCIPLES

1. Samples should be taken in the presence of the Food Business Operator.
2. All sampling operations shall be carried out over a sufficiently short period of time so as to avoid any alteration in the composition of the samples.
3. Increments from each lot shall be mixed to give a bulk sample of an appropriate quantity. Laboratory samples are obtained by the successive division and reduction of the bulk sample.
4. Samples shall be as representative as possible of the lots from which they are taken. Therefore, as the composition of a lot is seldom uniform, a sufficient number of increments shall be taken and carefully mixed, thus giving a bulk sample from which, the laboratory samples are obtained by successive divisions or otherwise.
5. All manual sampling equipment and mechanical samplers used shall be clean, dry and free from foreign odours and made from material, which will not contaminate the commodity being sample. Manual equipment must be sterilized with 70% alcohol immediately before use. The metal tool should be dry before being used to collect samples.
6. Sampling shall be carried out in such a manner as to protect the samples, sampling instruments, and the containers in which the samples are placed, from environmental contamination.
7. All precautions to prevent contamination/deterioration of the commodity and damage to pre-packaged units must be adopted.

HEALTH AND SAFETY PRECAUTIONS

While sampling the following health and safety precautions must be adhered to:

a. Use of protective clothing (lab coat with long sleeves and buttoned up).
b. Wearing gloves and wash hands before and after sampling.
c. Use of eye protection (safety glasses/goggles/face shield).
d. Confining long hair (under a cap or tied and tucked into coat).
e. Use of face masks to protect from toxic fumes. In certain cases, the atmosphere can

be asphyxiating or toxic due to the build-up of gases from grain and fungal metabolism.

f. The sampler should have safe access to and egress from the place where the sample is taken, and the places where the samples are taken for storage.

g. The sample storage areas should have adequate light and ventilation and should be arranged to satisfy the requirements for safety as well as any special ones arising from the characteristics of the material being sampled.

h. Care should be taken to guard against collapse of stacked containers or solids in bulk.

TOOLS USED IN SAMPLING

All sampling tools must be designed and manufactured so as to serve their intended purpose and preserve the original characteristics of the sampled goods. Sampling tools must meet these general requirements:

1. They must be robust enough to withstand handling operations;
2. They must be easy to clean;
3. All parts must be made of materials resistant to:
    I. the effects of the goods being sampled (e.g. fruit acid or chemicals);
    II. the cleaning agents (e.g. bleach or surfactants);
    III. they must also conform to safety requirements.
4. They must also conform to safety requirements.

Sampling devices used for different food products depend on the physical form of the food (e.g liquid, powder, granules, seeds, grains etc.). These include:

Sampling liquids : vacuum pumps, dipping vessels, pipette-type samplers, sampling scoops, piston-tube samplers etc.

Sampling solids in powder or granulated form : spear samplers, tube-type samplers, zone samplers, sampling trowels, spiral samplers,

Sampling frozen goods : hand-drill samplers, etc.

Examples of few samplers are described below and representative pictures shown (Figure 7):

a) Stirrer (Plunger) : It is a device used for manual mixing in vessels. It contains a surface sufficient to produce adequate disturbance of the products for mixing liquids and

semi-solid products in large as well as small vessels. It is an equipment commonly used to mix the milk or cream to make it uniform in composition throughout the container or can. It is usually made up of stainless steel or aluminum or any metal which will not adversely react with the milk or any other dairy product. It consists of a disc containing several perforations. A long handle is fixed to it at the centre which helps in its to and fro movement in the milk or dairy product. Design of the container should be such that it should not damage the inner surface of the container during mixing.

b) Agitator: It is an apparatus used for mechanical agitation of the liquid or semi-solid products. Agitators are mostly provided with a propeller and are introduced into transport, tanks through the inspection port. Paddles agitators consist of usually flat blades attached to a vertical shaft and normally operated at low speed (100-rpm).

c) Dipper : This device consists of a small cup fixed to one end of a long handle and is mainly used to collect the sample from the container. The tapered form of the cup permits nesting of the dippers. The capacity of the dipper is usually 50 ml.

d) Tube Samplers : The tube samplers are advantageous in that a representative sample can be obtained regardless of how long the milk has stood before sampling. A column of milk which represents the milk from top to bottom of the container is collected as sample.

e) Piston-tube sampler : Syringe-like sampler consisting of a body and a piston. Made from PTFE or polypropylene (PP) with a stainless-steel connecting rod. The piston-tube sampler has three different uses: (i) it can be used like a large syringe to suck in liquids of medium viscosity; (ii) it can be transformed by a slight adjustment into a pipette which is especially suitable for drawing of aggressive liquids or foodstuffs; or (iii) thick or semi-solid materials may be sampled when the end is removed and the sampler is inserted into the material. After withdrawal the contents of the sampler are pushed out into a wide mouth container using the piston. It can be used for liquids, oils, emulsions, pastes

f) Borers : The borers are used for sampling of powdered products. For example, milk powder, flour etc. It should be made entirely of polished stainless steel. The protruding borer edge and point should be sufficiently sharp to serve as a scraper and to facilitate sampling.

g) Sampling Trowel (Sampling scoop/hand scoop) : Trowel are made from plastics (PP) or metal (stainless steel), of variable volumes and different handle lengths. Sampling of solids such as grain, free flowing powders and granules.

h) Spiral screw sampler : the sampler consists of a robust spiral body and a handle made from metal (stainless steel). Usual dimensions: lengths from 35 cm, diameter up to 3 cm.

The spiral sampler is pressed into the sampled material by pushing and twisting, which ensures the sample is loaded into the spiral. The sampler is then withdrawn and the sample is scraped off by a spatula or scraper into the wide mouth container. Used for paste-like foodstuffs such as peanut butter vegetable or animal fat, jam or honey.

i) Sampler for frozen foods (ice borer) : The sampler consists of two parts: a borer and a borer head (sampling cylinder) The sampling cylinder is detachable. The sampler operates on the principle of a screw: the sampler screws into the sample material and simultaneously extracts and conveys the sample into the sampling cylinder. Sampling from frozen and deep-frozen materials and semi-solid substances e.g Deep-frozen goods such as meat or fruit juice concentrates

j) Hand drill sampler : (Conical sampler, tubular sampler): Conical or tubular hand drill with sharp cutting edges and a solid handle, drilling depth 13 cm. Taking samples from soft and semi-solid materials. The sampler into is inserted into the material diagonally taking care drill does not touch the bottom. Then a half turn is made with the drill and pulled out of the sample. The upper approx. 2.5 cm of sampled material is removed. Useful for cheese, butter, cottage cheese paneer, solidified oils etc.

k) Spear-type sampler : this is a metal or plastic sampler. Made of stainless steel or polypropylene (PP). Usually equipped with a telescopic rod. Used for taking direct samples of bulk goods from sacks, bags or plastic drums, if these goods are in powder or granulated form. The sampler is introduced into the product by piercing the packaging. When the desired zone is reached the sample, chamber is opened using the telescopic handle. As soon as the probe is filled with the sample, the spike of the probe is screwed shut, the spike is withdrawn, and the sample is transferred into a wide mouth container. The hole in the packaging must be closed using tape or a sticker (or a control seal). Also suitable for vertical zone sampling of free-flowing materials such as grain, sugar, flour, semolina, milk powder.

l) Zone sampler : The zone sampler is a metal spear-type sampler with a body having several openings (closed chambers) along its length. The sampler has a robust body made of stainless steel or anodised aluminium. Useful for taking of samples from bulk goods in transport containers, big bags, silos and tanks or goods packed in bags, sacks, barrels or drums. It is suitable for both very fine powders, granules and coarse grains, semolina and nuts. Sampling is possible up to a depth of 2.5 metres. Used for cross-sectional sampling. The zone sampler of appropriate length is introduced into the material at different angles. Samples can be taken from several depths at the same time. In this way, you can check visually whether the product is homogenous throughout its entire volume. Example of samplers used

in bulk sampling are shown in Figure 8.

Spoons, scalpels, spatula, scoops, knives made up of stainless steel etc are used for solid and semi solid products. Other versatile tools may be useful for sampling, for example knives, stainless steel axes, scissors, swabs forceps, tongs, cleaning brushes and flashlights etc.

m) Sampling by hand : This method is appropriate for all species of grains, legumes, oilseeds etc. Moreover, it is potentially the most suitable method for seed that could get damaged using triers, seeds with wings, seeds with low moisture content. Hands must be washed and the procedure carried out wearing gloves. The open hand is pushed into the container, hand with seeds inside is closed and then hand is withdrawn, taking great care that fingers remain tightly closed around the seeds to prevent escape (Figure 9).

SAMPLE CONTAINERS

Where foods are in retail packaging, the whole retail packages is the sample. Where goods that are in bulk or in wholesale packages smaller samples must be taken. It is important that the correct type of storage container is used for the foodstuff sampled. the container used for packing samples taken must meet the following requirements:

I. it must not be affected by the sample (especially important for foodstuffs which may be acidic, etc.);

II. it must ensure that the quality (integrity) of samples is maintained;

III. it must be designed and manufactured in a way that allows leak-proof or air-tight closure;

IV. it must be strong enough to withstand transport and storage;

V. it must be designed to ensure proper sealing and preclude unauthorised handling.

The packaging material recommended for food stuff are: Paper bags, Polyethylene (PE) and polypropylene (PP) bags, bottles, Glass jars, etc (Table 3). The stoppers and caps used for closing the sample holders (bottles/containers) must ensure a tight seal to prevent any leakage or evaporation of the samples. The material of which the containers and stoppers are made must not be susceptible to chemical attack by the samples and must not interact with or contaminate them. Depending on the nature of samples taken, cork plugs, crown caps, plastic or metal screw caps can be used. If cork plugs are used, they should be wrapped in polyethylene before closure. The use of rubber plugs is prohibited.

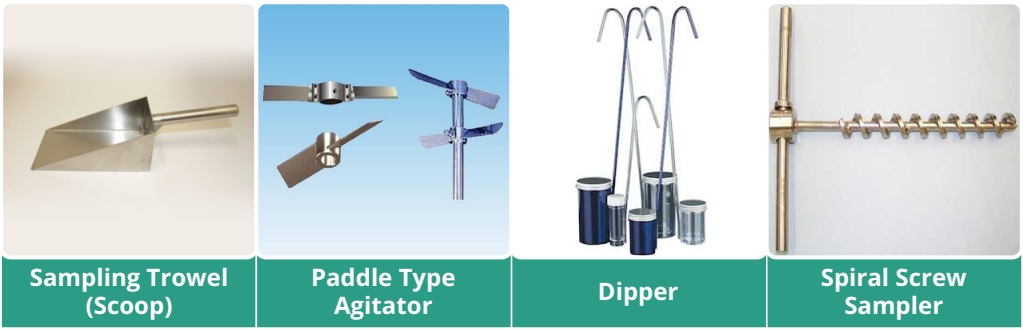


Figure-7 : Sampling devices used in the bulk sampling of food

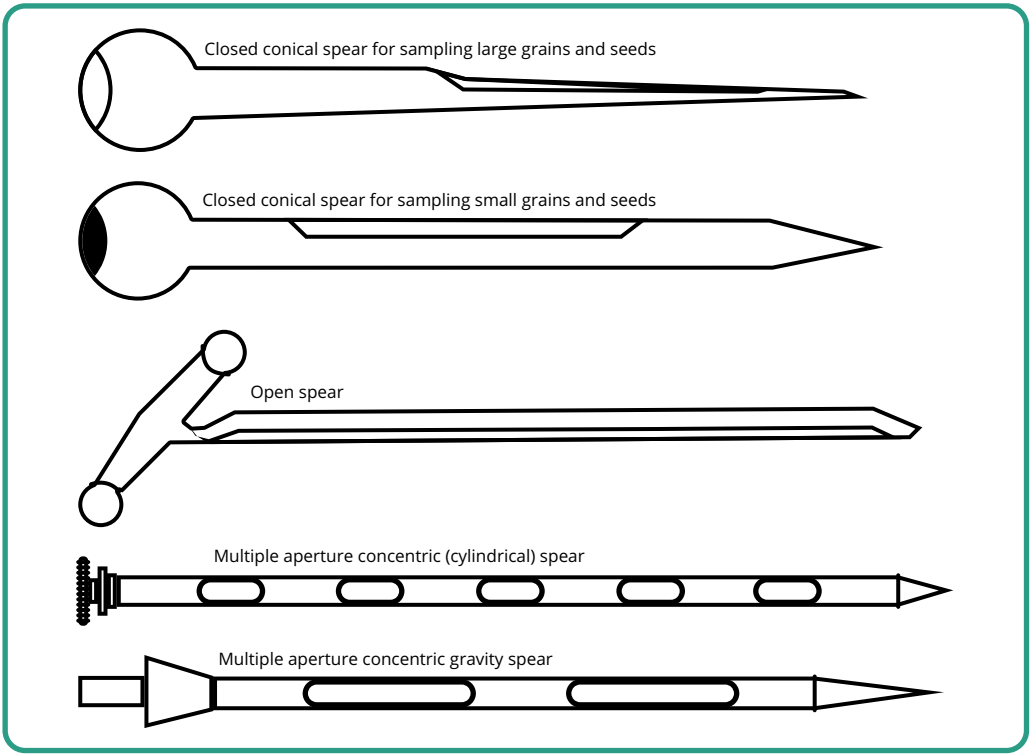


Figure-8 : Schematic of apparatus for use in sampling of stationary lots in bulk and bags

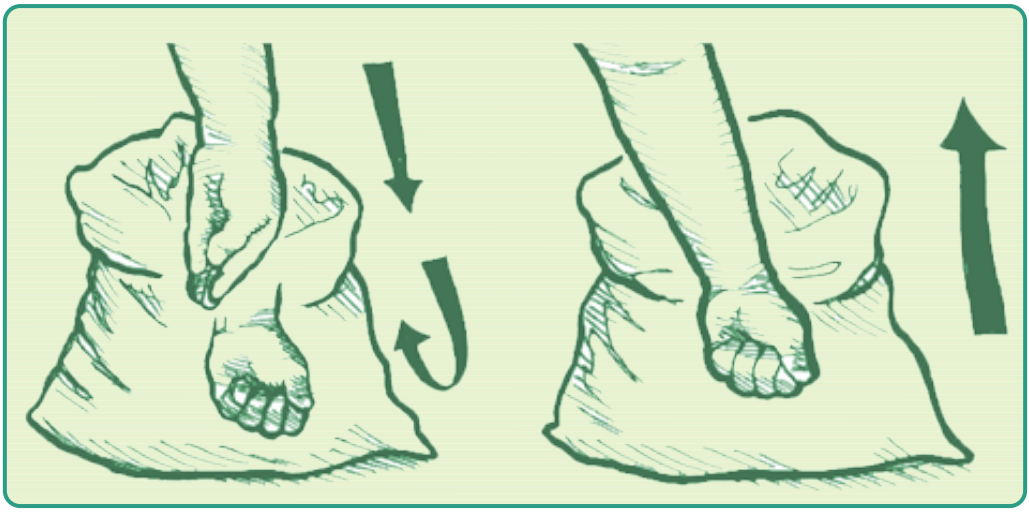
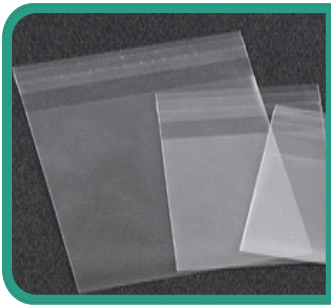


Figure 9 Schematic of sampling by hand

Adapted from Seeds Toolkit Module 3 : Seed Quality Assurance. Published by The Food and Agriculture Organization of the United Nations and Africa Seeds Rome, 2018.

Table-3 : List of containers recommended for collecting food sampled in bulk



- Food taken in form of pieces such as confectionary, chewing gum, chocolates etc.
- Food in their retail sale packages
- Dried fruit and nuts
- Grains (wheat, rice etc)
- Pulses, oilseeds
- flour, semolina
- sugar
- starch
- coffee powder, tea leaves

Non-volatile liquids, such as:

- High valued foods (Whole Spices, saffron)
- Vegetable oils
- Juices and syrups
- Non-alcoholic beverages

Powdered and granulated materials or pastes, such as:
- Jam
- Sugar
- Starch
- Instant beverages
- Granulated tea
- Solidified vegetable oils and fats
- Semolina
- Soya Grits

- Cereals and grains,
- Legumes and pulses
- Oilseeds

- Milk and cream
- Light sensitive oils (e.g olive oil)
- Alcoholic beverages

SAMPLING PROCEDURE TO BE FOLLOWED FOR COLLECTING SAMPLE

The persons responsible for drawing the samples should:

- Check all the available information about the commodities/retail packages etc. to be sampled and determine what quantities should be sampled. See also minimum size of samples as listed in the FSS Rules and Regulations, 2011.
- A representative sample from the lot should be collected

REPRESENTATIVE SAMPLING PROCEDURE

Probability sampling deals with the selection of a representative sample from a lot based on chance eliminating human bias. The probability of including any item in the sample is known and the sampling error can be calculated. Probability sampling uses some form of random selection (Figure 10). In a random selection method, the analyst must set up some process or procedure that assures that the different units in the sample population have

equal probabilities of being chosen. The following are the most common probability sampling techniques:-

Simple random sampling : In this case, the number of units in the population are known. Each unit is assigned an identification number and a certain number of these identification numbers are selected according to the sample size by using random number tables or computer-generated random numbers. The sample size is determined according to the lot size. The units selected randomly are analysed, and the results are taken as the estimate of the lot. A simple random sample is meant to be an unbiased representation of a group. Example of how to get a simple random sample: put 100 numbered small apples into a basket (this is the population N). Select 10 apples from the basket without looking (this is your sample n). Note that it's important not to look as you could (unknowingly) bias the sample. Simple random sampling is useful when the lot size is small.

Since we know the sample size (n) and the lot (N) and it becomes a simple matter of division : n/N x 100 or 10/100 x 100 = 10%

This means that every apple in basket has a 10% or 1 in 10 chance of being selected using this method.

Systematic sampling : If a systematic pattern is introduced into random sampling, it is referred to as "systematic (random) sampling". For instance, if the pre-packaged foods (Biscuit packet) in a store are arranged in such a way that numbers can be attached ranging from 0001 to 1000. Choose a random starting point, e.g. 25, and then pick every 25th packet thereafter (25, 50, 75, 100.....1000) to give a sample of 40.

This method is also used when a complete list of sample units is not available, but when samples are distributed evenly over time or space, such as on a production line. The first unit is selected at random followed by every n th unit after that or at regular time intervals (8h, 16h, 24h.....nth h).

Stratified sampling : If the lot is widely dispersed, it may be extremely costly to reach them or perhaps, the lot is not homogeneous and the sub-groups are very different in size. In such a case, precision can be increased through stratified sampling.

The segments are based on some predetermined criteria such as geographic location, size or demographic characteristic. Stratified sampling involves dividing the population (size N) into a certain number of mutually exclusive homogeneous subgroups (size N1, N2, N3, etc.) or strata. Random samples are obtained from each or stratum. This can be used only when subpopulations of similar characteristics can be observed within the whole

population. Let us consider a company that produces tomato juice in different plants. If the residual activity of poly galacturonase in tomato juice produced in a particular day is to be evaluated, we can stratify the samples from various batches of each production plant into a subgroup and then select samples from each subgroup for analysis.

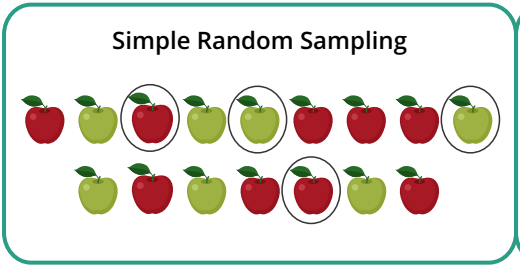
Cluster sampling : In cluster sampling also, the population is divided into subgroups or clusters followed by randomly selecting only a certain number of clusters for analysis. The main difference between cluster sampling and stratified sampling is that in the latter samples are taken from every single subgroup, while in cluster sampling only randomly selected clusters are sampled. The clusters selected for sampling may be either totally inspected or subsampled for analysis. This sampling method is more efficient and less expensive than simple random sampling, provided clustering is possible. Considering the above said tomato juice example, when using cluster sampling we would group them similar to the previous case, but we would select randomly just a few subgroups for the purpose of study.

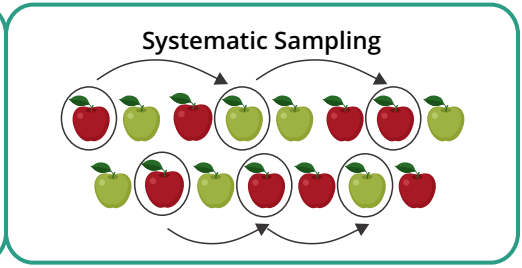
Composite (Bulk) sampling : This is used to obtain samples from bagged products such as flour, seeds, and larger items in bulk. Small aliquots are taken from different bags, or containers, and combined into a single sample (the composite (Bulk sample) that is used for analysis after mass reduction. Collecting the sample can be at random (Figure 11) or systematic (Figure 12).

Composite sampling can also be used when a representative sample of a whole production day in a continuous process is needed. Equal aliquots are taken at different times (random or regular), and then a representative sample is obtained by mixing the individual aliquots. A typical example of composite sampling is a sampling plan for nutritional labelling. A composite of 12 samples with at least six subsamples are taken and analysed for compliance with nutrition labelling regulations.

SAMPLING FROM A STATIONARY LOT OF BULK GRAIN

Unless otherwise specified consignments shall be considered in lots of a maximum of 500 tonnes or such part thereof as constitutes a single consignment (Table 4).





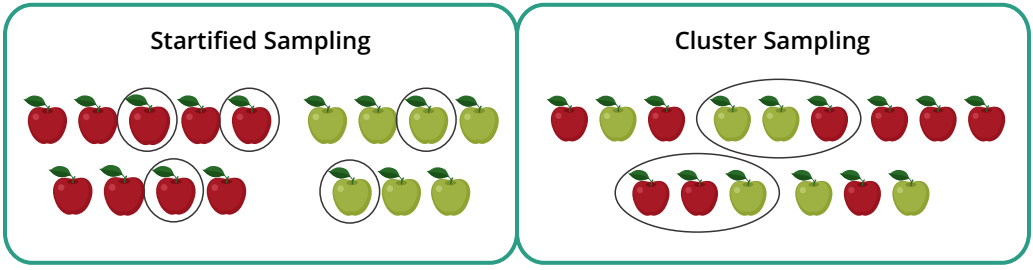


Figure-10 : Schematic of for taking a representative sample.

(Adapted from **https://www.scribbr.com/methodology/sampling-methods/** accessed on 7th September, 2020).

Figure-11 : Schematic of taking a representative sample by simple random sampling.

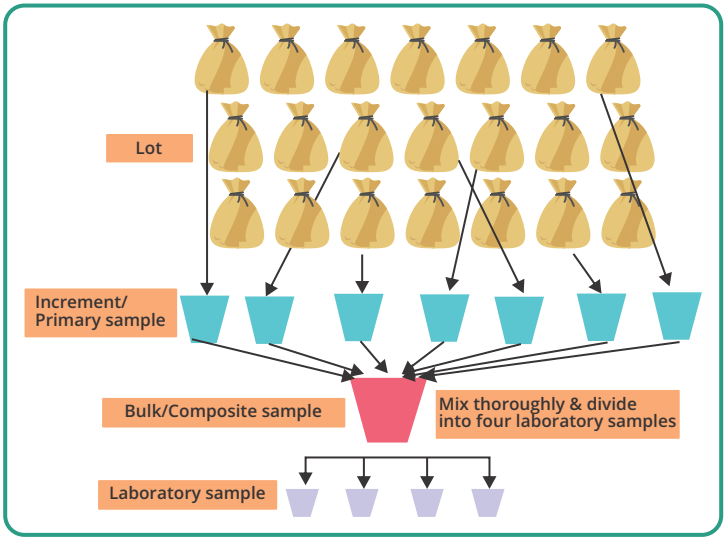


Figure-12 : Schematic of taking a representative sample by simple systematic sampling.

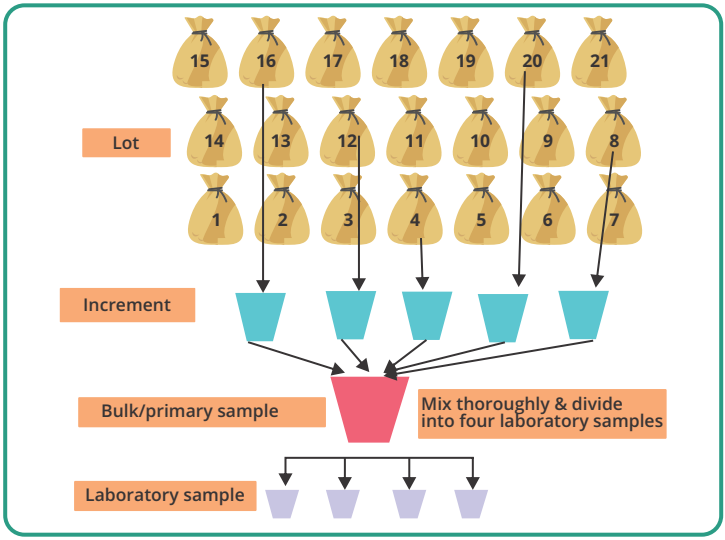


Table - 4 : Number of increments for sampling stationary lots of bulk grain, pulses and oilseeds up to 500 tonnes.

Lot size (tonnes)	Size of the bulk sample (kg)*	Number of increments for the production of the bulk sample
≤50	5	10
75	7.5	15
100	10	20
200	20	40
250	25	50
≥500	50	100

**In case of lots from 50 to 500 tonnes, the size of the bulk sample should be 0.01% of the total lot size. In case of lots smaller than 50 tonnes, the size of the bulk sample should be 5 kg. In case of lots larger than 500 tonnes, the size of the bulk sample should be 50 kg.*

SAMPLING FROM BAGS, SACKS, TOTE BINS AND RIGID CONTAINERS

This procedure is for free-flowing material such as grain, pulses, oilseeds and products such as flour, sugar, semolina, grits, Dalia etc. For lots in containers holding up to and including 100 kg, the sampling intensity is as follows:-

- For containers/bags holding between 15 kg and 100 kg (inclusive) of seed, the number of increments according to Table 5.
- For containers holding less than 15 kg of seed/grain, containers must be combined into sampling units not exceeding 100 kg, e.g. 20 containers of 5 kg, 33 containers of 3 kg or 100 containers of 1 kg. The sampling units must be regarded as containers as described in Table 6.

Increments should be taken from different parts of a bag/container (for example top, middle and bottom) by means of a sack/bag spear (Figure 13) from the number of bags/containers specified in Table 6.

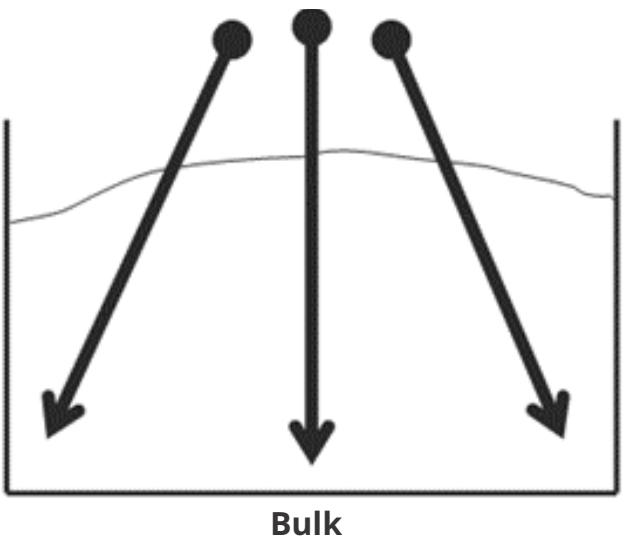


Figure 13: Schematic of taking increment from a sack or bag.

Table-6 : Number of bags/rigid containers of holding up to and including 100 kg of free-flowing grain, pulses, oilseeds and semolina sugar etc. to be sampled.

Number of bags / containers in consignment	Minimum number of increments#	Approximate Size of bulk sample (kg)
1-4	3 increments from each container/bag	For 50 to 500 tonnes, the size of the bulk sample should be 0.01 % of the total lot size. In case of lot sizes smaller than 50 tonnes, the size of the bulk sample should be 5 kg. In case of lot sizes larger than 500 tonnes, the size of the bulk sample should be 50 kg.
5-8	2 increments from each container/bag	
9-15	1 increment from each container/bag	
16-30	15 increments, one each from 15 different containers.	
31-59	20 increments, one each from 20 different containers	
60 or more	30 increments, one each from 30 different containers	

#At each sampling point (static sampling) the increment quantity should be decided and collected. All increments must be of equal size. Containers or bags chosen at random.

Table-7 : Minimum number of increments to be taken from lots in bags/containers holding more than 100 kg of products per bag.

Lot size per bag/container	Minimum number of increments	Approximate Size of bulk sample (kg)
Up to 500 kg	At least five	10
501-3000 kg	One increment for each 300 kg, but not less than five	10
3001- 20,000 kg	One increment for each 500 kg, but not less than 10	10
20001 kg and above	One increment for each 700 kg, but not less than 40	20

When sampling seed in containers, holding more than 100 kg of seed per bag / container, the sampling intensity according to Table-7 is regarded as the minimum requirement.

SAMPLING FROM CARTONS CONTAINING PRE-PACKAGED UNITS OF GRAINS / SUGAR / FLOUR / SEMOLINA ETC.

Pre-packed units are usually place in outer cases or cartons containing a convenient number of units. The procedure shown in Table 8 shall be used to determine the appropriate number of outer cases or cartons to be sampled.

Care shall be taken to ensure that a prepacked unit is taken in a random manner from the entire contents of the case or carton for sampling. The selection of prepacked units occupying the same corresponding position in a number of cases or cartons shall be avoided. Each prepacked unit taken in this manner shall be considered as increments

Table-8 : Number of cartons containing pre-packaged food products such as cereals, pulses, flour, sugar etc.

Number of cartons in consignment	Minimum number of prepacked units to be taken as an increment
1-10	One from each carton
11-100	10, taken at random
>100	Square root (approx.) of total number, taken according to a suitable sampling scheme. (e.g see Box 2)
The cartons are chosen at random.	

SAMPLING PROCEDURES FOR RETAIL PACKAGES

Box 2. Sampling scheme for consignments of more than 100 cartons containing packaged grain/ oilseeds/flour/sugar/semolina etc.

The consignment shall be divided into (n-1) group containing n or (n-1) cartons; the remaining cartons constitute a group

EXAMPLE 1: A consignment comprising 200 cartons

The square root of 200 = 14.142, therefore n=14

Make 14 groups of 14 bags (i.e total of 196 cartons);

Draw up a list from 1 to 14; cross out one number, for example 7;

sample the 7th carton from each group of 14;

the remaining group (i.e. 4) is smaller than 14, sample one bag from this group at random.

A total of 14 cartons has therefore been selected. Take one packaged unit from each carton

EXAMPLE 2 : A consignment comprising 1200 cartons

The square root of 1200 = 34.64, therefore n=35

Make 34 groups of 34 cartons each (i.e. total of 1190 cartons);

Draw up a list from 1 to 34; cross out one number, for example 12;

Sample the 12th carton from each group of 34 cartons;

The remaining group (i.e. 10) is smaller than 34 cartons, sample one carton from this group at random.

A total of 35 cartons has therefore been selected. Take one packaged unit of grain from each

Retail packages are defined as packages where the weight of the smallest individual pack within the consignment does not usually exceed 5 L or 5 kg, i.e. various cans, bottles, jars and bags. Several retail packages may be packed in a case.

A retail package should be considered to be any pack specifically prepared for direct sale to an individual for domestic use. The quantity could be as small as 10–25 g as in herbs and spices. For other commodities it will usually mean a package of between 100 g and 2 kg (or 2 L).

In any consignment, all the retail packages in the packing case must be of the same size containing material of the same type, style, and grade shall constitute a lot. The number of packing cases to be selected from a lot for drawing the samples shall depend on the size of the lot and shall be in accordance with Table 9. Depending on the quantity in the consignment, the recommended minimum number of packing cases to be sampled for the purpose of creating a bulk sample is shown in Table-9 and Box 3.

Table-9 : Number of packing cases of retail packages to be sampled.

Lot size (number of packing cases)	Recommended number of packing cases to be sampled	Recommended number of individual units to be selected
1- 200	3	6
201-300	4	8
301-500	5	10
501-800	6	12
801-1300	7	14
1301-3200	8	16
>3201	10	20
Adapted from IS : 2860 ·1984 Reaffirmed 2008 Methods of Sampling and Test for Processed Fruits and Vegetables.		

Where the retail packages are not packed in a case (e.g. on the shelf of a grocery store), follow Table 9 where column 1 represents number of individual retail packages (e.g. if the lot contains 250 packs of potato chips/biscuits the sample collected will be 8 packs). Where the packages are small, ensure that the final sample is at least 250 g.

The consignment must be homogeneous (all packages have the same label, content, net weight or volume, production or batch number and/or expiry date). In principle the minimum amount/weight of identical final samples, required by the laboratory, should be enough.

Where there is any doubt over the uniformity of the packages, for example where there are visible differences between the contents, you must take additional packages in excess of the quantity required to ensure your sample is representative. The articles of high

value are usually sampled as one representative piece

Different lots must be sampled separately. Labels on the packing may indicate whether the consignment contains different production batches or dates, and whether the products in different lots vary in quality. The integrity of packages and the expiry date must always be examined. Retail packages and finished articles taken as samples must not be opened or their contents moved to other sample containers.

Precautions must be taken to avoid erasing or concealing the information on the original packing. Your label should not cover the commercial labels of the original product (trademark, manufacturer, content, expiry date, duty stamps etc.). It is recommended that sampled retail packages are placed in a plastic bag or paper box and that the labels and seals are fixed to the bag or box.

Box 3. Sampling scheme for retail packages

Arrange all the packing cases in a systematic manner and count them as 1, 2, 3, 4, 5.....etc., up to r and so on. Every rth case so counted shall be withdrawn,

r being the integral part of N/n

where

N= total number or cases in the lot

n= number of cases to be chosen (column 2 of Table 9)

if, r is a fractional number, its value should be taken as equal to its integral part.

From each of the packing cases selected two units shall be drawn at random so as to get the total number of cans from the lot as shown in 'col 3 of Table 6.

EXAMPLE A consignment comprising 1200 cases of packaged breakfast cereal.

r = 1200/7 = 171.43

r = 171

Arrange the packing cases in rows

Select one packing case for every 171 cases

e.g. 20th, 191st, 362nd, 533rd, 704th, 875th, 104th

Take 2 packets of cereal from each of these cases to get 14 unit packs.

PROCESS OF PREPARING A BULK SAMPLE

The process of getting a bulk (composite) sample from a lot involves 1) drawing increments on random or systematic basis from various locations of the lot and mixing them together to form a homogeneous sample and 2) dividing this homogenous composite sample into four representative samples to initiate the process of legal compliance to FSS Rules and Regulations, 2011.

DRAWING INCREMENTS

When taking the number and/or the size of increment, besides meeting the minimum sampling intensity the FSO must ensure that the bulk sample is sufficient to make four laboratory samples, where one is sent to the primary testing laboratory and three samples are stored if requested and/or for dispute resolution

Increments of approximately equal size must be taken, irrespective of where in the lot or container it is taken (e.g. if a minimum of 10 increments are to be taken, all the ten increment must be of the same size e.g 1 kg each)). Taking different size increments is not acceptable

When the food product is in containers/bags, the containers to be sampled must be selected at random or according to a systematic plan throughout the lot. Increments must be drawn from the top, middle and bottom of containers. For bags follow the directions shown in Figure 11 &12. Containers/bags must be opened or pierced for collecting the increments. After collecting the sample, they must then be closed or the contents transferred to new containers.

The sampling equipment used must neither damage the product nor select according to seed size, shape, density, chaffiness or any other quality trait. All sampling apparatus must be sterilised before use to prevent cross contaminations. Triers used must be long enough so that the opening at the tip reaches at least half of the diameter of the container. When the container is not accessible from opposite sides, the trier must be long enough to reach the opposite end. Taking more increments increases the confidence level that the bulk sample accurately represents the original lot.

At each sampling interval (systematic sampling) or sampling point (static sampling) an increment a minimum of 1 kg can be collected used to make the bulk sample. The bulk sample prepared by combining all the individual increments and mixing them thoroughly. Divide the bulk sample to obtain four numbers of laboratory samples by using one of the sample dividers described below.

SAMPLE DIVISION

When a number of incremental samples have been taken and a large bulk sample created, a sample divider may be used to reduce the total sample size. For example, 10 kg of bulk sample grain may be reduced to two equal portions of 5 kg. Each 5 kg may be divided to get four samples of 2.5 kg. Which on further dividing provides eight x 1.25 kg samples. Repeated use can further reduce the size of the sample until an appropriate quantity for the final samples is reached.

The following sample dividers can be used:-

- Coning and Quartering rods
- Riffle splitter
- Centrifugal divider
- Boerner Divider

Coning and quartering rods : Mix the sample thoroughly on a clean non-absorbent surface. Draw the grain into a conical heap. Flatten the top of the heap and divide into quarters using iron rods. Reject the two diagonally opposite quarters and mix the remaining two (Figure 14). Repeat the complete process until the required laboratory sample is obtained.

Riffle Splitter : A riffle splitter (sometimes known as a Jones splitter) is a mechanical device with a series of alternating chutes that deposit one-half of the sample into one discharge bin and the other half into a second bin. The basic components of a riffle splitter include the scoop, an even number of chutes, or riffles, and a pair of collection pans (Figure 15A). The method is limited to free-flowing samples. Riffle splitters utilize multiple fractions (chutes), increasing the number of increments in each round.

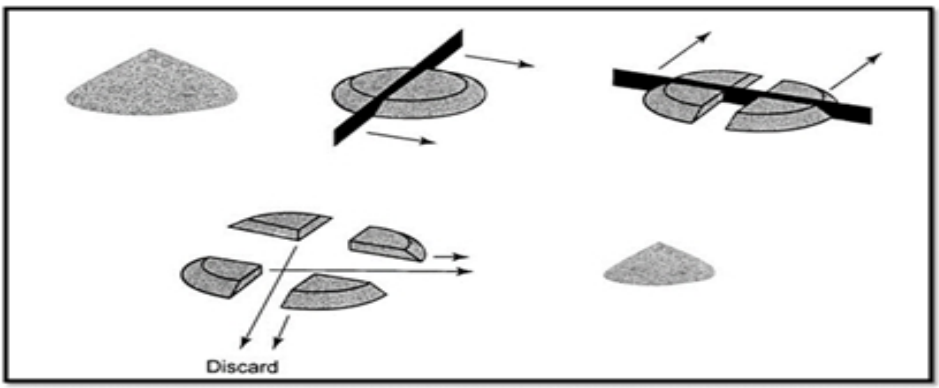


Figure -14: Coning and quartering

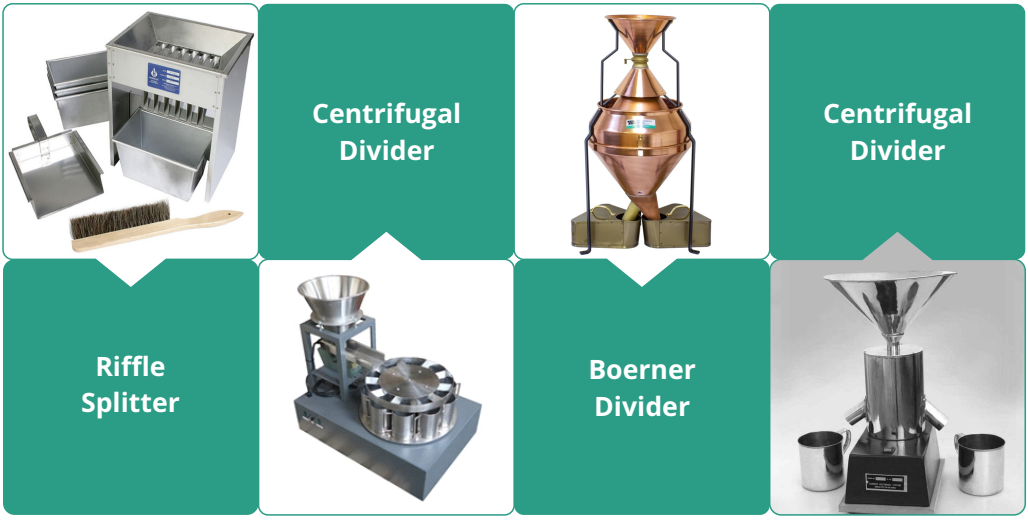


Figure-15 : Devices used to divide and prepare a representative laboratory sample from the bulk sample.

Riffle splitters can perform well, but the results rely on the skill and training of the operator. The sample needs to be fed into the riffle splitter.

Centrifugal divider : this is another very useful sample divider, which uses centrifugal force to mix and scatter the material over the dividing surface. In this divider the material flow downwards through a hopper into a shallow disc. When this disc is rotated by an electric motor the material is thrown out by centrifugal force and fall downward. The circle or the area where the material falls is equally divided into two parts by a stationery baffle so that one half fall into one spout and another half in another spout.

Boerner Divider : is an apparatus that divides a composite sample into two equal representative samples with gravity. The Boerner Divider is calibrated to provide accurate splits of + /– 1% on a 1000g sample. The sample is placed in the hopper and then released by moving a valve or slide gate located in the hopper throat. The grain through gravity is evenly dispersed over a cone that has 38 pockets or openings. The grain falling down the sides of the cone is cut into 38 separate streams and all these steams re-joins into two streams and empties into the two pans at the bottom. Since the composite sample passes through 38 different streams to later join into two separate streams, it results into two accurate representative samples that are then collected in two pans for further processing.

PREPARING THE LABORATORY SAMPLE FROM BULK SAMPLE

Quantity of Sample : the sample finally submitted to the laboratory by the FSO is

described as the laboratory sample and will take the form of one of the four samples prepared from the Bulk sample. The bulk sample shall be divided to obtain the required number of laboratory samples by use of the apparatus described above.

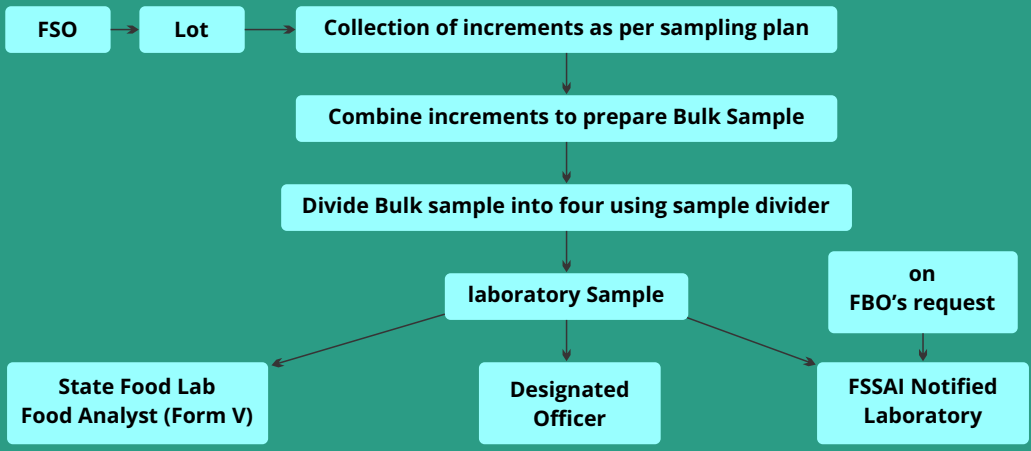


Figure-16 : Flow chart of sampling procedure for preparing a laboratory sample for chemical and physical analysis.

The minimum amount of sample that needs to be collected from the bulk sample for chemical and physical analysis other than microbiological analysis is defined in the FSS Rules and Regulations. The minimum quantity of sample to be sent to the laboratory is listed in Table 10. The FSO must ensure that he prepares four replicates of the sample for analysis and archiving as shown in flow chart (Figure 16).

Sample Integrity : Samples are collected and packaged in a manner that preserves the sample and the analytes of interest and assures that no significant change in composition occurs from the moment of sampling until the analysis is complete. Procedures assure that sample or analyte contamination or degradation does not occur. Suitable containers and storage temperatures are chosen to assure sample integrity. (For example, plastic packaging or permanent markers may interfere with pesticide or hydrocarbon analysis while foil packaging may interfere with metals analysis. Vitamins may degrade in sunlight. Some samples are frozen. Some samples require the use of a preservative to retain the analytes of interest.)

Transportation : A large amount of time and effort is wasted if the sample arrives in a state which is unfit for the analysis. Samples should be transported in a manner that prevents deterioration of the sample matrix or contamination of the sample and preserves the analytes

of interest. All samples are handled, packaged, temperature controlled and transported to prevent compromising the identity or integrity of the sample. Samples are packed with shock absorbing materials to protect against breakage of containers or damage to seals.

Frozen samples should remain frozen; perishable products may be frozen, if freezing does not interfere with the planned analysis; products requiring refrigeration (e.g., ice cream, meat and poultry for bacteriological analysis) are shipped with ice packs or in dry ice. e.g. For frozen samples, pre-chill sterile containers before use and keep frozen with dry ice. Use ordinary ice or ice packs for holding and transporting unfrozen samples that require refrigeration.

Laboratory samples should be individually wrapped to avoid cross contamination during transport. Samples for microbiological examination should remain aseptic. Even if the sampled food arrives in good condition, transportation conditions should be controlled to assure the analyte of interest does not deteriorate in transit.

ASEPTIC SAMPLING FOR MICROBIOLOGICAL ANALYSIS

Aseptic sampling is a technique used to prevent contamination by the sampling method. Aseptic sampling involves the use of sterile sampling implements and containers. Samples are collected and submitted in a manner which will prevent multiplication or undue reduction of the bacterial population. Contamination from atmospheric conditions or handling is prevented. Controls of the sterile containers, gloves and other sampling equipment are submitted with samples to verify the sterility of the technique and the environmental conditions during the timeframe of sampling. Samples collected using aseptic technique permit testimony that the microbiological findings accurately reflect the condition of the lot at the time of sampling and, ideally, at the completion of manufacture.

RECOMMENDED ASEPTIC TECHNIQUES FOR COLLECTING SAMPLES FOR MICROBIOLOGICAL ANALYSIS

When collecting samples for microbiology analysis use aseptic sampling procedures:

a. Use only sterile equipment and containers, and properly re-sterilize sampling tools before using them again. Wiping with 70 % alcohol is recommended.

b. Make contact with the source material and the sample only with the sampling tool or the container not with your hands.

c. Use sterile gloves if a sample must be touched with the hands. An aseptic sample should not be touched with bare hands.

d. Minimize exposure of the product, sampling equipment, and the interior of sampling containers to the environment. For example, avoid collecting samples in areas where dust or atmospheric conditions may contaminate the sample.

e. When opening sterile sampling containers, work rapidly. Open sterile sampling containers only to admit the sample and close it immediately. Do not touch the inside of the sterile container, lip, or lid.

f. Avoid unnecessary contact. The sample and sampling tool should not contact the interior, lip, or lid of the sterile container.

Have the following materials on hand prior to collection of samples:

- Permanent felt marker for labelling samples.
- An extra bag to put garbage/waste in as you sample, as some of the sampling "kits" may have to use disposables forceps, inner bags etc.
- Sample sheet / forms / notebook to record product information.
- Appropriate clothing: clean gloves, clean lab coat, steel-toe safety boots, hair net, safety glasses etc.
- Cooler with ice packs or dry ice

PROCEDURE COLLECTION OF FOOD SAMPLES FOR MICROBIOLOGICAL ANALYSIS

- Wash your hands before you start with the sample collection.
- Collect all samples aseptically so as to not contaminate the sample.
- Wear clean gloves, clean lab coat, hair net.
- Collect FIFTEEN (where n=5) or FORTY-FIVE (where n=15) sample units per lot unless otherwise specified in Appendix B.
- Select a systematic or random sample from the lot.
- Each sample unit should be at least 250 g of intact, whole food sample in the form in which it will be sold or distributed.
- Unopened, original containers should be sampled, when possible.
- A sample unit will consist of more than one container when the lot consists of containers smaller than 250 g. e.g. three of ~100 g containers in each sample unit
- Place each food sample unit into a separate sterile sealable bag or clean plastic bag.

- Make sure that the top of the bag is adequately closed.
- Label the outside of the bag with detailed information that will identify each sample unit, including:
    I. Collection date and time
    II. Name of the facility and FSSAI Licence/registration number
    III. Lot size and number
    IV. Name of the product and type of food (including specific details, such as brand name and product type, the way it is processed or specific ingredients which will separate it from other similar products)
    V. Sample unit weight
    VI. Production date/Batch Number and Code
    VII. Name of the FSO that collected the sample

- Use new sample bag for each sample unit.
- Include the sample sheet/lab requisition form in a separate plastic bag with the sample.
- Place the food samples into a clean and sanitized cooler with ice packs.
- Keep the samples at refrigeration temperatures (i.e. 0 to 4°C) and bring them or ship the cooler to the laboratory as soon as possible.
- The temperature of refrigerated samples must not exceed 7°C upon its arrival at the laboratory.
- Samples must be analysed within 24 h of sampling.
- Do not freeze the samples unless laboratory has been consulted or it is a frozen food.

The food sample should be taken as per food category and micro-organism to be tested listed in Appendix B tables of Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011. Sample should be representative of the whole lot / batch / container and homogenized. Preservatives shall not be added to sample units intended for microbiological examination.

Three sets, each containing 'n' number of samples (n as defined in the sampling plan,

e.g. if n=5, then total no. of samples to be drawn is 15) shall be drawn. Each of these three sets shall be tested in three different ISO 17025 certified laboratories notified by FSSAI (Figure 17). The final decision shall be based on the results of three laboratories. In the case of Food Safety Criteria requirements given in FSS (Food Products Standards and Additives) Regulation, 2011, results from all the three laboratories should indicate compliance with specified criteria.

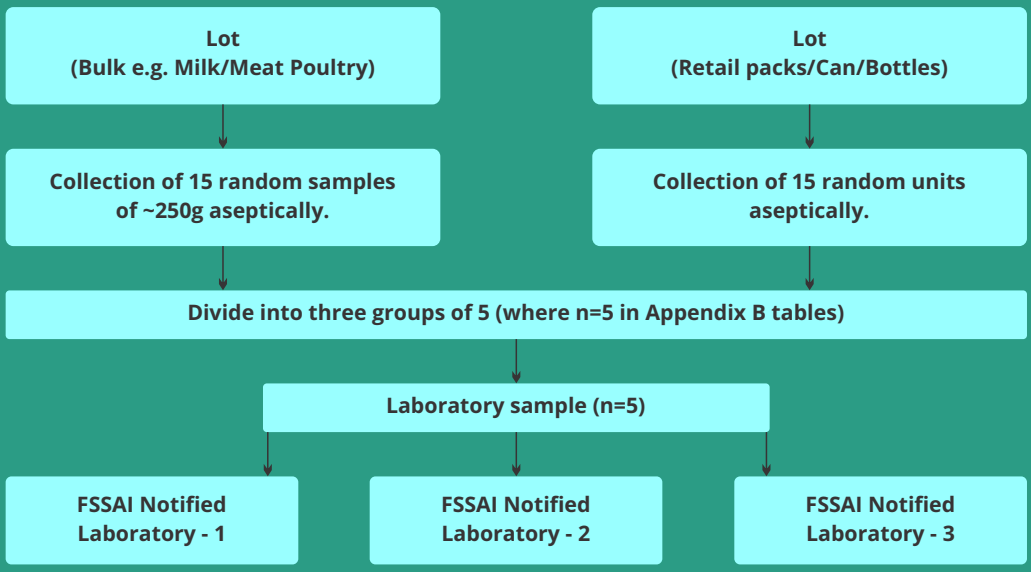


Figure-17 : Flow chart of sampling procedure for preparing laboratory sample for microbiological analysis.

PROCEDURE FOR SAMPLING UNDER FOOD SAFETY AND STANDARDS ACT, 2006

Authorized persons for taking food samples:-

- Food Safety Officer may take samples of food for analysis under clause A of sub section 1 of section 38 and clause (c) of sub section (1) of section 47 of the Food Safety and Standards Act, (2006).
- Authorized Officer may take samples of imported article of food for analysis under sub section (5) of section 47 of the Act.

PROCEDURE FOR TAKING SAMPLE (SECTION 47 OF FSS ACT, 2006)

Rule 2.4.1 of FSS Rules, 2011 mentions the procedure to draw sample under Food Safety and Standards Act, 2006 and manner of sending it for analysis. While taking the sample, the Food Safety Officer shall follow the procedure specified hereunder:

- FSO shall call one or more witnesses at the time of lifting of the samples, obtain the signatures from the witnesses in all the forms and documents prepared and serve the notice in Form V A to the food business operator, be it a manufacturer, a distributor or a supplier, then and there.
- If a sample is drawn from an open container, a sample of the same article is also to be drawn from a container in original condition bearing the same declaration and intimate the same to the Food Analyst.
- Food Safety Officer shall pay the cost (at market rate) of such sample to the person from whom the sample is taken.
- Sample shall be taken in clean dry bottles or jars or in other suitable containers which shall be closed to prevent leakage, evaporation or to avoid entrance of moisture in case of dry substance and shall be carefully sealed. If a sealed package is taken as a sample, no further sealing is required. The quantity of a sample to be sent to the laboratory is listed in Table 10.

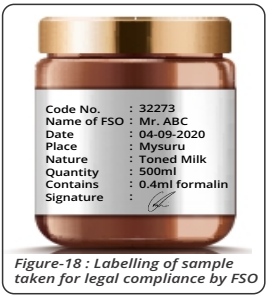


Figure-18 : Labelling of sample taken for legal compliance by FSO

- Sealed sample shall be properly addressed and labelled (Figure 18) with following information:

  i. Code number of the sample

  ii. Name of the sender with his official designation

  iii. Date and place of collection

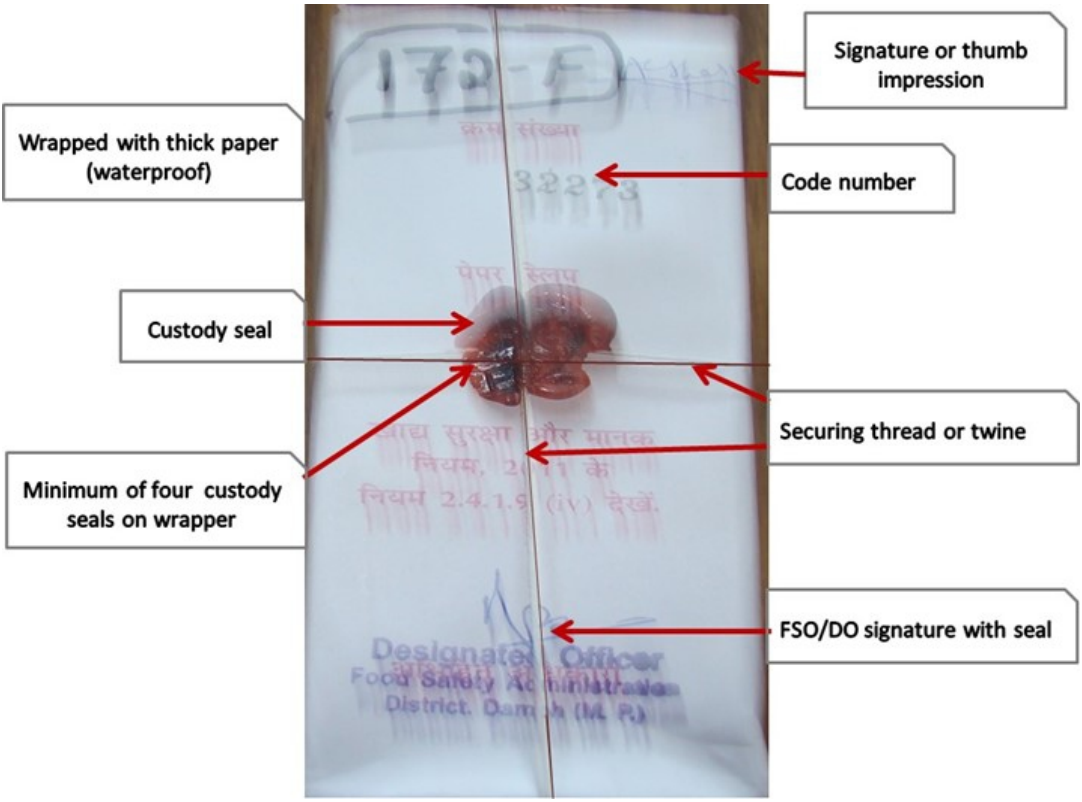
  iv. Nature of articles being sent for analysis

  v. Nature and quantity of preservative, if any, added to the sample.

- The bottle, jar or other container shall then be completely wrapped in fairly strong thick paper. The ends of the paper shall be neatly folded in and affixed by means of gum or another adhesive.
- A paper slip of the size that goes round completely from the bottom to top of the container, bearing the signature of the Designated Officer or any officer authorized by Food Safety commissioner and code number of the sample, shall be pasted on the wrapper (Figure 19).
- The signature or thumb impression of the person from whom the sample has been taken, shall be affixed in such a manner that the paper slip and the wrapper both

carry a part of this signature or the thumb impression. If the person from whom the sample is taken refuses to affix his signature or thumb impression, the signature or thumb impression of one or more witnesses shall be taken in the same manner.

Figure-19 : Details of packaging sample for dispatch to laboratory for analysis.



- The paper cover shall be secured by means of strong twine/ thread both above and across the sample container and the twine/ thread shall be fastened on the paper cover by means of sealing wax and using seal, leaving distinct and clear impression, at the top and bottom of the packet and the other two on the body of the packet along with the knots of the twine/ thread (Figure 19).
- The sample shall be divided into four parts or take four already sealed packages and mark and seal or fasten up each part in such a manner as its nature permits and take the signature or thumb impression of the person from whom the sample has been taken on the label.
- The sealed container of one part of the sample shall be dispatched for analysis along

with memorandum in Form VI shall be sent in a sealed packet to the Food Analyst under appropriate condition to retain the integrity of the sample (Figure 16).

- The sealed container of the second and third parts of the sample and two copies of memorandum in Form VI shall be sent to the Designated Officer by any suitable means.
- The sealed container of the remaining fourth part of the sample and a copy of memorandum in Form VI shall be sent to an FSSAI notified laboratory along with fee prescribed by the Authority, if so, requested by the Food Business Operator, under intimation to the Designated Officer.
- The fourth part shall also be deposited with Designated Officer if Food Business Operator does not request to send the sample to an accredited lab.
- The Food Safety Officer shall also send a copy of the memorandum and specimen impression of the seal used to seal the packet to the Food Analyst along with the sealed container of first part of the sample.
- In case of bulk containers that were opened by the owner prior to sampling, its existing conditions should be described in detail.
- The FSO or the Authorized Officer, while taking sample for the purpose of analysis under the provisions of the Act except in the case where the sample is meant for microbiological testing/analysis, may add to the sample, a preservative as may be prescribed from time to time in the regulations for the purpose of maintaining it in a condition suitable for analysis. Whenever any preservative is added to a sample, the nature and quantity of the preservative added shall be clearly noted on the label to be affixed to the container.
- It is also important to mention about the perishability of the sample.
- It is very important that the FSO/Authorized Officer be able to document sample integrity from time of collection to delivery to the analyst, particularly when enforcement action is being considered.
- When rodent infestation is observed, the FSO/DO should select the portions actually sampled to reflect the violated nature of the lot. In addition, exhibits should include diagrams and photographs to demonstrate the violate conditions reported.
- The quantity of samples to be collected and sent for analysis to the food laboratory is specified in Sub-Section 2.3.1 (Table 10) of Food Safety and Standards Regulations

(Laboratory and Sample Analysis) 2011.

- Samples for Microbiological Analysis are collected following the schematic shown in Figure 17 and Box 3 following Special precautions described in Section. Preservatives shall not be added to sample units intended for microbiology analysis.

At the time of lifting of samples, the FBO can request the FSO in writing to send the fourth part of the sample and a copy of memorandum in Form VI to a FSSAI notified laboratory along with the prescribed fee payable by FBO. The FSO must then send the sample to a lab within the state or in a neighbouring state under intimation to Designated Officer. The fourth part of the sample is deposited with the Designated Officer if the FBO does not have any request.

Box 4. Sampling scheme for Microbiology Analysis

For example, a single 10 kg wheel of cheese is to be analysed.

Cheese as per Appendix B, Table 1B of Appendix B for Salmoella the sampling plan is n=5, c=0 and Absent/25g

Fifteen samples of '200 g should be taken randomly from a wide variety of locations around the wheel.

Five samples each must be sent to three different laboratories

If Salmonella is present in a food, then the odds of detecting it are enhanced.

Cereal based Complementary Food in sealed cans in a store is to be analysed for Listeria monocytogenes.

As per Appendix B Table 2B ten '25 g' analytical units must be analysed and it should be absent in all 10 units (n=10, C=0, Absent/25g).

Since each can will be considered as a single unit 30 sealed cans must be sampled randomly.

Ten cans each must be sent to three individual laboratories for analysis.

FSO must therefore collect 30 sealed cans

SAMPLE DISPATCH

Samples should be dispatched as per the procedure mentioned above. The sample drawn should be transported to the testing laboratory as quickly as possible preferably within 24 hrs. Following precautions should be taken:

- Dehydrated and dry foods stored without refrigeration should not be allowed to absorb any atmospheric moisture.
- Liquids or semi solid foods contained in unopened container should be transported to the lab in refrigerated condition (4^0C to 8^0C) or without refrigeration as mentioned

in the label regarding storage requirement s of the food products.

- Samples drawn from original packing transferred to new container should be held at 4 ^{0}C to 8^{0}C during transportation, but should not be frozen.
- Meat and meat products, poultry and fish should preferably be transferred under wet ice refrigeration to avoid dehydration at the surface of the sample.
- Frozen food products should be kept in dry ice while transportation.
- All samples packaged for dispatch must be secured with shock-absorbing materials to protect them from damage enroute.
- Samples of frozen foods to be sent overnight may be packed in insulated cartons containing dry ice that will last for that length of time.
- If special precautions in handling or storing samples are needed, the FSO/ Authorized Officer should ensure that persons who will be handling the samples are informed.

DOCUMENTATION REQUIRED WITH RESPECT TO LEGAL COMPLIANCE

Various forms in defined formats have been referred in FSS Rules, 2011 and FSS (Laboratory and Sample Analysis) Regulation, 2011 which are required to be used at the time of sampling of products and related actions. These are as listed in Table 11.

Table 11 Forms and documentation requirements

Documents to be dispatched with the sample to laboratory	
Memorandum to Food analyst (Form VI of FSS Rule 2011)	One part of the sample shall be sent in a sealed packet to the State Food analyst.
Memorandum to Designated Officer (Form VI of in FSS Rule 2011)	Two copies to be sent to the designated officer by any suitable means along with second and third part of the sample;
Memorandum to FSSAI notified laboratory (Form VI of FSS Rule 2011)	A copy shall be sent to an accredited laboratory along with the fee prescribed by the Authority, if so requested by the food business operator under intimation of the designated officer.
Documentation for seizure of articles of food by Food Safety Officer	
Form VA/B in FSS Rules, 2011	Notice to FBO from whom the sample is to be taken;
Form of order/bond (Rule 2.3.2 FSS Rules 2011 Form III & Form IV)	He shall after affixing the seal, on the article of food make an order in Form III to the FBO not to dispose of the stock and may require the FBO to execute a surety bond in Form IV;
Seizure Memo (receipt) in Form II (Rule 2.3.1 of FSS Rules 2011	For every article of food seized by the FSO and the matters connected therewith (as per 2.3 of food Safety & Standards Rules 2011).

Other Forms related to Samples	
Form VII A in FSS Rules, 2011	Report of the Food Analyst;
Form A in FSS (Laboratory and Sample Analysis) Regulation, 2011	Certificate of Analysis by the Referral Food Laboratory;
Form B in FSS (Laboratory and Sample Analysis) Regulation, 2011	Report of the Food Analyst.

- FSO has been given the powers with respect to search, seizure and sampling for adulterants and sealing of premises (in limited cases).
- If any adulterant is found in the possession of a manufacturer or distributor of, or dealer in, any article of food or in any of the premises occupied by him and such FBO is unable to explain why he is in possession of such adulterant, the FSO can seize such adulterants and take samples of it for analysis.
- It is also recommended that the FSO records in writing any such decision to seize adulterants and provide a copy of such written record to the FBO if appropriate.
- Apart from this, all other processes, forms, reports etc. with respect to the search, inspection, seizure and sampling of the adulterants is the same as for any other food article.

The FSO must exercise caution and must base his decision on the actual activities of the FBO as there are instances where a food article could be used as an adulterant in another a food article but by itself does not constitute an adulterant. For e g – if water is mixed with milk, it will be considered an adulterant but water by itself is not an adulterant.

SAMPLING OF IMPORTED FOOD ARTICLES BY AUTHORISED OFFICER

Authorised officer at the ports shall conduct visual inspection and take the sample of import food products The Authorised Officer shall draw two parts of food sample of each description or measures (except for aseptic sealed packages); and forward to the food analyst such quantity of sample as specified under the Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011. All the requirements of sampling, storage and transportation are the same as described above for the FSO.

FOOD TESTING LABORATORIES UNDER FSSAI

Section 43 (1) of FSSAI, 2006, provides that the Food Authority may notify food laboratories and research institutions accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL), India or any other accreditation agency for the purposes of carrying out analysis of samples by the Food Analysts under this Act. The testing

laboratories that analyse samples for legal compliance are:

- State Food/Public Health Laboratories
- Referral Food Laboratories
- FSSAI Notified Laboratories
- Mobile Food Testing Laboratory

The role of each of these laboratories has been specified (Figure-20).

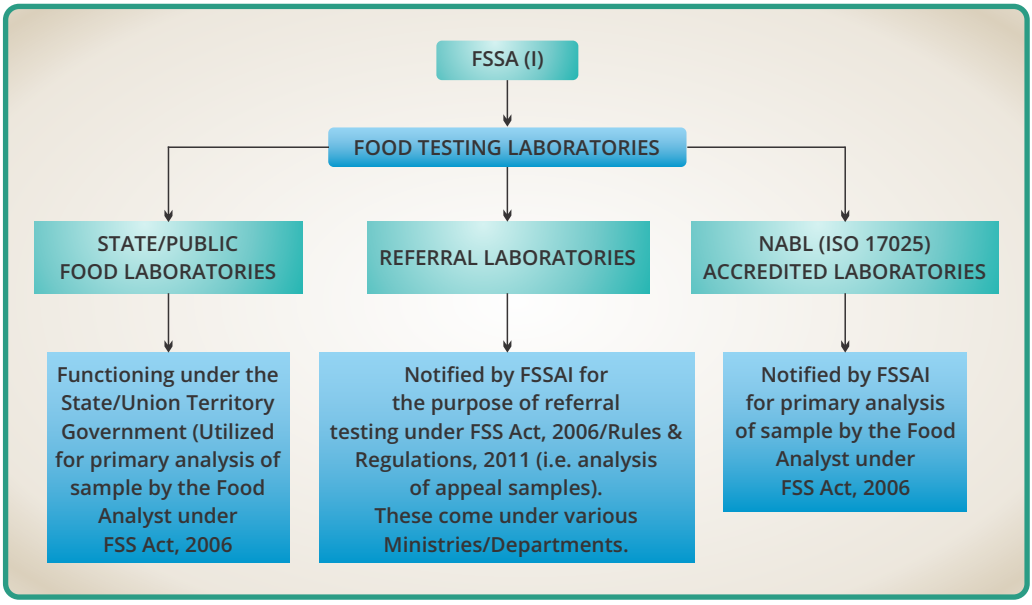


Figure-20 : Schematic showing the framework of regulatory testing laboratories under FSSAI.

These food testing laboratories are involved in multiple functions:

- Enforcement of food laws by virtue of testing food against the prescribed quality and safety parameters
- In surveillance and monitoring activities to ensure compliance of the food product against the laid down standards
- Assist in testing of imported foods thereby ensure transparent mechanism of trade and also compliance to national regulations
- Risk assessment activities for reviewing existing and developing new food safety standards

As per Annexure 3 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011, all FBOs must ensure testing of relevant chemical and/or

microbiological contaminants in their food products in accordance with FSS Regulations as frequently as required on the basis of historical data and risk assessment to ensure production and delivery of safe food through their own or NABL accredited/FSSAI notified labs at least once in six months.

State Food Testing Laboratories : FSSAI inherited 72 State Food Testing laboratories notified under Prevention of Food Adulteration Act (under the transition provision under Section 98 of FSS Act, 2006), These laboratories are involved in the primary testing of samples in their respective state for legal compliance and surveillance.

FSSAI recognizes and notifies NABL (ISO 17025:2017) accredited food testing laboratories in the following categories:

- Primary food testing laboratories
- Referral food laboratories
- Reference food laboratories

Primary Food Testing Laboratories means a food laboratory notified by the Food Authority under sub-section (1) of section 43 for the purposes of carrying out analysis of food samples taken under Section 47 of the said Act.

Referral Food Laboratory means a food laboratory established or recognized by notification by the Food Authority under sub section (2) of section 43. The Food Authority recognizes Referral Food Laboratories for the purposes of carrying out analysis of appeal samples. The Referral Laboratory analyses the food samples sent by DO or any authority authorized by the Food Authority and submits the certificate of the analysis to the concerned authority. In addition, the laboratory is entrusted to:-

- Carry out all relevant investigations in order to fix the standards for any article of food
- Carry out investigations as directed by the Food Authority in collaboration with other laboratories or Food Analysts in the various States or with any other food laboratories and institutes that the Food Authority may approve on its behalf for the purpose of standardising the methods chosen for analysis
- Ensure that the laboratories follow the scientific protocol that has been laid down for handling/testing articles of food
- Maintain high standards of accuracy, reliability and credibility in the operations of their laboratory and ensure that they are achieving and maintaining the required levels of accreditation and reliability.

- Lay down mechanisms that ensure that the personnel of the laboratories follow the highest professional standards and discipline.
- Carry out any such conditions as the Food Authority may lay down for referral laboratories.
- Have the capacity to organize professional training, workshops and seminars for Food Analysts, laboratory personnel in those States as specified by the Food Authority.

Reference Food Laboratory means a food laboratory referred to in regulation 3 of Food Safety and Standards (Laboratory and Sampling Analysis) Regulation, 2011. FSSAI has recognised National Reference laboratory (NRL) to set up a country wide standard for routine procedures, validation of such standard procedure/testing methods, development of new methods and ensuring proficiency in testing across the food laboratories with special reference to the risks or food categories. The functions of the reference laboratory are to carry out the following functions:

- To be a resource centre for provision of information for certified reference materials and reference materials;
- To develop standards for routine testing procedures and reliable testing methods;
- To provide technical support in the area of competence;
- Evaluate the performance of other notified laboratories;
- Coordinate exchange of information amongst notified food laboratories;
- Collaborate for data generation among the network of notified food laboratories and referral food laboratories and collate the data related to their specific domain; and
- Any other functions as may be specified by the Food Authority.

ROLE OF FOOD ANALYST AND THEIR FUNCTIONS

Personnel are the heart of every laboratory. They have to be reliable, precise, and motivated. An ISO 17025:2017 accredited laboratory should have a management system in place to provide objective evidence that the personnel are adequately qualified and regularly trained to perform the analysis. Each individual engaged in the conduct of food testing or responsible for the supervision of the laboratory should have education, training, and experience, or a combination thereof, to enable that individual to perform the assigned function satisfactorily to build a sustainable food testing laboratory. Furthermore, a sufficient

number of personnel for the timely testing are essential. Food testing is evolving constantly, therefore continuous education and training of personnel is of high importance.

Food Analyst (FA) : As per Section 45 of FSS Act, 2006, the State Commissioner of Food Safety may, by notification, appoint such persons as he thinks fit, having the qualifications prescribed by the Central Government, to be Food Analysts. Provided that no person, who has any financial interest in the manufacture or sale of any article of food shall be appointed to be a Food Analyst under this section. Food Analysts may be appointed for analysis of different articles of food.

The required basic qualifications of a FA include either a Master's degree in Chemistry/Biochemistry/Microbiology/Dairy Chemistry/Food Technology/Food and Nutrition or a Bachelor of Technology in Dairy/Oil or Veterinary Sciences from a university established in India by law or is an associate of the Institution of Chemists (India) by examination in the section of Food Analysts conducted by the Institution of Chemists (India) or any other equivalent qualification recognized and notified by the Central government for such purposes and has not less than three years' experience in the analysis of food. The FA must be declared qualified for appointment as a Food Analyst by a board appointed and notified by the FSSAI.

Analysts who had previously been declared qualified as Public Analyst under Prevention of Food Adulteration Act, 1954 are also eligible to be considered as FAs. The FA should undergo all specialized training programmes specified by the Food Authority periodically and any other that enhances their knowledge of analysis.

Duties of Food Analyst FA is required to analyse the article of food sent to him for analysis. In analysing the article of food, the FA should follow all instructions and shall adhere to such procedure as adopted by the Food Authority from time to time. The report of analysis shall be signed by the Food Analyst. After completion of analysis of article of food, the Food Analyst shall send his report to the Designated Officer, the Purchaser of article of food, as the case may be, in Form VII A.

A FA must use:-

a) Fit-for-purpose methods or methods otherwise identified as suitable by a regulatory/enforcement agency.

b) Document procedures and records for method validation that, at a minimum, meet the requirements of a responsible regulatory agency.

c) Use statistical procedures and data presentation as required by a regulatory agency

d) Maintain confidentiality and data integrity

e) Follow all Good Food Laboratory Practices

f) Follow and implement all safety procedures

g) Be well versed with handling all safety equipment

h) Use all physical protection (lab coat, safety glasses, closed shoes)

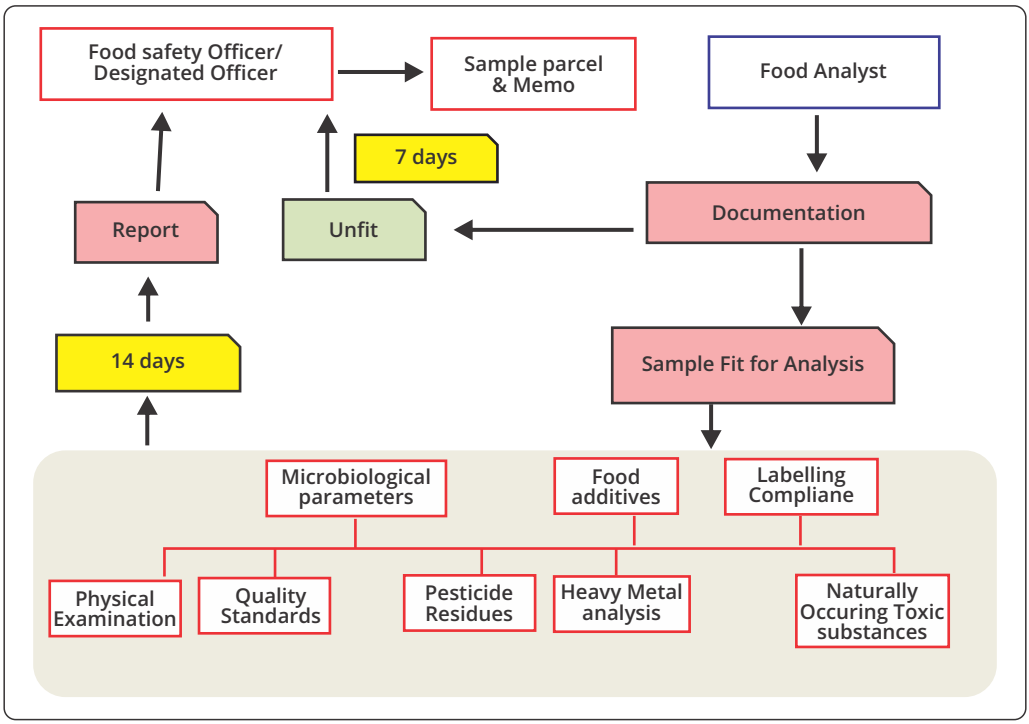


Figure-21 : Flow chart showing the role of the Food Analyst in compliance testing.

Sample analysis : On receipt of a package containing a sample for analysis from the FSO or any other person the FA carries out the following and takes action accordingly (Figure 21):

1. Compares the seal on the container and the outer cover with specimen impression received separately and notes the conditions of the seal and documents the same. In case of a discrepancy the FSO/DO is informed.

2. If the sample container is found to be in broken condition, signs of leakage or unfit for analysis, the FA should communicate the same to the FSO/DO within a period of seven days from the date of receipt of the sample and send requisition to him for

sending second part of the sample.

3. The sample package is opened and details as suggested in Box 5 are documented.

Box 5. Documentation of Sample Details by Food Analysis

Registered Parcel Number and date	Copy of memorandum in parcel: Yes/No
Name and Designation of sender	Name of the sample as per memorandum
Date of parcel receipt	Code number of sample as per memorandum
Date of opening parcel	Whether signature of FSO on sample container: Yes/No
Condition of seal	Name and Signature of witness
Details of sample container	Name and signature of FA opening parcel
Number of samples in parcel	

4. The analysis must be carried out as per the standards laid down for the food commodity, within a period of fourteen days from the date of receipt of the sample. The analysis includes testing for quality, physical examination, microbiology parameter, testing for food additives, mycotoxins, pesticide residues, heavy metals. In case of pre-packaged foods, the label must be evaluated to see if conforms to the FSS (Packaging and Labelling) Regulation, 2011 (Figure 21).

5. The analysis report shall be prepared as per Form VII A and four copies of the same shall be sent to the Designated Officer (Table 11), indicating the method of sampling and analysis, giving an opinion

6. If the sample cannot be analysed within fourteen days of its receipt, the FA must inform the DO and the Commissioner of Food Safety giving reasons and specifying the time required for completing analysis.

7. The DO keeps two copies of analysis report, sends one copy to the FSO for record and one copy to Food Business Operator from whom the sample was taken.

8. DO will analyse report to determine whether an offence has been committed under the FSS Act. If the DO believes an offence has been committed, he will determine whether the offence is punishable by adjudication or whether it is punishable by prosecution.

9. If the DO is of the opinion, for reason(s) to be recorded in writing, that the report delivered by the FA is erroneous, he must forward one of the parts of the sample kept

with him to the Referral laboratory for analysis. The complete process is summarised in Figure 23.

10. FBO can file an appeal before the DO in Form VIII within 30 days of receipt of the Report. The DO will give an opportunity of hearing to the FBO and shall decide on such appeal within 30 days. If the DO decides, he may forward one part of the sample to the Referral Laboratory for opinion and the report of the Referral laboratory in this matter shall be final.

11. In the case of the Microbiology parameters there is no provision for retesting. The sample is analysed simultaneously by three different laboratories.

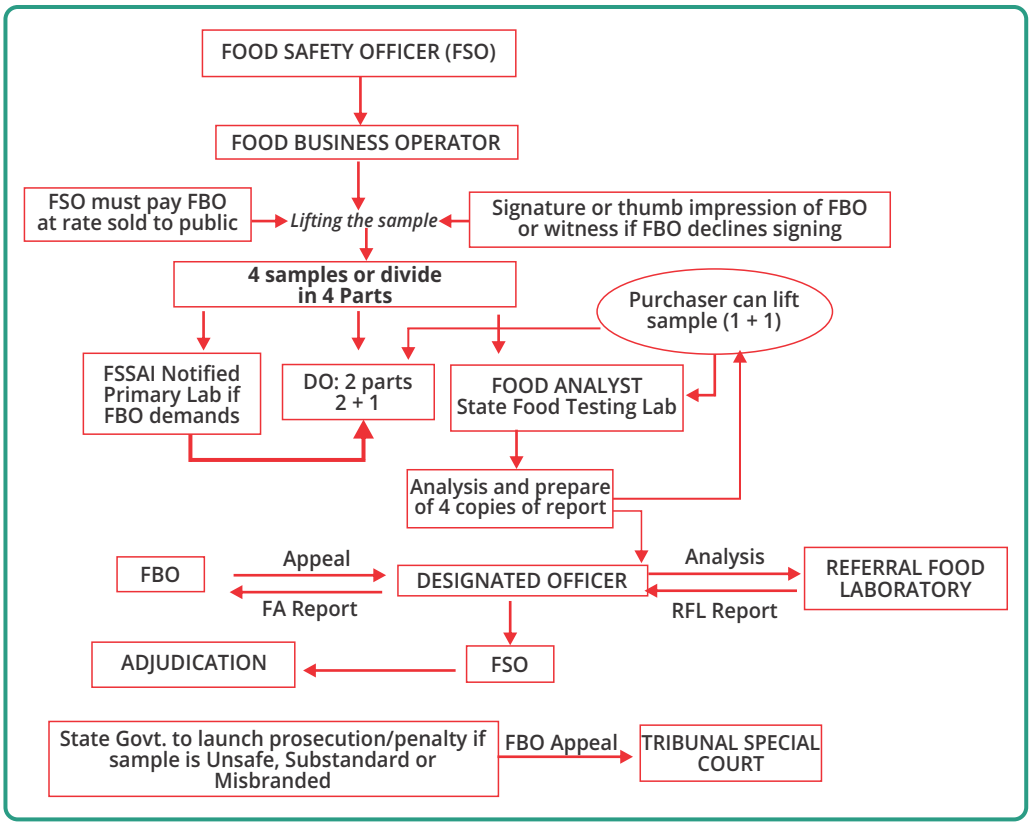


Figure-23 : Flow diagram summarized the process of sample analysis for regulatory compliance under FSSAI 2006.

CAPACITY BUILDING IN FOOD TESTING

Food testing is an integral and important part to ensure food safety. FSSAI through its Quality Assurance (QA) Division works towards fulfilling the vision of providing safe and

wholesome food to the citizens of our country by strengthening its food testing laboratory infrastructure & capacity building across the country.

Quality Assurance Division is responsible for:-

- Recognition and notification the notified of Primary and Referral laboratories.
- Strengthening of country's food testing system through the 72 State Food Testing Laboratories under Central Sector Scheme.
- Ensuring availability of approved Food Testing Methods by compilation of testing methods through 'Manuals of Methods of Analysis' with constant updating.
- Conducting Food Analyst Examination (FAE) and Junior Analyst Examination (JAE).
- Conducting of Targeted Surveillance to ensure food safety in the country.
- Organizing training programs for strengthening capacity of the laboratory personnel of State Food, Primary Notified and Referral food testing laboratories.
- Partnership with various national and international bodies such as AOAC International, ICMSF for smooth function of activities related to quality assurance

FSSAI has formulated a scheme to provide support to State Food Laboratories for upgrading the laboratory infrastructure along with trained manpower for utilizing the sophisticated test equipment. Six Initiatives of the scheme are shown in Figure 24.

The 'Scheme to Strengthening of Food Testing Laboratories (SOFTeL)' enable the States/UTs:

- To analyse the regulatory and surveillance samples drawn by the FSO within the shortest possible time frame;
- To analyse the safety parameters in food samples such as Heavy metals, Pesticide residues, Antibiotic and drug residues and Naturally occurring toxic substances along with Microbiological examination;
- To ensure compliance of FSSAI standards on food;
- To enable the laboratories to achieve ISO 17025 certification through NABL, India;
- To become a resource point for training and facility up-gradation for other existing Government / Public Food testing laboratories in the State; and to introduce online laboratory data management system through Laboratory Information Management System (LIMS).

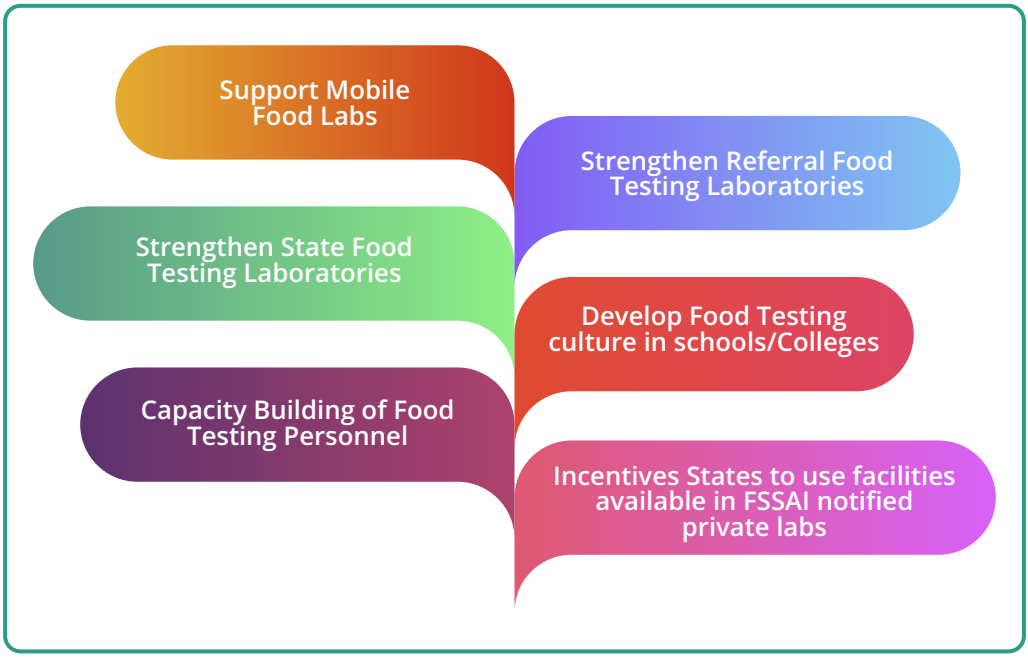


Figure-24 : Six initiatives of FSSAI under the 'Scheme to Strengthening of Food Testing Laboratories (SOFTeL).

LIST OF ISO AND OTHER STANDARDS ASSOCIATED WITH ACCEPTANCE SAMPLING

List of ISO standards concerning Acceptance Sampling:-

- ISO 2859-1:1999, Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
- ISO 2859-1:1999/Cor 1:2001
- ISO 2859-2:1985, Sampling procedures for inspection by attributes -- Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection.
- ISO/CD 2859-2, Sampling procedures for inspection by attributes -- Part 2: Sampling plans indexed by limited quality (LQ) for isolated lot inspection
- ISO 2859-3:2005, Sampling procedures for inspection by attributes -- Part 3: Skip-lot sampling procedures
- ISO 2859-4:2002, Sampling procedures for inspection by attributes -- Part 4: Procedures for assessment of declared quality levels

- ISO 2859-5:2005, Sampling procedures for inspection by attributes -- Part 5: System of sequential sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection.
- ISO 2859-10:2006, Sampling procedures for inspection by attributes -- Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes.
- ISO 3951-1:2005, Sampling procedures for inspection by variables -- Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot by-lot inspection for a single quality characteristic and a single AQL
- ISO 3951-2:2006, Sampling procedures for inspection by variables -- Part 2: General specification for single sampling plans indexed by acceptance quality limit (AQL) for lot by-lot inspection of independent quality characteristics.
- ISO 3951-3:2007, Sampling procedures for inspection by variables -- Part 3: Double sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
- ISO/WD 3951-4, Sampling procedures for inspection by variables -- Part 4: Procedures for assessment of declared quality levels
- ISO 3951-5:2006, Sampling procedures for inspection by variables -- Part 5: Sequential sampling plans indexed by acceptance quality limit (AQL) for inspection by variables (known standard deviation)
- ISO 8422:2006, Sequential sampling plans for inspection by attributes
- ISO/DIS 8423, Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation) 16) ISO 8423:1991, Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation
- ISO 8423:1991, Sequential sampling plans for inspection by variables for percent nonconforming (known standard deviation).
- ISO 8423:1991/Cor 1:1993
- ISO/TR 8550:1994, Guide for the selection of an acceptance sampling system, scheme or plan for inspection of discrete items in lots
- ISO/TR 8550-1:2007, Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots -- Part 1: Acceptance sampling.

- ISO/TR 8550-2, Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots -- Part 2: Sampling by attributes
- ISO/TR 8550-3:2007, Guidance on the selection and usage of acceptance sampling systems for inspection of discrete items in lots -- Part 3: Sampling by variables.
- ISO 13448-1:2005, Acceptance sampling procedures based on the allocation of priorities principle (APP) -- Part 1: Guidelines for the APP approach
- ISO 13448-2:2004, Acceptance sampling procedures based on the allocation of priorities principle (APP) -- Part 2: Coordinated single sampling plans for acceptance sampling by attributes
- ISO 14560:2004, Acceptance sampling procedures by attributes -- Specified quality levels in nonconforming items per million
- ISO 18414:2006, Acceptance sampling procedures by attributes -- Accept-zero sampling system based on credit principle for controlling outgoing quality
- ISO 21247:2005, Combined accept-zero sampling systems and process control procedures for product acceptance
- ISO/DIS 24153, Random sampling and randomization procedures
- ISO/CD 28801, Sampling by attributes -- Double sampling plans with minimal sample sizes indexed by producer's risk quality (PRQ) and consumer's risk quality (CRQ)
- ISO 3534-2:1993: Statistics – Vocabulary and symbols – Part 2
- General Guidelines on Sampling CAC/GL 50-2004
- IS 14818:2000 Cereals and pulses and milled products -Sampling of static batches
- IS0 13690: 1999 Cereals and pulses and milled products -Sampling of static batches
- ISO 542:1990 Oilseeds — Sampling. Reviewed and confirmed in 2006
- ISO 664, Oilseeds — Reduction of laboratory sample to test sample.
- IS: 4905 ·1968 (Reaffirmed 2001) Methods for random sampling
- BIS IS 2500-1: 2000(R2017) Sampling Procedure for Inspection by Attributes - Part 1:
- Sampling Schemes Indexed By Acceptance Quality Limit (AQL) For Lot-By-Lot Inspection
- BIS IS 4905: 2014 Random Sampling and Randomization Procedures
- BIS IS 14818: 2017 Cereal and Cereal Products - Sampling

Table-10 Minimum quantity of Laboratory sample	
Article of Food / Material	**Quantity**
Milk	500 ml
Sterilized Milk / UHT Milk	500 ml
Malai / Dahi	200 g
Yoghurt / Sweetened Dahi	500 g
Chhana / Paneer / Khoya / Shrikhand	250 g
Cheese / Cheese spread	200 g
Evaporated Milk / Condensed Milk	200 g
Ice-cream / Softy / Kulfi / Ice candy / Ice lolly	300 g
Milk Powder / Skimmed Milk Powder	250 g
Infant Food / Weaning Food	500 g
Malt Food / Malted Milk Food	300 g
Butter / Butter Oil / Ghee / Margarine / Cream / Bakery Shortening	200 g
Vanaspati, Edible Oils / Fats	400 g
Carbonated Water	3 L
Baking Powder	100 g
Arrow root / Sago	250 g
Corn flakes / Macaroni Products / Corn Flour / Custard Powder	200 g
Spices, Condiments and Mixed Masala (Whole)	500 g
Spices, Condiments and Mixed Masala (Powder)	500 g
Nutmeg / Mace	250 g
Asafoetida	100 g
Compounded Asafoetida	150 g
Saffron	20 g
Gur / jaggery, Icing Sugar, Honey, Synthetic Syrup, Bura	250 g
Cane Sugar / Refined Sugar / Cube Sugar, Dextrose, Misri / Dried Glucose Syrup	200 g
Artificial Sweetener	100 g
Fruit Juice / Fruit Drink / Fruit Squash	1 L
Tomato Sauce / Ketch up / Tomato Paste, jam / Jelly / Marmalade / Tomato Pure / Vegetable Sauce	300 g
Non-Fruit Jellies	200 g
Pickles and Chutneys	250 g
Oilseeds / Nuts / Dry Fruits	250 g
Tea / Roasted Coffee / Roasted Chicory	500 g
Instant Tea / Instant Coffee / Instant Coffee-Chicory Mixture	100 g
Sugar Confectionery / Chewing Gum / Bubble Gum	200 g
Chocolates	200 g

Article of Food / Material	Quantity
Edible Salt	200 g
Iodised Salt / Iron Fortified Salt	200 g
Manual for Food Safety Officers (draft for designing)	1 kg
Atta / Maida / Suji / Besan / Other Milled Product / Paushtik Fortified Atta / Maida	500 g
Biscuits and Rusks	200 g
Gelatin	150 gms
Bread / Cakes / Pasties	250 gms
Catechu	150 g
Vinegar / Synthetic Vinegar	300 g
Food Colour	25 g
Food colour preparation (Solid / Liquid)	25 g/100 mL
Natural Mineral Water / Packaged Drinking Water	4000 ml in three minimum original sealed packs
Silver Leaf	2 g
Prepared Food	500 g
Proprietary Food, (Non-Standardised Foods)	500 g
Canned Foods	6 sealed cans
Food not specified	500 g
Food packaging material taken from manufacturer	8 x 1000 x 9 sq.cm. surface area
Food packaging material from small consumer packages	Complete packaging material used for one container

NOTES

CHAPTER-7

ADJUDICATION OFFENCES & PENALTIES

7 ADJUDICATION OFFENCES & PENALTIES

AUTHORITIES RESPONSIBLE FOR ENFORCEMENT OF THIS ACT

OFFENCE

Contravention of provisions of Food Safety and Standards Act 2006, Food Safety and Standards Rules, 2011 and its Regulations by any individual or companies is called an Offence.

Under FSS Act 2006, the offences are defined under

Section 48 (General provisions relating to offences)

A person may render any article of food injurious to health by means of one or more of the following operations, namely:

- Adding any article or substance to the food e.g. an adulterant, contaminant, extraneous matter etc.
- Using any article or substance as an ingredient in the preparation of the food. e.g. inferior quality of raw materials, or food additives which are not allowed in that food category as per FSS Rule, 2011.
- Abstracting any constituents from the food. e.g. nutrient (fat) from milk, while on label displaying the quantity as per norms.
- Subjecting the food to any other process or treatment, other than defined. e.g. heat-treated honey as raw honey.

(2) Following point need to be considered before declaring offence,

(a) (i) Normal conditions of use of the food by the consumer and its handling

(ii) Information provided to the consumer via label on specific adverse health effects

(iii) Probable cumulative toxic effects

(iv) To health sensitivities and probable cumulative effect of a specific category of consumers where the food is intended for that category of consumers

(b) **Exemption :** The fact where the quality or purity of the article, being primary food, has fallen below the specified standard or its constituents are present in quantities not within the specified limits of variability, in either case, solely due to natural causes and beyond the control of human agency, then such article shall not be deemed to be unsafe or sub-standard or food containing extraneous matter. e.g. fruits or dried fruit in packaged condition- moisture % will change gradually with time. Peeling of dried dates fruit- seems like extraneous matter but its outer skin (epicarp) of Dates.

OFFENCES WITH

- Any foods sample, declared as sub-standard food by food analyst, is considered as an Offence (Section 51)
- Any false complaint against any food safety officer, is considered as an Offence (Section 39)

Section 49: General provision relating to Penalties

Adjudicating Officer or the Tribunal, while delivering the quantum of penalty, shall give due consideration to following, as a result of contravention

- The amount of gain or unfair advantage, wherever quantifiable
- The Amount of loss caused or likely to cause to any person
- The repetitive nature of the contravention,
- Whether the contravention is without his knowledge, and
- Any other relevant factor.

Penalties in relation with Food can be differentiated in two categories under below mentioned sections of Chapter IX

- Penalties with Monetary fine only

  Section 50 to Section 58

- Penalties with Monetary fine + Imprisonment

  Section 59 to Section 67

Penalties in relation other than food i.e. For Enforcement of the Act mentioned under different sections of Chapter VII.

1. Section 33 – Prohibition Orders
2. Section 34 – Emergency prohibition notices and orders
3. Section 39 – Liability of food safety officers in certain cases.

Consolidated table for Penalties with Monetary fine plus Imprisonment

Section	Offence	Liability	Penalty in rupees (max.)
50	Penalty for selling food not of the nature or substance or quality demanded	Seller If Petty food manufacturer registered as seller too {Sec 31(2)}	5 lakh 25 thousand {Sec 31(2)}
51	Penalty for sub-standard food	Manufacturer / Seller, Distributor / Storage / Importer	5 lakh
52	Penalty for misbranded food	Manufacturer / Seller, Distributor / Storage / Importer	3 lakh

Section	Offence	Liability	Penalty in rupees (max.)
53	Penalty for misleading advertisement	Person who publishes, or is a party to the publication of a misleading advertisement	10 lakh
54	Penalty for food containing extraneous matter	Manufacturer / Seller, Distributor / Storage / Importer	1 lakh
55	Penalty for failure to comply with the directions of Food Safety Officer	FBO or Importer	2 lakh
56	Penalty for unhygienic or unsanitary processing or manufacturing of food	Manufacturer or Processor	1 lakh
57	Penalty for possessing adulterant. If adulterant (i) not injurious to health (ii) injurious to health	Manufacture, sales, distribution or import of any adulterant	(I) 2 lakh (ii) 10 lakh
58	Penalty for contraventions for which no specific penalty is provided	Any individual / person	2 lakh
59	Punishment for unsafe food. If unsafe food cause no injury, non-grievous injury, grievous injury, death	Manufacturer / Seller, Distributor/ Storage, Importer	(I) 6 Months / 1 lakh (ii) 1 Year / 3 lakh (iii) 6 Years / 5 Lakh (iv) not less than 7 years but extended up to lifetime & fine shall not be less than 10 lakh
60	Punishment for interfering with seized item	Any person	06 months and 2 lakh
61	Punishment for false information	Any person	03 months and 2 lakh
62	Punishment for obstructing or impersonating a Food Safety Officer	Any person	03 months and 1 lakh
63	Punishment for carrying out a business without license	FBO-Manufacturer, Packer, Distributor etc. [Note:-Only Exemption from licensing under sub-section (2) of section 31 of this Act)]	06 months and 5 lakh
64	Punishment for subsequent offences	Any person	(I) twice the punishment as imposed on a first conviction,

Section	Offence	Liability	Penalty in rupees (max.)
			(ii) fine on daily basis which may extend up to one lakh rupees (iii) cancellation of license
65	Compensation in case injury of death of consumer	FBO-Manufacturer, Packer, Distributor etc	(a) not less than five lakh rupees in case of death; (b) not exceeding three lakh rupees in case of grievous injury; and (c) not exceeding one lakh rupees, in all other case of injury: Also may be, (a) order for cancellation of licence, re-call of food from market, forfeiture of establishment & property in case of grievous injury or death of consumer; (b) issue prohibition orders in other cases
66	Offences by companies	Company and nominated for food safety / or In-charge / or responsible person of company / establishment / branch	Penalty or Punishment accordingly to contravention as per act
67	Penalty for contravention of provisions of this Act in case of import of articles of food to be in addition to penalties provided under any other Act.	FBO / Importer	(1) Any penalty as per-Foreign Trade (Development and Regulation) Act, 1992 (22 of 1992) and the Customs Act, 1962 (52 of 1962). (2) Penalty or Punishment accordingly to contravention as per this act (FSS act 2006)

OVERVIEW OF ADJUDICATION

ADJUDICATION AND FOOD SAFETY APPELLATE TRIBUNAL (SECTION 68 TO 76)

Section 68 & 69 : Adjudication officer & its power

- Adjudication officer: - ADM of district or above (Notified by State Govt)
- Have powers of a Civil Court
- Judicial proceedings as per section 193 and 228 of IPC (45 of 1860)
- A court as per sections 345 and 346 of the Code of Criminal Procedure, 1973(2 of 1974).
- Hear representation and decision based on inquiry
- Impose penalty for contravention and as per offence
- Quantum of penalty-due regard with Section 49

Section 66 : Offences by companies

(1) Where an offence under this Act which has been committed by a company, every person who at the time the offence was committed was in charge of, and was responsible to, the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly: Provided that where a company has different establishments or branches or different units in any establishment or branch, the concerned Head or the person in-charge of such establishment, branch, unit nominated by the company as responsible for food safety shall be liable for contravention in respect of such establishment, branch or unit: Provided further that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act, if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

EXPLANATION

For the purpose of this section:-

(a) "company" means anybody corporate and includes a firm or other association of individuals; and

(b) "director" in relation to a firm, means a partner in the firm. 67. Penalty for contravention of provisions of this Act in case

Section 69 : Power to compound offences

- Designated officer: - Empowered by Commissioner of Food Safety
- Accept penalty up to Rs One lakh from petty food manufacturer, retailers, hawkers etc.
- No imprisonment under this act.

Section 70 : Establishment of Tribunal

- Formed by Central govt. or State govt. by notification
- To hear appeal from decisions of Adjudicating Officer under Sec. 68
- Tribunal has only one Person-Presiding Officer-appointed by Central or State govt.
- Presiding Officer- District judge only (current or previous)

Section 71 : Procedure & powers of Tribunal

- Guided by principles of natural justice and FSS Act, 2006 & FSSR Rules, 2011
- Same powers similar to civil court under the Code of Civil Procedure, 1908
- Tribunal proceedings are Judicial proceeding –same as Civil court or Criminal Court
- Appeal against Tribunal can be filed in High Court within 60 days of decision/order

SPECIAL COURT

Section 72 : Civil Court not to have jurisdiction

Civil court have "**NO**" jurisdiction in respect of any matter which Adjudicating Officer or the Tribunal court is empowered.

Section 73 : Power of court to try cases summarily

Offences not triable by Adjudicating officer or by Special court can be tried in a

summary way by Judicial Magistrate of the first class or by a Metropolitan magistrate

Section 74 : Special courts and Public prosecutor

- Empowers Central or State government to constitute "Special Courts".
- Empowers Central or State government to appoint one Public Prosecutor(PP) and more than one Additional PP or Special PP.
- Especially, for trials of offences related to grievous injury or death of the consumer.
- For such offence, where, punishment of imprisonment 03 years or more as per FSS act 2006.

REGULAR COURT

Section 75 : Power to transfer cases to regular court

Special Court can transfer any offence (if found not triable by special court/or no such jurisdiction to try such offence), for the trial of such offence to regular court.

Section 76 : Appeal

Appeal against Special court can be filed in High Court within 45 days from the date on which order was served, after payment of fee. Appeal under this section shall be disposed by 2 Judge (min.) bench of a High Court.

Section 77 : Time limit for prosecutions

Notwithstanding anything contained in this Act, no court shall take cognizance of an offence under this Act after the expiry of the period of one year from the date of commission of an offence. Provided that the Commissioner of Food Safety may, for reasons to be recorded in writing, approve prosecution within an extended period of up to three years.

PREPARING AND FILING A CASE

Adjudication Proceedings

- Designated officer(DO), received Form VIIA (report of food analysis) from food analyst.
- DO has to verify non-conformance of sample, appeal or no appeal and result of appeal
- DO will examine case basis section and confirm penalty with fine only or penalty with imprisonment or no penalty.

- In case of no penalty on conformance of sample, FBO (food business operator) will be informed.
- In case of penalty with fine only, DO will ask FSO (Food safety officer) to file an application for adjudication of offence with Adjudication officer against seller or manufacturer etc.
- FSO will file application with Adjudicating officer.
- Adjudicating Officer will initiate proceeding after receipt of application from FSO.
- Based on integrity of evidence and due regard of Section 49, Adjudication officer can either impose penalty or dismiss the case.
- Adjudication officer can also hold the proceeding under section 50 to 58 and 64 to 67 of FSS Act, 2006 and issue notice to person/s for proper representation.
- After proper representation and evidence verification, adjudicating officer based on merit, can either impose penalty or dismiss the case.
- Every order will be signed by Adjudicating officer.
- Copy of the order will be send to concern person/s.

Section 42 : Procedure for launching prosecution

- Food Safety Officer- Inspection of premises, sample drawn and sending to food analyst.
- Food analyst- analysis of sample, preparation of report and sending report within 14 days to Designated officer and Copy to Commissioner of Food Safety.
- DO based on report-decide whether contravention is punishable with imprisonment or fine.
- In case of contravention with imprisonment, within 14 days, DO send recommendation to Commissioner of Food Safety for sanctioning prosecution.
- Based on gravity of offence, Commissioner referred matter to Regular court or Special court.
- Commissioner of Food Safety communicates decision to DO and FSO, who then launch prosecutions in applicable court.
- In case sample was taken under Section 40, purchaser is also informed.

Section 80 : Defences which may or may not be allowed in prosecution

(A) Defence relating to publication of advertisements

(1) In any proceeding for an offence under this Act in relation to the publication of an advertisement, it is a defence for a person to prove that the person carried on the business of publishing or arranging for the publication of advertisements and that the person published or arranged for the publication of the advertisement in question in the ordinary course of that business.

(2) Clause (1) does not apply if the person—

(a) Should reasonably have known that the publication of the advertisement was an offence; or

(b) Had previously been informed in writing by the relevant authority that publication of such an advertisement would constitute an offence; or

(c) Is the **food business operator** or is otherwise engaged in the conduct of a food business for which the advertisements concerned were published.

(B) Defence of due diligence

(1) In any proceedings for an offence, it is a defence if it is proved that the person took all reasonable precautions and exercised all due diligence to 56 prevent the commission of the offence by such person or by another person under the person's control.

(2) Without limiting the ways in which a person may satisfy the requirements of clause(1), a person satisfies those requirements if it is proved—

(a) that the commission of the offence was due to—

(i) An act or default of another person; or

(ii) Reliance on information supplied by another person; and

(b) (i) The person carried out all such checks of the food concerned as were reasonable in all the circumstances; or

(ii) It was reasonable in all the circumstances to rely on checks carried out by the person who supplied such food to the person; and

(c) That the person did not import the food into the jurisdiction from another country; and

(d) in the case of an offence involving the sale of food, that—

(i) the person sold the food in the same condition as and when the person purchased it; or

(ii) the person sold the food in a different condition to that in which the person purchased it, but that the difference did not result in any contravention of this Act or the rules and regulations made thereunder; and

(e) that the person did not know and had no reason to suspect at the time of commission of the alleged offence that the person's act or omission would constitute an offence under the relevant section.

(3) In sub-clause (a) of clause (2), another person does not include a person who was—

(a) an employee or agent of the defendant; or

(b) in the case of a defendant which is a company, a director, employee or agent of that company.

(4) Without limiting the ways in which a person may satisfy the requirements of clause (1) and item (i) of sub-clause (b) of clause (2), a person may satisfy those requirements by proving that—

(a) in the case of an offence relating to a food business for which a food safety programme is required to be prepared in accordance with the regulations, the 57 person complied with a food safety programme for the food business s that complies with the requirements of the regulations, or

(b) In any other case, the person complied with a scheme (for example, a quality assurance programme or an industry code of practice) that was—

(i) Designed to manage food safety hazards and based on national or international standards, codes or guidelines designed for that purpose, and

(ii) Documented in some manner.

(C) Defence of mistaken and reasonable belief not available

In any proceedings for an offence under the provisions of this Act, it is no defence that the defendant had a mistaken but reasonable belief as to the facts that constituted the offence.

(D) Defence in respect of handling food

In proceedings for an offence under section 56, it is a defence if it is proved that the person caused the food to which the offence relates to be destroyed or otherwise disposed of immediately after the food was handled in the manner that was likely to render it unsafe.

(E) Defences of significance of the nature, substance or quality of food

It shall be no defence in a prosecution for an offence pertaining to the sale of any unsafe or misbranded article of food to allege merely that the food business operator was ignorant of the nature, substance or quality of the food sold by him or that the purchaser having purchased any article for analysis was not prejudiced by the sale.

Legal Metrology (Packaged Commodities) Rule, 2011

Penalty or fine for contravention of Legal Metrology rules as per Legal Metrology Act.

Rule 32. Fine for contravention of rules.

Whoever contravenes any provisions of these rules, for which no punishment is provided, shall be punished with fine of Rs 5000.

Rule 32A. Sum of compounding of offences.

The sum of compounding of offences committed under the Act shall be as specified in the following Table, namely:-

S. No.	Offence	Compounding amount	
		If the application for compounding is by retailers or wholesale dealers	If the application for compounding is by manufacturers or importers
1	Contravention of section 29	Rs. 2000	Rs. 10000
2	Contravention of sub section (1) of section 36	Rs. 5000	Rs. 25000
3	Contravention of sub section (2) of section 36	Rs. 10000	Rs. 50000

Above 32 rules mentioned below too with nature of contravention 520

New Rule on Compounding of some offenses

A new sud-rule, Namely, Rule 32 (3) has been introduced:

Rule 32(3)(1)	Quoting in non-standard units in packages (S.29)	2000 / 10000
Rule 32(3)(2)	Failure to confirm to the declaration on packages (S.36(1))	5000 / 25000
Rule 32(3)(3)	Error in net quantity beyond MPE (S.36(2))	10000 / 25000
Rule 32(3)(4)	Selling of products beyond MRP	2000 / 5000

Applicable to retailers / wholesalers / Applicable to manufacturers and importers

NOTES

CHAPTER-8

OTHER RELEVANT ACTS

8 OTHER RELEVANT ACTS

Directorate of Marketing & Inspection (DMI) in the Department of Agriculture, Cooperation and Farmers Welfare, Ministry of Agriculture, Cooperation & Farmers Welfare is implementing the provisions of Agricultural Produce (Grading & Marking) Act, 1937. The Act empowers the Central Government to make Rules for (a) fixing grade designation to indicate quality of any scheduled article. (b) Defining the quality indicated by every grade designation and (c) specifying grade designation marks to represent particular grade designations. Standards notified as per the provisions of the Act are popularly called AGMARK Standards. These standards differentiate between quality of agriculture produce through different grades and 2-3 grades are prescribed for each commodity. Grades help farmers to get prices for agricultural commodities as per the quality produced by them and consumers get the desired quality. Till date, grade standards for 227 agricultural commodities have been notified. These include fruits, Vegetables, cereals, pulses, oilseeds, vegetable oils, ghee, spices, honey, creamery butter, wheat atta, besan, etc.

AGMARK Certification Scheme :-

Two types : (1) Voluntary (2) Mandatory

Voluntary Scheme

- For agricultural commodities for domestic trade and export.
- Total 227 Commodities notified

S.No.	Group	Commodities
1	Food grains &allied products	32
2	Fruit & Vegetables	57
3	Spices and Condiments	27
4	Edible Nuts	8
5	Oil Seeds	18
6	Vegetable Oil and Fats	19
7	Oil Cakes	8
8	Essential Oils	8
9	Fiber Crops	5
10	Livestock, Dairy and Poultry	10
11	Other Products	35
	Total	**227**

Food products for which Agmark certification is mandatory as per Food Safety and Standards (Prohibition and Restriction on sales) Regulation, 2011 are as under:

1. Blended Edible Vegetable Oils (BEVO)
2. Fat Spread
3. Ghee having less RM value and a different standard for BR than that specified for the area in which it is imported for sale or storage

BUREAU OF INDIAN STANDARDS – BIS

Bureau of Indian Standards (BIS) is the National Standards Body of India, functioning under the aegis of Ministry of Consumer Affairs, Govt. of India for harmonious development of the activities of standardization, conformity assessment and quality assurance of goods, articles, processes, systems and services.

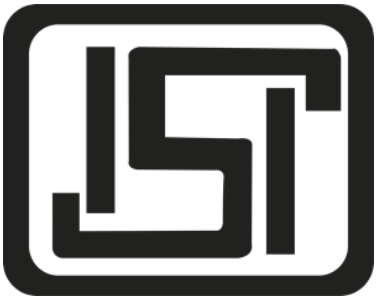
BIS is engaged in formulating Indian Standards in various technology areas and service sectors under the Bureau of Indian Standards Act, 2016 by a process of consultation involving Government and regulatory bodies, consumers, manufacturers, technologists, scientists and testing laboratories through duly constituted technical committees comprising of Sectional Committees, Subcommittees and Panels for dealing with specific group of subjects. In the Food and Agriculture sector, BIS has formulated over 2150 Indian standards covering food product and equipment specifications, test methods and hygiene codes covering the entire feed and food chain from farm to fork.

BIS does not make technical regulations. However, there are technical regulations which make compliance to BIS standards mandatory. Technical regulations are issued by various Departments/Ministries of Government of India.

BIS has its Headquarters at New Delhi and its 05 Regional Offices (ROs) are at Kolkata (Eastern), Chennai (Southern), Mumbai (Western), Chandigarh (Northern) and Delhi (Central). Under the Regional Offices are 28 branch offices (BOs) which offer certification services to the industry and serve as effective link between State Governments, industries, technical institutions, consumer organization etc. of the respective region.

BIS operates a product certification scheme by which it grants licences to manufacturers covering practically every industrial discipline. Though the BIS product certification scheme is essentially voluntary in nature, Government of India, in public interest (for example public health and safety, security, infrastructure requirements, mass consumption) has enforced mandatory BIS certification on various products through various quality control orders or under regulations issued from time to time under various Acts.

Food Products with mandatory BIS Certification as per Food Safety and Standards (Prohibition and Restriction on Sales) Regulations, 2011 are as under :



- Infant formula (IS 14433)
- Milk cereal based weaning food (IS 1656)
- Processed cereal based weaning food (IS 11536)
- Follow up formula (IS 15757)
- Packaged drinking water (IS 14543)
- Packaged mineral water (IS 13428)
- Milk Powder (IS 1165)
- Skimmed Milk Powder (IS 13334, Part 1 &2)
- Partly Skimmed Milk Powder (IS 14542)
- Condensed Milk, Partly Skimmed and Skimmed Condensed Milk (IS 1166)

EXPORT INSPECTION COUNCIL (EIC)

The EIC is the official export–certification body of India which ensures quality and safety of products exported from India. The EIC functions under the Ministry of Commerce and has a mandate to ensure that products notified under the Export (Quality Control and

Inspection) Act, 1963 meet the requirements of the importing countries in respect of their quality and safety.

This assurance is provided through either a consignment-wise inspection or a quality assurance/food safety management based certification through its field offices, Export Inspection Agencies (EIAs) and a network of 30 sub offices backed by NABL accredited laboratories at various places. EIC provides mandatory certification for various food items namely fish & fishery products, dairy product, honey, egg products, meat and meat products, poultry meat products and meat by products, feed additives and pre-mixtures, while other food and non-food products are certified on voluntary basis.

AGRICULTURAL AND PROCESSED FOOD PRODUCTS EXPORT DEVELOPMENT AUTHORITY AND MARINE PRODUCTS EXPORT DEVELOPMENT AUTHORITY

Agricultural and Processed Food Products Export Development Authority (APEDA) and Marine Products Export Development Authority (MPEDA) also function under Ministry of Commerce, Government of India. The main work of these authorities is to promote the export, assure the quality of the product as per international standards, formulate the standards for export etc.

APEDA is mandated with the responsibility of export promotion and market development of agricultural commodities and processed foods. The products under the purview of APEDA includes fresh fruits and vegetables, floriculture, processed foods, meat, poultry, milk and other livestock products, food grains, cereals, seeds and allied products.

MPEDA regulates exports and market promotion of marine products outside India. It is mandated to take all measures required for ensuring sustained, quality seafood exports from the country including carrying out inspection of marine products, implementation of financial assistance schemes for infrastructure development for better preservation & modernised processing, fixing standards, specifications, and imparting trainings to fishermen, fish processing workers, aquaculture farmers and other stake holders in the respective fields related to fisheries.

OTHER IMPORTANT FOOD LABELLING LOGO TO BE SEEN ON THE LABELS

FSSAI LOGO AND LICENSE NUMBER:

The FSSAI logo and license number under the Act shall be displayed on the label of the food package in contrast color to the background as shown below:

In case of multiple units, the FSSAI logo and license number of the brand owner shall be displayed and in addition the license number of the multiple unit(s) where product is ultimately prepared shall also be displayed. In case of imported food products, the importer shall display FSSAI logo and license number along with name and address of importer. Every food business operator shall display on all its premises, where food is stored, processed, distributed or sold, any/ all vehicles, transport equipment that carries food from one place to another, Registration/Licence No. (as the case may be) along with other information as may be required and specified by the Authority from time to time. Fortified food and organic food shall be marked with the logo as specified in **Schedule-III** of Food Safety and Standards (Labelling and Display) Regulation, 2020 Schedule-I regulations. FSSAI may specify logo for any other food as decided from time to time.

VEGETARIAN AND NON-VEGETARIAN LOGO

As per FSS (Packaging and Labelling) Regulations, 2011, a "Non- Vegetarian Food" means an article of food which contains whole or part of any animal including birds, fresh water or marine animals or eggs or products of any animal origin, but excluding milk or milk products, as an ingredient and "Vegetarian Food" means any article of Food other than Non-Vegetarian Food. It is mandatory for all food manufacturers to indicate as to whether the food item contains any non-vegetarian ingredients or not. To enable the consumer to know whether any packaged food is vegetarian or non-vegetarian, this will be indicated in the form of a brown triangle in square or green circle in a square on the package. A brown triangle is to indicate the presence of non-vegetarian ingredients in the food item, while a green circle indicates that the food item is vegetarian. The green circle and brown triangle in a square are indicated as veg & non-veg logos respectively.

Vegetarian and non-vegetarian marks

The green dot symbol (left) identifies vegetarian food, and the brown triangle symbol (right) identifies non-vegetarian food.

ORGANIC FOODS (JAIVIK BHART)

Organic foods are products of holistic agricultural practices focusing on biodiversity, soil health, chemical free inputs etc., and produced in accordance with Organic Production Standards as per the FSS (Organic Foods) Regulations, 2017. The Jaivik Bharat logo for organic

food is an identity mark to distinguish organic products from non-organic ones. The logo is supported with the tagline "Jaivik Bharat", at the bottom, which signifies Organic Food from India. Employing a simple approach to communicate an effective message, the green color of the logo symbolizes nature along with articulating that these foods are produced in environment-friendly manner without using chemical fertilizers and pesticides. It highlights the letter "O" used in the word "Organic" as well as represents the facet of holistic health at a global platform. To show a sturdy relationship with the same, leaves have also been used in the logo in the form of a tick mark incorporated inside the circle represented by the letter "O". The logo showcases that the product bearing it has been authenticated as organic for the choice for consumption. Effectively intertwining all the elements of environment, the logo communicates adherence to the National Organic Standards. Every certified organic food container shall have 'Jaivik Bharat' Logo.

FOOD FORTIFICATION (F+ LOGO)

Fortification is the addition of key vitamins and minerals such as Iron, Iodine, Zinc, Vitamins A & D to staple foods such as rice, wheat, oil, milk and salt to improve their nutritional content. These nutrients may or may not have been originally present in the food before processing or may have been lost during processing. Deficiency of micronutrients or micronutrient malnutrition is a serious health risk. Access to safe and nutritious food is a must and sometimes due to lack of consumption of a balanced diet, lack variety in the diet or unavailability of food, one does not get adequate micronutrients. Often, there is considerable loss of nutrients during the processing of food as well. One of the strategies to address this problem is fortification of food. This method complements other ways to improve nutrition such as diversification of diet and supplementation of food. The Food Fortification logo is an identity mark to distinguish fortified products from non-fortified ones as per the standards notified under FSS (Fortification of Food) Regulation, 2018.

IRRADIATION OF FOOD ('RADURA' LOGO)

Food irradiation is a physical process in which food commodities, bulk or pre-packaged are exposed to controlled doses of energy of ionizing radiation such as gamma rays or X-rays to achieve different technological objectives. These technological process includes extension of shelf-life, destruction of storage and quarantine insect pests, and killing of parasites, pathogens and spoilage microorganisms. Radiation processing can thus be used for enhancing food safety, food security and international trade. It became mandatory in 2007 to treat Indian mangoes with gamma radiation for control of quarantine insect pests before export to the USA. In India more than a dozen irradiation facilities have been established by private entrepreneurs for treatment of food. For commercial application of the technology in India, Atomic Energy (Control of Irradiation of Food) Rules were notified in 1991, and later amended in 1996. In 2012, a new amendment resulted in the notification of the current Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012. Atomic Energy Regulatory Board (AERB) is the regulatory authority in India for enforcing these rules. In 1994, Government of India amended Prevention of Food Adulteration Act (1954) Rules and approved irradiation of onions, potatoes and spices for domestic market. Additional items were approved in April 1998 and in May 2001.

PROCESSED BY RADIATION

Name of the Product:

Purpose of Radiation Processing:

Operating License No. :

Batch Identification No. (BIN) (as provided by facility):

Date of Processing.....……"

Regulations on radiation processing have been notified under Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2011 in 2016. In February 2004, Ministry of Agriculture, Government of India, amended plant protection and quarantine regulations to include irradiation as quarantine measure in the Plant Quarantine (Regulation of Import into India) Order, 2003, enabling use of the technology in overcoming quarantine barriers and getting market access. The new regulations have approved radiation processing of food and agro commodities on generic food class basis. Licensed radiation processing facilities have to comply with the conditions of approval, operation, and process control prescribed under the Atomic Energy (Radiation Processing of Food and Allied Products) Rules, 2012. Further, as per FSS (Food Product Standards and Food Additives) Regulations, 2011, the irradiated products are labelled and can be identified with the ***'Radura'*** logo.

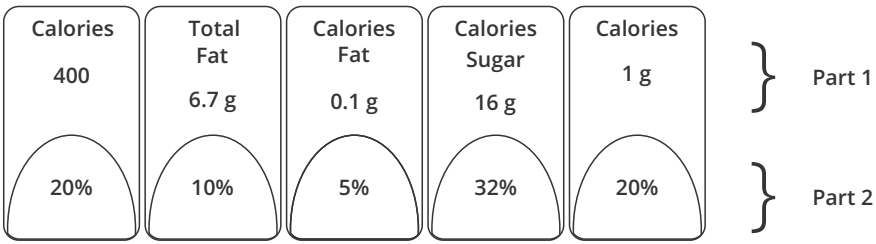
FRONT OF PACK LABELLING (TO BE INTRODUCED)

To curtail the rising consumption of processed foods that are high in fat, sodium, and

sugar, Front-of-pack nutrition labelling is widely considered to be a powerful and simple tool for discouraging consumption of processed foods. FSSAI has proposed the symbol-based front-of-pack nutrition labelling, and intend to make it mandatory. In an attempt to encourage consumers, make healthier food choices, the new food labelling regulations propose to display red colour-coding on front-of-the-pack labels on packaged food products that have high-fat, high-sugar and high-salt content levels. Once the new regulations are notified, this requirement would be implemented in phased manner for a period of three years. The following information shall be declared on the front of pack:

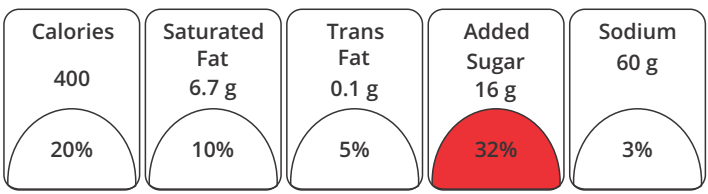
- The name of food;
- Declaration regarding veg or non-veg;

Per serve contribution of energy, total fat, trans fat, total sugar and salt (sodium chloride) to RDA as is shown below:



Part 1 - Declares the amount of energy, total fat, trans fat, total sugar and salt (sodium chloride) per serve;

Part 2 - Declares the per serve percentage (%) contribution to RDA as provided under regulation 4.2 (3)(b) of the proposed regulations. The block(s) of nutrient(s) for "High Fat, Sugar and Salt" (HFSS) food shall be coloured 'RED' as depicted below:



In case the value of energy Total 15 (kcal) from total sugar is more than 10 per cent of the total energy (kcal) provided by the 100 g/100 ml of the product; the value of energy (kcal) from trans-fat is more than 1 per cent of the total energy (kcal) provided by the 100 g/100 ml of the product; and total fat or sodium content provided by the 100 g/100 ml of the product is more than the threshold values as specified in Schedule – I of the regulations.

NOTES

CHAPTER-9

QUALITY CONTROL OF IMPORTED FOODS & CODEX

9 QUALITY CONTROL OF IMPORTED FOODS & CODEX

FOOD IMPORTS SYSTEM

FSSAI has the mandate to regulate import of foods into the country and ensure that it is safe and wholesome for human consumption. As per Section 25 of the Food Safety & Standard Act, 2006, all imports of articles of food are subject to the provisions of the Act. It stipulates that no person shall import into India any article of food in contravention of the Act or any rules and regulations made thereunder. Exercising the power of the Act, the Central Government on the recommendation of the Food Authority has notified the Food Safety and Standards (Import) Regulation, 2017, Further, all the orders for simplifying food imports are available on FSSAI on following link : https://fssai.gov.in/advisories.php

FOOD SAFETY AND STANDARDS (IMPORT) REGULATIONS, 2017

Key Highlights

a) No imports of food article are permitted in India without a valid import license from the Central Licensing Authority of FSSAI.

b) The consignments of food articles are referred to FSSAI for clearance by the Customs Authorities through Food Import Clearance System.

c) The food consignments are subject to scrutiny of documents, visual inspection, sampling and testing in order to determine whether or not they conform to the safety and quality standards laid down under various Food Safety and Standards Regulations, 2011.

d) Food Authority may review the risks associated with articles of food imports from time to time and adopt a risk-based framework and risk based inspection process for clearance of imported articles of food or even include them in the prohibited items list.

e) Powers and duties of Authorised Officers notified for the purpose of food import clearance is prescribed under Chapter IX of these Regulations.

f) In case of imported packaged food consignments, special dispensation for rectification of labels is provided under Reg 6 (4) of FSS (Import) Regulations, 2017.

g) Provisional No Objection Certificate can be issued for certain types of imported food consignments without waiting for the analysis report from lab on the basis of an

undertaking from the Importer as prescribed under Chapter V of these Regulations.

h) Importer can apply for retest, if the sample is found non-Conforming to the Food Safety Standards by the primary laboratory.

i) Requirement of NOC from FSSAI is exempted under following conditions by submitting an undertaking (details are mentioned in Chapter 4 of FSS (Import) Regulations, 2017):

   i. Articles of food imported for personal consumption

   ii. Imported food consignment meant for Display Purpose in Trade Fair/Exibition

   iii. Imported food consignment meant for Research & Development purposes

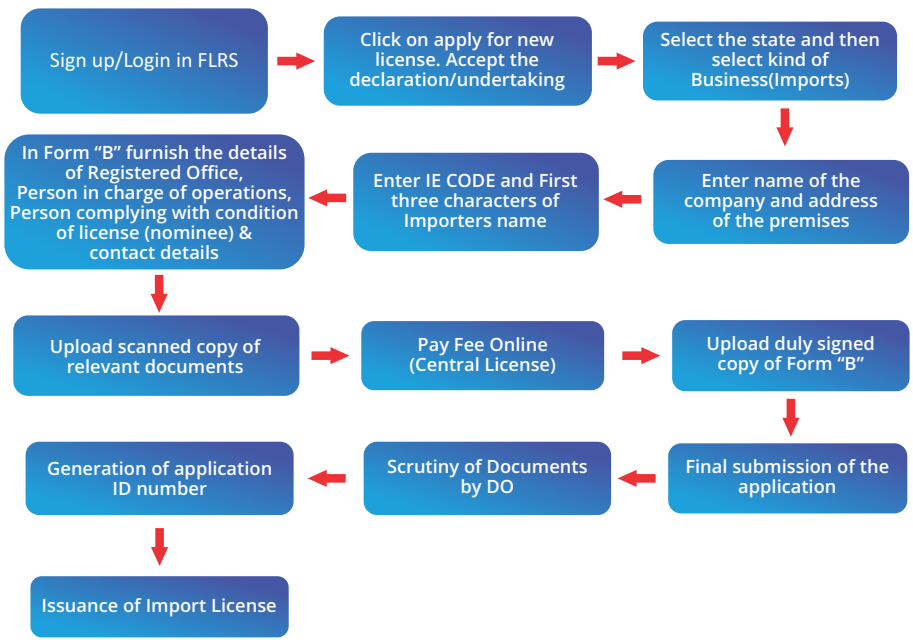
   iv. Imported food consignment meant for Sports Events

   v. Imported food consignment meant for 100% Export and Re-export

HOW TO OBTAIN IMPORT LICENSE

For obtaining food import license, the applicant/ prospective Importer requires a valid Import Export Code (IE code) issued by Directorate General of Foreign Trade (DGFT). The link for obtaining the import license under Food Licensing and Registration System (FLRS) is https://foodlicensing.fssai.gov.in.

Fig 1: Process Flow Chart for obtaining FSSAI Import Licence.



The applicant fills in the required information online and uploads mandatory documents in FLRS, as per the process detailed above. The format of required documents has been provided in the FLRS portal under the list of supporting documents for Central license. Importer is required to scan the documents and upload them in pdf format with the annual fee of Rs. 7500 payble for import license. The importer can apply for license for a period of one year and upto a maximum of five years.

As per Food Safety & Standards (Licensing and Registration of Food Business) Regulation, 2011, a license shall, subject to the provisions of these Regulations, be issued by the concerned Licensing Authority within a period of 60 days from the date of issue of an application ID number which is generated after successful completion of the application and uploading the required documents by the importer .

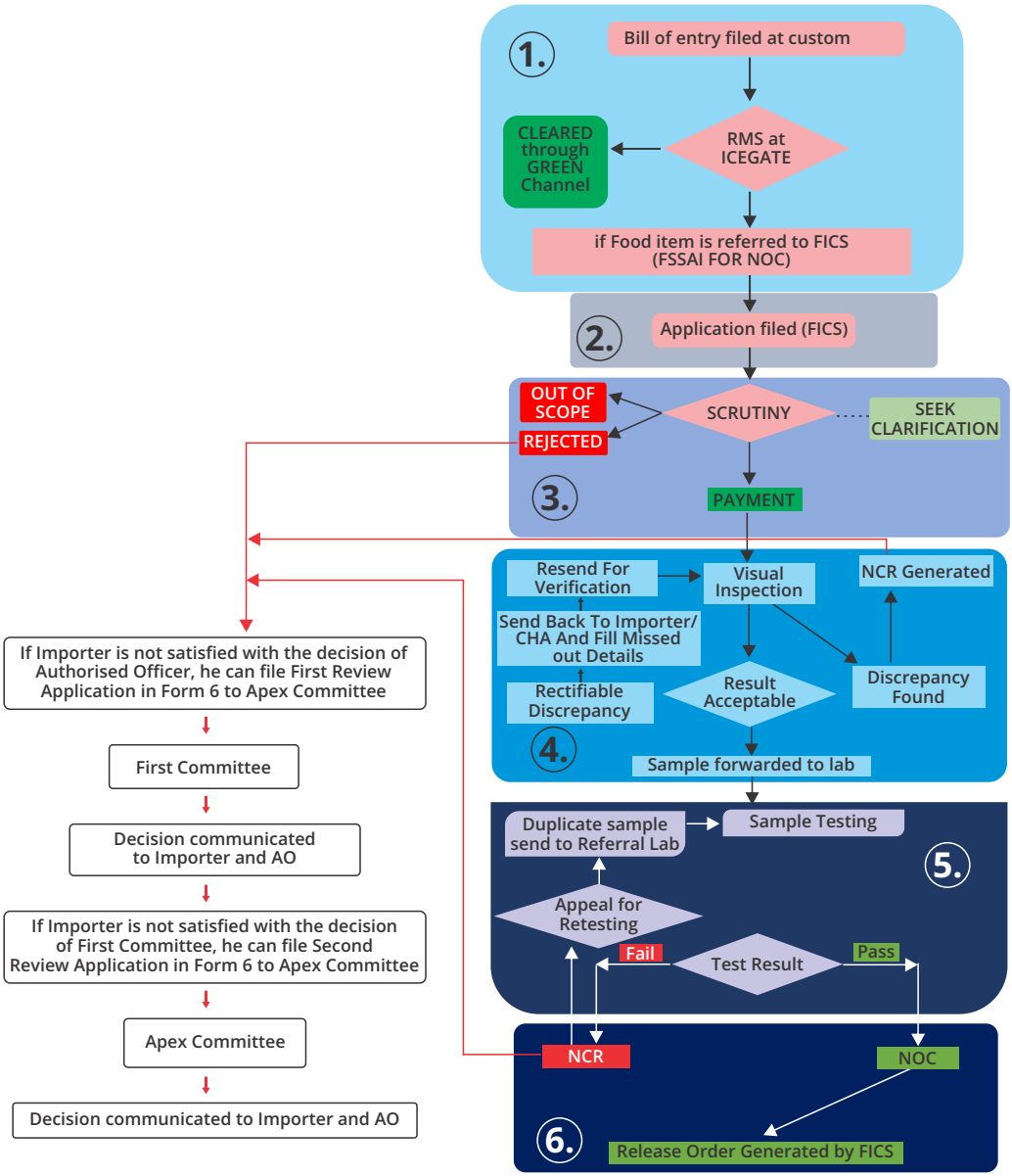
The importer shall have to fulfil the following conditions subsequent to obtaining an import licence:

- Inform Authority about any change or modification in activities /content of license.
- The importer must file Annual Return in Form D-1as per conditions of license mentioned in FSS (Licensing and Registration of Food Business) Regulation, 2011 and submit it to the concerned Regional Office of FSSAI (Designated Officer) on or before 31st May of each year for each class of food handled during the previous financial year.
- Importer must apply within 30 days before the expiry of license for renewal. If not renewed, the license gets expired and the FBO has to apply afresh for a new license.

OVERVIEW OF FOOD IMPORT CLEARANCE SYSTEM IN INDIA

FSSAI has its presence at six locations through its own Authorised Officers at Chennai, Kolkata, Mumbai, Delhi, Cochin and Tuticorin covering 22 points of entries. Further, at other Point of Entries throughout the country FSSAI has notified Customs officials as Authorised Officers for the purpose of regulating food imports. FSSAI has in place its own Food Import Clearance System (FICS) which is an online system, integrated with the customs ICE-GATE (Indian Customs Electronic Commerce / Electronic Data interchange Gateway) under SWIFT (Single Window Interface for Facilitating Trade).

STEPS OF FOOD IMPORT CLEARANCE PROCESS AND REVIEW PROCESS



RISK MANAGEMENT SYSTEM (RMS)

Food Safety & Standards (Import) Regulations, 2017 provides for selective sampling & testing of food article on the basis of risk profile and parameters as set by FSSAI. To minimise the sampling size and time and hence to expedite the clearance process of imports in line of

ease of doing business, risk based sampling system called Risk Management System (RMS) has been introduced under Single Window Interface for Facilitating Trade (SWIFT) by department of Customs in consultation with FSSAI based on certain criteria like **risk category of the food items, compliance history of the importers** and **country of origin** etc. RMS has been introduced to encourage and incentivize self-compliant importers.

In case of low risk food items, 5% random selection is done provided earlier 5 consecutive consignments of the same product imported by the same importer have complied with the FSS Regulations. In case of high risk items, if 5 consecutive consignments imported by the same importer have complied with the FSS Regulations, then only 25% of next 20 consignments of the same products imported by the same importer are sampled. Thereafter, only 5% of the future consignments of the same products imported by the same importer would be sampled even for high risk item.

CLEARANCE OF IMPORTED FOOD BY THE FOOD AUTHORITY

Upon arrival of the food consignments at the port, the importer or Custom House Agent (CHA) shall file an Integrated Declaration Form as specified by the Customs. The Form forwarded from Customs to the Food Import Clearance System of Food Safety and Standards Authority of India shall be processed in the following manner:

- The Authorised Officer shall scrutinise the Form and may seek clarification if required;
- Upon satisfactory scrutiny, the applicant shall pay the fees as specified by the Food Authority for scrutiny of documents, visual inspection and drawing of sample;
- Where a single bill of entry is made up of articles of food consignment consisting of multiple categories of articles of food, inspection fee shall be paid for each category of articles of food;
- On receipt of the fees, the Authorised Officer shall intimate the details of date and time of inspection to the Food Importer to facilitate the presence of the Food Importer or his Custom House Agent/ Authorised representative at the time and place of inspection.

The Food Importer or his authorised representative shall remain present at the customs area at the appointed time to participate and facilitate visual inspection, assist in drawing of samples, if required, assist in the import clearance proceedings as instructed by the Authorised Officer or his representative and witness proceeding, sealing of samples by the

Authorised Officer or his representative and affix his counter signatures on the sealed samples. If the Food Importer or his Custom House Agent is not present to facilitate the inspection and sampling in spite of two opportunities having been granted, the Authorised Officer may refuse to grant further opportunity for inspection and sampling of the food consignment, and any further opportunity in this behalf may be granted by the Chief Executive Officer or any officer authorised by him to do so.

STORAGE FACILITIES FOR IMPORTED FOODS

No consignment of food articles shall be stored in a manner that one type of articles of food come in contact with other type of articles of food. The imported articles of food shall be stored in accordance with the specified storage conditions in the custom warehouse before clearance, if not stored properly, the concerned Authorised Officer may refuse to grant no objection certificate for import clearance of the food consignment. The port authorities and custodian of freight stations shall ensure adequate and conducive storage infrastructure; meeting the safe storage of various types of imported food consignments in the customs area till the imported articles of food is cleared by the custom authority. The Authorised Officer shall take an undertaking from the importer in FORM - 12, and issue provisional no objection certificate to the importer to move the food consignment to a well-equipped storage facility. The Authorised Officer may issue a no objection certificate to the importer if he is satisfied on the basis of the analysis report conforming to standards. The importer or customs shall ensure sale only after clearance based on no objection certificate.

VISUAL INSPECTION

The Visual inspection by the authorised officer or an officer deputed by him, is to be conducted for the purpose by which the **physical condition of the food** consignment, scrutiny of documents and compliance of packaging and labelling regulations are ascertained for the food safety compliance prior to drawing of samples.

The Authorised Officer or his representative shall ensure compliance with the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 and with a valid balance shelf life in respect of imported article of food. After visual inspection if the authorised Officer is satisfied that the Food Importer has complied with the provisions of these regulations, he shall draw two parts of food sample from the imported articles of food in the customs area in the presence of Food Importer or his Custom House Agent for testing the samples. The Authorised Officer shall reject the consignment not complying with the provisions of Packaging and Labelling Regulations, 2011 at the visual inspection and no sample shall be drawn from the consignment.

Salient points to be remembered during the time of physical inspection by various officers or its representative.

- **Imported food product should bear**
  - The label of Imported Food Products should be either in Hindi (Devnagari Script) or in English
  - Name & Address of the Importer
  - FSSAI Logo with License No.
  - Veg/Non Veg in case of pre-packaged food
  - Date of Manufacture and Date of Expiry to calculate residual self-life as per the instructions of DGFT/Requirements under FSSAI Act/Regulation.
  - Name & Address of the Manufacturer or Packer
  - Generic name of the product
  - Net contents Declaration
  - List of Ingredients on the label
  - List of Additives on the label
  - Nutritional Declaration in case of Re-packed food
  - In case of Proprietary food, generic name and nature of composition to be verified
  - In case of Nutraceuticals product, the content of nutraceuticals should match within RDA limit.
  - Samples to be drawn out of each product description depending on batch No., Lot No., Date of manufacture, Nature of ingredients and variation of Additives
  - Checking of temperature Log sheet in case of pre cooled and frozen product
  - Matching of container No. or Airway Bill No. with Bill of Entry raised in EDI System
  - In case of Aseptic or bulk frozen pack, the representative sample should accompany with consignment along with certificate showing integrity of the sample drawn out of same consignment, to be taken for analysis
  - No imported consignment of packaged drinking water to be allowed without prior approval from BIS

- No imported blended edible vegetable oil for imported consignment should be allowed without approval of AGMARK
- The imported milk products particularly for infant and intended for complementary food should be allowed without BIS license/Mark
- All the imported Milk products should accompany with Veterinary Drug Residue Certificate from the Exporting country
- Consignment of imported alcoholic beverage should adhere to the label requirements and statutory wordings as mentioned in the Alcoholic beverages – "Drinking alcohol is injurious to health", "Drinking of alcohol during driving is prohibited", etc.
- All Proprietary Food Products should mention the nearest category in the Food safety and Standards (Food Product Standards and Food additives) Regulation, 2011 Regulation to match with the permitted allowed additives. Only approved ingredients under FSSR, 2011 are allowed for Proprietary Foods. All imported Proprietary Food consignment should accompany with Certificate of Analysis form any Laboratory accredited under IS 17025 of exporting country.
- All imported food chemical consignments should either match with the requirement of purity as mentioned under FP & FA Regulation or as per CODEX standards.
- All combinations of imported Food Ingredients should match with the Standards mentioned in Food safety and Standards (Food Product Standards and Food additives) Regulation, 2011 or their ingredients and additives standard should match with the intended use for the product category mentioned in FSSR, 2011.

RECTIFIABLE LABELLING DEFICIENCIES

In case of imported packaged food consignments, the following special dispensation on labelling shall be allowed for the ***rectifiable labelling deficiencies*** at the custom bound warehouse by affixing a single non-detachable sticker or by any other non-detachable method next to the principle display panel:

(a) Name and address of the importer;
(b) Food Safety and Standards Authority of India's Logo and license number,
(c) Non-Veg or Veg Logo
(d) Category or sub category along with generic name, nature and composition for proprietary food

In respect of the rectifiable labelling deficiencies referred the Authorised Officer may pass an order directing the Food Importer or his authorised agent to carry out the permissible labelling rectifications, within a specified time in the customs area without altering or masking the original label information in any manner.

SAMPLING OF IMPORTED FOOD IN RESPECT OF IMPORTED ARTICLE OF FOOD

Authorised person to conduct Visual inspection and take the sample of import food products :

As per Food Safety and Standards (Import) Regulations 2017, Authorised Officer appointed by the Chief Executive Officer of the Food Safety and Standards Authority of India by an order for the purpose of performing functions (Food Import Clearance), is authorised to take the samples of import food products for analysis as per sub section (5) of section 47 of the FSS Act. He shall follow the procedure as specified in Food Safety and Standards (Import) Regulation 2017.

The Authorised Officer shall draw two parts of food sample of each description or measures (except for aseptic sealed packages); and forward to the food analyst in such a quantity of sample as specified under the Food Safety and Standards (Laboratory and Sample Analysis) Regulations, 2011;

Sealed samples :

a) If the imported articles of food is packed in a sealed bulk container by the manufacturer in order to maintain aseptic or hygroscopic condition, which is required to retain the character of the article of food, the manufacturer shall provide two representative sealed samples from the same batch along with a declaration by the manufacturer stating that the articles of food in the sealed container match with the representative samples placed in the sample containers.

b) Where the representative sealed sample referred to in clause (a) with a manufacturer undertaking is not provided by the Food Importer, the Authorised Officer is empowered to break open the seal and collect a sample for lab analysis.

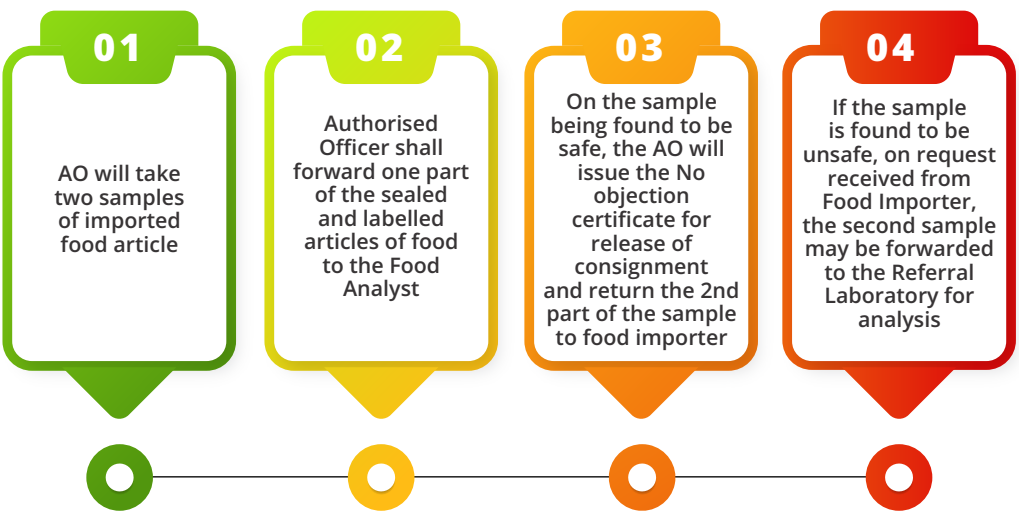
c) The Authorised Officer may collect a representative sample from the sealed container, for lab analysis, wherever the provided sealed representative samples appear to be doubtful.

The sealed sample of imported articles of food shall bear the following information on the Label:

- Code number of the sample;
- Date and place of collection;
- Quantity of sample;
- Name of articles of food and
- Category as per the Food Safety and Standards (Food Product Standards and Food Additives) Regulations-2011.
- Name and quantity of preservative added while drawing the sample, if any;
- Name and signature of the Food Importer or his Custom House Agent and;
- Name and signature of the sender with official seal.

In respect of imported articles of food having shelf-life less than seven days, the applicant shall declare the same in FORM - 13 allowing the Authorised Officer to draw sample and issue provisional no objection certificate to the customs, without waiting for the analysis report from laboratory and on receipt of the report analysis from the laboratory, the Authorised Officer shall communicate to the customs along with no objection certificate if products conform to the standard. In case of non – conformance of the sample, the Authorised Officer shall immediately inform the Importer or Custom Broker, to initiate recall of that consignment and submit a compliance report as specified in the Food Safety and Standards (Food Recall Procedure) Regulations, 2017.

PROCESS FLOW OF SAMPLING AND ANALYSIS



The Authorised Officer shall forward one part of the sealed and labelled articles of food to the Food Analyst. The remaining parts of the food sample after forwarding one part of the sealed and labelled articles of food, shall be stored in appropriate conditions by the Authorised Officer or his authorised representative. On the sample being found to be safe, the remaining sample shall be returned to the food importer. If the sample is found to be unsafe, on request received from Food Importer, the second sample may be forwarded to the Referral Laboratory for analysis. The importer can apply for retest within fifteen days of receipt of the non-conformance report of primary laboratory.

The Authorised Officer will inform the laboratory immediately on receipt of advance notice of arrival from the importer under the Pre-Arrival Document Review of the articles of food; to ensure that the laboratories authorised by the Food Authority comply with all the specified procedures and perform all parameters of testing as specified in the regulations or permissions accorded by the Food Authority. The laboratories authorised by the Food Authority shall maintain records of laboratory analysis of the imported articles of food in the format as specified by the Food Authority;

The Authorised Officer shall maintain the record of food imports, inspection, sampling and related activities, action taken, review process within the jurisdiction of customs ports assigned to him and such other duties assigned by the Food Authority from time to time in writing and by photographs and audio and videography.

APPEAL ON REJECTION (REVIEW PROCESS)

Importer can file review application with grounds of appeal in Form-6 to Director (Imports) against Non-Conforming Report issued by Authorised Officer. If Importer is not satisfied with the decision of first review, then he can file second review application with grounds of appeal in Form-6 of FSS (Import) Regulations, 2017 to CEO, FSSAI.

DISPOSAL OF REJECTED FOOD CONSIGNMENTS AND FOOD SAMPLES

Rejection of imported food consignments

On receipt of the non-conformance report, the Custodian or importer shall dispose of the imported food consignment in accordance with the provisions of the Customs Act, 1962 (52 of 1962). However, no food consignment shall be disposed off until the period of limitation is over for filing of review application against the order of the Authorised Officer.

Unless otherwise specified, the Customs Authority may not refer the imported food consignments to FSSAI for clearance in the following cases:

IMPORT FOR OTHER PURPOSES

Food Import for Personal consumption

Any person bringing in any article of food for his personal use, value as allowed by customs from time to time, shall have to only submit the declaration in **FORM-7** of FSS (Import) Regulations, 2017.

Food imported by Diplomatic Missions

The clearance of Food Imports imported by diplomatic missions shall be dealt in accordance with provisions of Vienna Convention on Consular Relations, 1963 (Article 50 of the Vienna Convention on Consular Relations, 1963).

Import of Food for Quality Assurance, Research and Development Purposes

The clearance of food imports for quality assurance, research and development purposes will be subject to furnishing of Undertaking as per **FORM-9** of FSS Import Regulation, 2017 by the Food Importer that the imported food will be utilized for aforesaid purposes only and not to be utilized or released into the domestic market or used for test marketing or market research purposes.

The food imported for the purposes of Exhibitions & Tasting

The clearance of food import exclusively for these purposes is exempted from the normal clearance procedures of the Food Authority subject to the submission of an undertaking as per the **Form-10** of FSS Import Regulation, 2017 before the Customs Authorities.

Import of Food for sports events

The clearance of Food import exclusively for these purposes will be subject to furnishing of Undertaking **Form- 11** of FSS (Import) Regulation, 2017 by the Food Importer.

Imported food consignment meant for 100% export / re-export

The articles of food imported by the manufacturers or processors for their captive use or production of value added products for 100 % exports; or the consignments of articles of food or ingredients or additives imported by the firms or companies for use of their sister concerns or wholly owned subsidiary companies, to be used for hundred per cent export production subject to a defined relationship agreement between the two entities in this behalf.

The importer shall submit an undertaking in **Form-8** of FSS (Import) Regulations, 2017 regarding the captive or end use of the imported product to the Customs Department at the time of filing the bill of entry, declaring that the imported articles of food is meant to be used by the importer for 100% export or re-import of articles of food for export again as the case may be, and that no part thereof shall be supplied for domestic consumption.

CODEX ALIMENTARIUS COMMISSION AND OTHER INTERNATIONAL STANDARDS SETTING BODIES

With an expanding world economy, liberalization of food trade, growing consumer demand, developments in food science and technology, and improvements in transport and communication, international trade in fresh and processed food has been increasing rapidly. To a large extent, due to more accessibility of countries to food export markets, health protection measures have taken a prominent place.

The process has been facilitated by the coming into force on 1st January 1995 of the World Trade WTO Agreement under which the Agreement on Application of Sanitary and Phyto-Sanitary (SPS) Measures and Agreement on Technical Barrier to Trade (TBT) that covers food safety and quality are important.

Under the WTO agreement, the SPS agreement has two-fold mandate, namely,

- Countries have a right to protect the life and health of its plants, animals and human beings; and
- While doing so, member countries should ensure that they do not create unnecessary barriers to trade.

The key provisions of the SPS Agreement are

All WTO member countries are required to follow a non-discriminatory approach, whereby, members of the WTO cannot discriminate between imported food products and those produced domestically. This means that same regulations will apply to food products of domestic origin and imported foods as well. It means that clearance of imported food product by the Customs at Indian ports (points of entry) is subject to the provisions of the Food Safety and Standards Act 2006 and the rules and regulations thereunder. Once cleared at the port of entry, the imported products also come under the purview of routine regulatory control (including monitoring) of the food safety enforcement agencies and FSOs.

The exporting countries have to comply with the standards (Regulations) of the importing countries. Thus, when India exports food products to another country, India has to comply with the Regulations of that country. Similarly, when any other country wishes to export its food products to India, that country have to comply with the Regulations notified under the Food Safety and Standards Act.

It must also be remembered that, in the context of food products, international standards in the framework of WTO are **ONLY** the CODEX standards laid down by CODEX Alimentarius Commission, a joint FAO/WHO body. While CODEX standards are international standards, these are voluntary in nature and the SPS Agreement encourages all WTO members to harmonize their National standards with CODEX standards.

It also needs to be understood that CODEX standards are the reference standard in the framework of WTO and under the SPS Agreement countries are expected to harmonize their National standards (Regulations) with those of CODEX. However, countries also have a right to adopt standards which are stricter than CODEX provided such standards are developed in a transparent manner and with sound scientific justification. Nonetheless, such standards have to be strict only to the extent necessary in the context of food safety. While adopting stricter standards, countries are required to ensure that they do not create unnecessary barriers to trade. Such barriers are against the spirit of WTO and can be challenged in the WTO system. While setting standards, countries are required to take into account the concerns (technical and economic feasibility) of developing countries.

In any case, if an exporting country finds it difficult to comply with the standards of the importing country due to lack of technical capacity, it can seek technical assistance for building capacity to meet the requirements of the importing country. The importing country has an obligation to provide the required technical assistance to the exporting country.

International standards Setting Bodies

In order that countries can exercise their right to protect the life and health of its plants, animals and human beings without creating unnecessary barriers to trade, the SPS Agreement has recognised the following three international standards-setting bodies, namely,

(i) **International Plant Protection Convention (IPPC),** which is based in Rome, sets international standards **for plant health**. IPPC works to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate mitigation measures for their control. In India, the nodal department is the

Directorate of Plant Protection, Quarantine and Storage (DPPQ&S) in the Ministry of Agriculture and Farmers' Welfare. The DPPQ&S is the National Plant Protection Organisation (NPPO) and regularly participates in the IPPC meetings. The DPPQ&S is also designated as the SPS Enquiry Point for plant health in India.

(ii) **Office International des Epizooties (OIE)**, also known as the World Organization for Animal Health is based in Paris and sets international standards **for animal health**. OIE's primary objective is to protect the health of animals and to ensure a safe and fair trade in animals and animal products worldwide, by ensuring transparency in the global animal disease situation and by publishing health standards for international trade. It also sets guidelines for animal welfare although this mandate does not fall under the SPS agreement. In India, the nodal department is the Department of Animal Husbandry and Dairying (DAH&D), in the Ministry of Fisheries, Animal Husbandry and Dairying. The Department of Animal Husbandry regularly participates in the OIE meetings. The Department of Animal Husbandry is also designated as the SPS Enquiry Point for animal health in India.

(iii) **CODEX Alimentarius Commission (CAC)** is an intergovernmental body of the United Nations, established jointly by FAO and WHO in 1963. The CODEX Alimentarius Commission functions with the help of a Chairperson and 3 Vice-Chairpersons. The CODEX Secretariat is located in Rome. CODEX Alimentarius Commission develops harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in food trade. These standards are based on science and scientific opinion provided by the independent international risk assessment bodies of FAO and WHO. These food standards and related texts aim at protecting consumers' health and ensuring fair practices in the food trade.

The CODEX Alimentarius Commission shall be responsible for making proposals to, and shall be consulted by, the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is:

(a) Protecting the health of consumers and ensuring fair practices in the food trade;

(b) Promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations;

(c) Determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;

(d) Finalizing standards elaborated under (c) above and publishing them in a CODEX Alimentarius either as regional or worldwide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable; (e) amending published standards, as appropriate, in the light of developments.

In India, the Food Safety and Standards Authority of India (FSSAI) is the National CODEX Contact Point (NCCP), which also regularly participates in the CODEX meetings and is involved in standard setting process in various CODEX Committees. The FSSAI is also designated as the SPS Enquiry Point for food safety in India.

The **CODEX Alimentarius** is a compilation of international standards for foods based on which a number of countries have developed their own national food regulatory policies and regulations. The CODEX international standards are a robust way to maintain consumer' health and prevent food borne illnesses. It includes standards for all the principal foods, whether processed, semi-processed or raw, for distribution. The CODEX Alimentarius includes provisions in respect of food hygiene, food additives, residues of pesticides and veterinary drugs, contaminants, labelling and presentation, methods of analysis and sampling, and import and export inspection and certification; and codes for the practices to prevent/reduce contamination of foods.

India is a member of CODEX Alimentarius Commission since 1964 and continues to be a partner in the international food standards development process. Currently the membership of CODEX Alimentarius Commission includes 189 CODEX Members (i.e. 188 Member Countries (including India) and 1 Member Organization (European Union)), 236 CODEX Observers (only those observers can participate in CODEX meetings that are approved by the Directors-General of FAO and WHO on the recommendations of CAC).

BENEFITS OF FOLLOWING CODEX ALIMENTARIUS

- It easy for countries to harmonize national legislations
- It provides flexibility in adaptation with international standards
- It saves financial resources in carrying out scientific risk assessment for framing standards (Regulations)
- Exchange of information between two or more countries is standardized and is easy
- It saves time and facilitates trade
- It helps countries to settle differences

NATURE OF CODEX STANDARDS

The CODEX standards can be:

General Standards : Dealing primarily with food safety, consumer information and trade requirements. The General Standards, Guidelines and Codes of Practices adopted are the CODEX texts that apply to all products and product categories, which typically deals with hygienic practice, labelling, additives, inspection & certification, nutrition and residues of veterinary drugs and pesticides.

Commodity standards : have a common format stating what the commodity is, how it is made and what it may contain and refer to a specific product or food groups e.g. CODEX Standard for Mangoes, CODEX Standard for certain Canned Fruits etc.

As of 2019, CODEX has developed 362 texts including standards for food products, codes of practice and guidelines, which are available in public domain at the CODEX website : http://www.fao.org/fao-who-CODEXalimentarius/en/

CODEX standards and related texts are voluntary in nature and are not a substitute for, or alternative to national legislation. It is the law/regulations of a country that the food producers/processors/industries have to follow. Countries should take legal steps at the national level to incorporate CODEX standards into their legislation for enforcement purposes.

COMMITTEES OF CODEX ALIMENTARIUS COMMISSION

CODEX Alimentarius Commission is assisted in its work by its subsidiary bodies that include an Executive Committee, ten General Subject Committees, 17 Commodity Committees (of which five are currently active), *Ad-hoc* Inter-Governmental Task Forces and six Regional Coordinating Committees (including one for Asia). The General Subject Committees carry out work that has relevance for all food commodities while Commodity Committees develop standards for specific foods or classes of food. Task Forces work on specific issues that do not fall under the purview of any other CODEX Committee.

The current list of active CODEX Committees/Task Force functioning under the CAC is:-

1. **Executive Committee of the CODEX Alimentarius Commission (CCEXEC)**
2. **General Subject Committees / Task Force**
   - CODEX Committee on Contaminants in Foods (CCCF)
   - CODEX Committee on Food Additives (CCFA)

- CODEX Committee on Food Hygiene (CCFH)
- CODEX Committee on Food Import and Export Inspection and Certification Systems (CCFICS)
- CODEX Committee on Food Labelling (CCFL)
- CODEX Committee on General Principles (CCGP)
- CODEX Committee on Methods of Analysis and Sampling (CCMAS)
- CODEX Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)
- CODEX Committee on Pesticide Residues (CCPR)
- CODEX Committee on Residues of Veterinary Drugs in Foods (CCRVDF)

3. Commodity Committees

- CODEX Committee on Cereals, Pulses and Legumes(CCCPL)
- CODEX Committee on Fresh Fruits and Vegetables (CCFFV)
- CODEX Committee on Fats and Oils (CCFO)
- CODEX Committee on Processed Fruits and Vegetables (CCPFV)
- CODEX Committee on Spices and Culinary Herbs (CCSCH)

4. Ad-hoc Inter-Governmental Task Forces

- Task Force on Anti-Microbial Resistance

5. FAO/WHO Coordinating Committees

- FAO/WHO Coordinating Committee for Africa (CCAFRICA)
- FAO/WHO Coordinating Committee for Asia (CCASIA)
- FAO/WHO Coordinating Committee for Europe (CCEURO)
- FAO/WHO Coordinating Committee for Latin America and the Caribbean (CCLAC)
- FAO/WHO Coordinating Committee for North America and South West Pacific (CCNASWP)
- FAO/WHO Coordinating Committee for Near East (CCNEA)

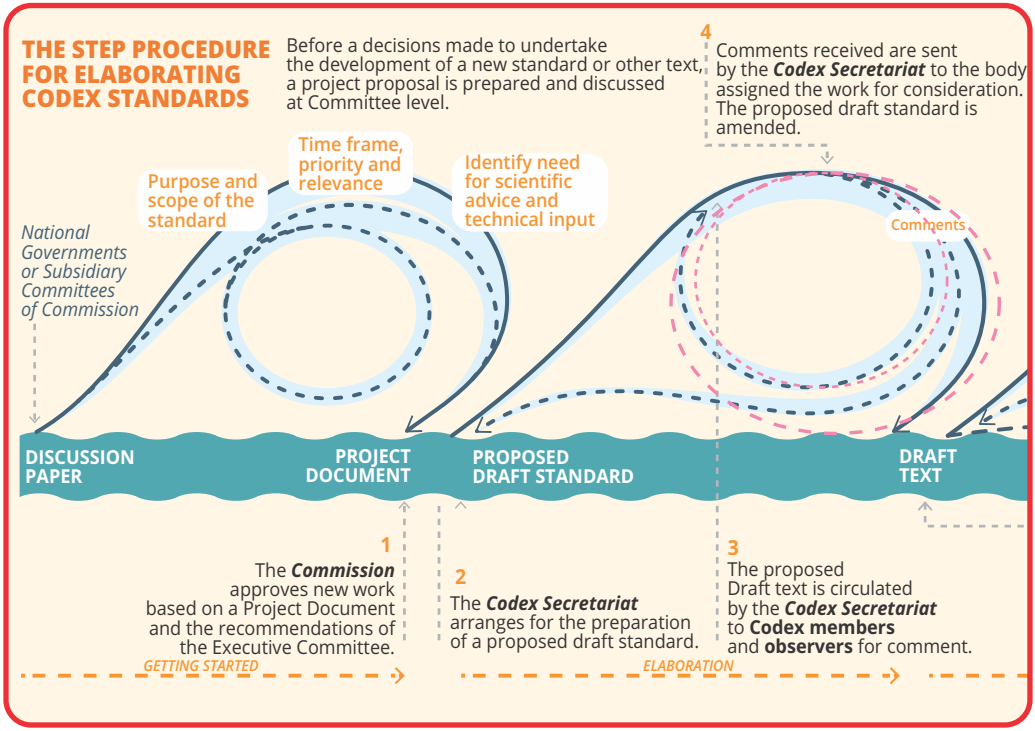
Each Committee meets once in a year or once in 2 years depending upon the workload and as per the decision of CAC.

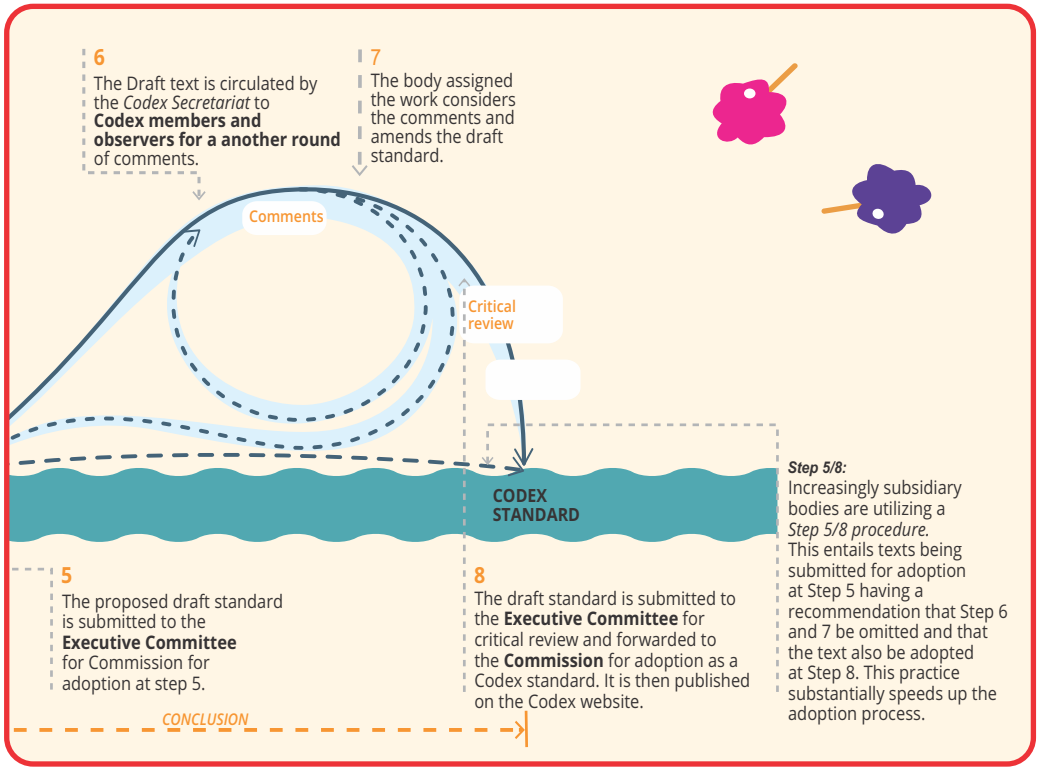
Electronic Working Groups (EWGs) are established by each CODEX Committee when deciding to develop work between sessions. The list of EWGs created since the 39th session of CAC (2016) are available at: http://www.fao.org/fao-who-CODEXalimentarius/committees/ewg/jp/.

HOW DOES CODEX ELABORATE STANDARDS?

The legal basis for the commissions operations and the procedures it follows are as per Procedural Manual of the CODEX Alimentarius Commission. A national government or a CODEX Committee of the Commission usually makes the proposal for a standard to be developed. They then prepare a discussion paper that outlines what the proposed standard is expected to achieve, and then a project document that indicates the time frame for the work and its relative priority.

The CODEX procedure ensures that adequate consultation occurs between Member Governments, and that there is adequate opportunity for review and for stakeholder input into the process. There are eight steps involved in the procedures:





Step1

The Commission decides to elaborate a worldwide CODEX standard and assigns the work to the appropriate CODEX Committee or a regional committee. The criteria for the establishment of work priorities that apply to general subjects and commodities are set out in the CODEX Procedural Manual.

Step 2

The Secretariat of the Commission arranges for the preparation of a proposed draft standard and Member country, who initially proposed the development of the standard, prepares the proposed draft standard.

Step 3

The proposed draft standard is sent to members of the Commission and interested international organizations for comments.

Step 4

Comments received at Step 3 alongwith proposed draft standards are considered at a physical session of the concerned Committee and the standards are modified, as required

and then advanced to Step 5 for preliminary adoption by the Commission.

Step 5

The proposed draft standard submitted by the concerned CODEX Committee, through the Secretariat of the Commission, is considered by the Executive Committee (for critical review), and then adopted by the Commission as a draft standard.

Step 6

The draft standard is sent to members of the Commission and interested international organizations for comments for the second time.

Step 7

Comments received at Step 6 along with proposed draft standards are considered at a physical session of the concerned Committee and the standards are further modified, as required and in a limited way, and then advanced to Step 8 for final adoption by the Commission.

Step 8

The draft standard submitted by the concerned CODEX Committee, through the Secretariat of the Commission, is again considered by the Executive Committee (for critical review), and then adopted by the Commission as the final CODEX International/Regional standard.

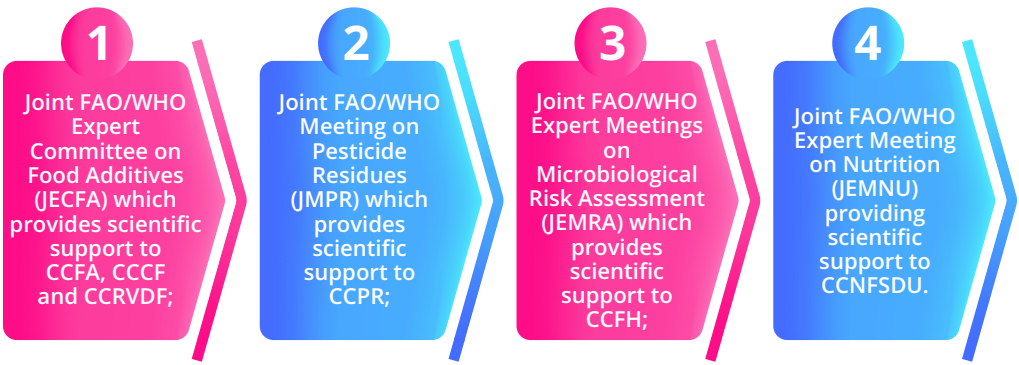
Thus, the normal elaboration process follows eight distinct steps, involving two rounds of comments by members and observers. A decision may be taken at step 5 to omit the second round of comments (steps 6 and 7). The Commission may also decide that standards be elaborated through an accelerated 5-Step Procedure with only one round of comments. However, while taking this decision, all appropriate matters shall be taken into consideration, including the likelihood of new scientific information becoming available in the immediate future.

This eight-step procedure for the elaboration of standards provides an opportunity for all countries to participate in the formulation of standards and other CODEX texts in an open and transparent way. The member countries also have the opportunity to interact in the process. In order to ensure that the standards do reflect the interest of member countries, each Member country should endeavour to effectively participate in the meetings of CODEX. As the standards are recognized as 'Benchmarks' by the WTO, the member countries should make every effort to harmonize their national standards with CODEX so that their domestic

standards are science based and backed by the collective wisdom of member countries and international non-governmental organizations.

SCIENTIFIC BASIS FOR CODEX WORK

Since CODEX standards are science based, the CODEX committees apply Risk Analysis principles in the process of development of standards and accordingly rely, where required, on the independent scientific advice provided by expert bodies organized by FAO/WHO. Risk Analysis is fundamental to the scientific basis of CODEX Standards. These bodies also give direct scientific advice to Member Governments. There are four FAO/WHO Expert Committees, serving as independent scientific bodies which performs risk assessments and provide advice to FAO, WHO and the member countries of both organizations on the subject areas viz. food additives, pesticide residues, veterinary drugs residues, contaminants, hygiene and nutrition to the respective committees. Namely, these are:



India is a member of CODEX Alimentarius Commission since 1964 and continues to be a partner in the international food standards development process. FSSAI had been designated as the National CODEX Contact Point (NCCP) in India for liaison with CAC in the year 2011. Before 2011, the National CODEX Contact Point was the Ministry of Health and Family Welfare. India has evolved immensely over the past two decades, participating actively in the CODEX meetings, hosting and co-hosting CODEX Committee meetings, Chairing and co-chairing various electronic and physical working groups.

Participating in CODEX helps a country in understanding the ever evolving global aspects of food regulations and keeping pace with them. It also helps to promote harmonization of domestic food standards including national food regulatory system with the work already done by CODEX and other International Organizations in the area of contaminants, residues of veterinary drugs, pesticide residues, food additives and other

vertical (products) standards.

As per Section 16(3) (m) of the FSS Act, 2006, it is the responsibility of FSSAI to promote consistency between international technical standards and domestic food standards while ensuring that the level of protection adopted in the country is not reduced with the relevant international standards. Further, the section 18 (2) (a) specifies that the Food Authority while framing regulations or specifying standards under this Act take into account international standards and practices, where international standards or practices exist or are in the process of being formulated.

The standards and other guidance texts adopted by CODEX Alimentarius Commission are the relevant international standards and are also the reference point within the frame-work of WTO as mentioned earlier. The FAO and WHO of the United Nations regularly encourage countries to harmonize their standards with those of the CODEX.

Accordingly, the CODEX standards can be adopted by India with or without modifications as required under the Indian conditions and based on science and has to be notified by FSSAI as regulations. This is called the Harmonization of national standards with CODEX and this is what FSSAI initiated in early 2013. Updation of food standards via the harmonization process is dynamic and continues on the basis of current science. Therefore, the importance of CODEX should never be undermined.

CODEX FUNCTIONING IN INDIA

The National CODEX Contact Point (NCCP) is set up at Food Safety and Standards Authority of India (FSSAI).

Functions of FSSAI as NCCP:

- FSSAI has established the National CODEX Committee (NCC) and various stakeholders for each committee are representatives from different Ministries like Ministry of Health and family Welfare, Ministry of Commerce, Women and Child Development, Ministry of Agriculture, Ministry of Food processing and Department of Animal Husbandry and Dairy Fisheries, representatives from educational institutions, representatives from Industry Associations like Confederation of Indian Industry and FICCI and experts/scientists from concerned areas.
- National CODEX Committee (NCC) has been set up under the Chairmanship of Chairperson, FSSAI, and Shadow Committees are chaired by CEO, FSSAI/ concerned Joint Secretaries on subject matters corresponding to the CODEX Committees.

- Prepare a guideline for finalising India's position in the CODEX Committees has been laid down by NCCP, which are followed by every shadow committee for its smooth and active functioning.
- The NCCP acts as the link between the CODEX Secretariat and the member countries for coordinating all relevant CODEX activities at the national and international level.
- It works in consultation with other relevant stakeholders to develop/ formulate India's position on various CODEX draft standards/ texts under consideration of CODEX Alimentarius Commission and its various committees/ task forces.
- Wherever required, NCCP, also collaborates with other relevant organizations at national level for generating scientific data necessary to support India's intervention in CODEX meetings.
- Submit new work proposals to CODEX in consultation with relevant stakeholders for setting standards and submit monitoring/occurrence data, which were also considered while establishing MLs/MRLs in CODEX.

INTERNATIONAL CERTIFICATION SYSTEM FOR FOOD

Certification is a conformity assessment procedure (CAP) which has become very important these days in international trade due to limitation of resources. Certification procedure is carried out by a third party which gives a written assurance in the form of Certificate that a product or a process is in conformity with the corresponding standard. The certification programme is carried out by a certification body, which does the inspection and delivers the certificate. The certification body must always be a third party, without any direct interest in the economic relationship between the supplier and buyer.

A certification body can carry out certification programmes only if it is evaluated and accredited by an authoritative body (a governmental or para-governmental institute), which ensures that the certification body has the capacity for carrying out certification and inspection in compliance with guidelines set by ISO, the European Union or some other entity.

An increasing number of certification programmes exist for food safety, related to both good practices and management systems, most of which refer to CODEX Alimentarius standards. These programmes have been set up by various types of national and/or global groups including government institutions, national standardization organizations (mostly private associations mandated by government), private certification bodies and the private sector (buyers, retailers and producers).

The FSO while exercising their duties may come across with FBOs who might have obtained different types of certifications like BRC, SQF, IFS, Dutch HACCP, ISO 22000 etc., however, these certifications cannot always be considered as guarantee toward compliance to the regulations laid down under FSS Act. **Therefore, the FSO should always verify/check the processes or products produced by such FBOs for their compliance to FSSAI's requirements despite to their having various certifications**.

In addition to the private certification bodies, in some countries a mandatory pre-shipment certification for export is issued by competent authority of the country. In India, Export Inspection Council (EIC) issues such certificates (Health Certificate) for products notified by Government of India and meant for export. The certificates issued by the EIC are an assurance toward compliance of the product to the requirements of a particular importing country only and cannot be considered as compliance to Indian legislations.

Similarly, National Plant Protection Organization (NPPOs) of country issue Phytosanitary Certificate for food/agricultural products however Phytosanitary Certificate is not a compliance to food safety requirements but provides assurance that it is free from particular pest or disease only. Food Products of animal origin some time accompany with Export Health Certificate from competent authority which may not always related to food safety and sometime only provide assurance toward free from specific animal diseases.

On the similar lines, the imported food product cleared by the custom/FSSAI import control system and available in the market, can always be verified for its compliance to Food Safety &Standards Regulations by the FSOs.

ROLE OF STATE FOOD DEPARTMENTS IN CODEX ACTIVITIES

For active involvement and contribution in CODEX work, it is importantthat stakeholders have the basic knowledge about CODEX working procedures and agenda items under discussion in various CODEX Committees.

All the documents related to CODEX i.e adopted standards, Code of practices, guidelines,agenda and reports of committee (previous and forthcoming) can beeasily accessible from the CODEX website. (http://www.fao.org/fao-who-CODEXalimentarius/home/en/).

Stakeholders and FSOs , based on their interest, can send comments/ views/suggestions, if any, on the agenda items which are under consideration to NCCP, FSSAI (Email: CODEX-india@nic.in), and thesefurther can be considered by the relevant shadow committee while finalizing India's comments. At this point, it is important to mention that

while providing any comment on the agenda document, as per the CODEX procedure, it needs to be supported by rationale or justification.

For active and effective participation in CODEX work, members should have an interest in the development of national and international standardsand also acquire knowledge of the working of CODEX. More details can be accessed through the link CODEX-india@nic.in.

NOTES

NOTES

CHAPTER-10

CAPACITY BUILDING OF FBO & CONSUMER

10 CAPACITY BUILDING OF FBO & CONSUMER

THE CHALLENGE : A SILENT EPIDEMIC

The deadly "silent epidemic" caused by our food habits goes largely ignored, despite multiple alarm bells. Nutrient deficiencies and toxicity from unsafe and poor dietary habits today are linked to nearly all modern health conditions. Diabetes and heart disease (that are rapidly increasing in India and other advanced nations) are also highly influenced by one's diet — and the same can be said for allergies, autoimmune disorders like arthritis, thyroid disorders and many more. The double burden of under nutrition coupled with increasing incidence of obesity, particularly among our children, is threatening our social and economic fabric.

- 60% of deaths in India are caused by diet related non-communicable diseases like diabetes, hypertension and cardiovascular disease
- 100 million cases of Food Borne Diseases (FBD) are reported every year, costing India more than Rupees one lakh crore annually.
- According to the United Nations Development Programme, nearly 40 per cent of the food produced in India is wasted or lost every year, high food loss and waste and ill-effects to the environment due to food production practices and water crisis are reaching breaking point.

So, if ever there is a time to change our food habits, it is now!

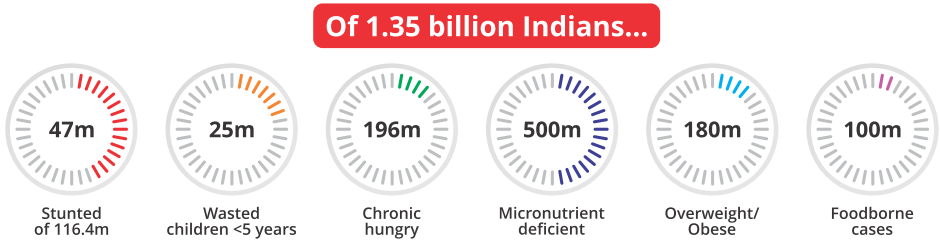


Figure 1: Malnutrition in India

Sources:

- Stunted and Wasted: Global Nutrition Report, 2018
- Chronic Hungry: FAO State of Food Security and Nutrition in the World, 2018
- Micronutrient deficiency: Rao ND, Min J, DeFries R, Ghosh-Jerath S, Valin H, Fanzo J (2018). Healthy, affordable and climate-friendly diets in India. Global Environmental Change 49: 154-165
- Foodborne cases: World Economic Forum and Harvard School of Public Health, 2014

The wisdom of the ages captured through Ayurveda and Yoga teaches us to be conscious and mindful of what we eat, when we eat and how we eat it. A balanced approach to preparing, eating and digesting food, based on every individual's unique body-mind type is the key to wellbeing and sound health. But with our changing lifestyles, food habits are increasingly driven by convenience and impulse; food is becoming a method of instant gratification rather than a means of nourishment and good health. The resultant triple burden of food-borne illnesses, under-nutrition, widespread micronutrient deficiencies, obesity and NCD-related mortality cause suffering, disability, loss of life or foregone incomes and wages. Unsafe food still costs India as much as $15 billion annually—a very high economic burden caused by food-borne diseases making it imperative to address the problem with a sense of urgency.

Thus, all people, especially the poorest and most vulnerable, should have access to safe and nutritious food which is fundamental to good health and sustaining life with human dignity. Due to unsafe food and infection by food borne pathogens, there is poor absorption of nutrients from food, particularly of vitamins and minerals that impact nutritional status of an individual. Enhanced food safety can be linked to improvements in productivity, food accessibility, and the affordability of nutritious foods.

The New National Health Policy released in March 2017 therefore focuses on the more sustainable concepts of preventive and promotive healthcare, in addition to palliative or "sick care". The most powerful tool of preventive and promotive healthcare is the consumption of safe and wholesome food.

EAT RIGHT INDIA MOVEMENT

In the preamble to the Food Safety and Standards Act, 2006, FSSAI is expected to ensure availability of safe and wholesome food for the people in India. Inspired by the focus on preventive and promotive healthcare in the National Health Policy 2017 and flagship programmes like Ayushman Bharat, POSHAN Abhiyaan and Swacch Bharat Mission, FSSAI has embarked on a large-scale effort to transform the country's food system in order to provide people safe, healthy and sustainable food through the "Eat Right India" movement.

The Eat Right India Movement is based on three key themes/pillars - Eat Safe, Eat Healthy, and Eat Sustainably.

- **Eat Safe :** Ensuring personal and surrounding hygiene, hygienic and sanitary

practices through the food supply chain, combating adulteration, reducing toxins and contaminants in food and controlling food hazards in processing and manufacturing processes.

- **Eat Healthy :** Promoting diet diversity and balanced diets, eliminating toxic industrial trans-fats from food, reducing consumption of salt, sugar and saturated fats and promoting large-scale fortification of staples to address micronutrient deficiencies.
- **Eat Sustainable :** Promote local and seasonal foods, prevent food loss and food waste, conserve water in food value chains, reduce use of chemicals in food production and presentation and use of safe and sustainable packaging.

These key themes are operationalised through six strategic priorities viz.

1) Robust standards and codes of practices

2) Credible food testing and effective surveillance

3) Strengthened compliance, enforcement and emergency response

4) Strong culture of self-compliance

5) Promoting healthy diets and sustainability

6) Empowered consumers

Priorities 1 to 3 are essentially core regulatory functions that are the basis of any national food control system. Here the focus is to strengthen food safety through science-based, robust and high-quality standards at par with global benchmarks, effective enforcement drives and efficient (or risk-based) compliance checks through judicious as well as innovative use of resources. This would include bringing all food businesses under the licence and registration regime, conducting periodic risk-based inspections and/or third-party audits, conducting robust checks on imported food, adopting integrated risk-based approach across the food value chain. For e.g., better regulation of food packaging materials, regulatory oversight on animal feed etc., increasing the level of surveillance, sampling and testing drives and building capacities for food testing through innovative approaches such as public-private partnerships, mobile food testing vans, rapid food testing kits etc.

But given the size, spread and complexity of India, where a large proportion of the food businesses are in the unorganised sector, assuring safe and nutritious food to 1.35 billion citizens needs the participation of every stakeholder, and traditional regulatory tools alone cannot achieve this. Priorities 4 to 6 thus focus on hitherto unaddressed areas of capacity building and social and behavioural change for all stakeholders viz. food businesses as well as

consumers. The idea is to educate and inform the citizens on the one hand, and train and build capacities of food handlers on the other, to bring in a culture of safe and wholesome food processes and habits. *Eat Right India* would also contribute towards healthy diets and UN sustainable development goals (SDGs) which are linked directly or indirectly to the food system; hence accelerating India's journey towards fulfilment of SDGs through healthy diets that are good both for people and planet

To maximise outreach, FSSAI is working with civil society organisations, academic and research institutions, corporate (food or non-food) and every other stakeholder in the system. To bring a nationwide transformation, it is imperative for State machineries to take up implementation of these projects and to incorporate messaging on safe and nutritious food in their existing healthcare schemes.

THE STRATEGY: EAT RIGHT INDIA MOVEMENT

As already stated, the strategy of *Eat Right India* is to ensure that our food is good for both, the people and the planet. The action plan thus encompasses a bouquet of initiatives to promote both the demand for, and supply of, safe and wholesome food, and do this in a sustainable way. While the supply side interventions are aimed at building capacities of food businesses to promote self-compliance, the demand side initiatives work towards motivating consumers to demand safe and healthy food.

Food safety is primarily the responsibility of the FBO, who is in the best position to know the manufacturing processes and critical points where food safety can be affected. Internationally, the most effective regulatory systems are those based on self-compliance by the FBO.

However, in India, under the earlier Prevention of Food Adulteration regime the approach was essentially adversarial, a disproportionate reliance on monitoring, inspections and deterrent punishments by the regulatory authorities rather than on self-compliance by the FBO. In essence, this placed the responsibility for food safety and hygiene primarily in the hands of the regulatory authorities instead of in the hands of the FBO, which is not a workable model.

Given the complex landscape of India's food business ecosystem, where millions of small, unorganized entities co-exist with giant domestic and multinational companies, innovative ways to ensure self-compliance across the food value chain is not an easy task. A 2-pronged approach has been adopted by FSSAI to promote self-compliance by FBOs:

- Large-scale training and capacity building and
- Benchmarking and certification schemes, both for clusters/agglomerations of FBOs

and for standalone entities.

Enforcement is then ensured through an appropriate mix of enabling self-compliance, backed by deterrent measures in case of non-compliance. This approach does not overburden the regulatory system and helps to overcome the challenges of limited manpower and other resources. It also enables self-reliance among food businesses, making them equal and active partners in ensuring food safety for all.

TRAINING & CAPACITY BUILDING OF FBOs

FOOD SAFETY TRAINING AND CERTIFICATION PROGRAMME OR 'FOSTAC'

Safety can be endangered at any point in the food value chain, from manufacture to storage to transport. FSSAI has specified procedures and practices to be followed by food businesses for actively controlling hazards throughout the food value chain. Every food business operator is required to have a documented FSMS plan and comply with good hygiene and manufacturing practices as laid down under Schedule 4 of FSS Regulation 2011.

Objective : To help FBOs understand and comply with Schedule 4 requirements, a "Food Safety Training and Certification" programme or 'FoSTaC' has been put in place, whereby Schedule 4 requirements have been simplified to deliver training.

While FoSTaC training is voluntary at present, the Food Authority has approved in-principle a decision to make the training mandatory. So every food business establishment will soon be required to have at least one trained & certified Food Safety Supervisor (FSS) through FoSTAC for every 25 food-handlers in their premises.

About FoSTaC : There are 19 certification courses developed by a panel of domain experts empanelled by FSSAI that are offered at three levels: Basic, Advanced & Special, covering the entire food value chain as under:

- **Basic -** 5 Courses of Short duration -4 Hours

  (Industry : Street Food Vending, Catering, Manufacturing, Storage & Transport, Retail)

- **Advanced -** 4 Courses of 8 Hours each

  (Industry: Catering, Manufacturing, Storage & Transport, Retail)

- **Special -** 9 Courses of 4-8 Hours each

  (Industry: Milk & Milk Product, Animal Meat & Meat Product's, Poultry Meat & Meat

Products, Fish & Seafood, Packaged Water, Bakery Level 1 and Level 2, Edible Oil & fats, Health Supplements)

The short course duration of 4 to 12 hours conducted over 1-2 days ensures food handlers can easily participate in the training programme without disturbing their work. The training is being delivered by FSSAI certified trainers with the help of empanelled Training Partners in the premises of the food business (in-house) or through online mode. Physical classes are also generally the norm except under certain emergency situation like COVID pandemic. At the end of the training, the successful candidates are tested and awarded a Food Safety Supervisor (FSS) certificate by FSSAI. FSS will in turn train other food handlers periodically.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	1. **State FDA -** The role of State FDA is the most crucial since they act as a catalyst by pulling all stakeholders together. Responsibility of ensuring food safety is with the state FDA who has to coordinate with the training partners, food businesses, market associations or other similar associations. 2. **Training Partner -** FSSAI empanelled training partner will play the role of mentor besides providing training. The trainer may handhold each of the trained FSS as a follow up to their individual learning process. 3. **Funding Partner -** Entire training & certification process involves some cost which can be borne by the FBO themselves, any business house from their CSR funds, government bodies, local bodies or the market association. 4. **Large FBO -** Large food businesses have a larger catchment area. Besides investing out of their CSR fund, industries can train their upstream and downstream supply chains.
Steps for Implementation	» For ease of access and transparency, the entire training program is managed (i.e. trainers invited and empanelled, training schedules fixed and certificates delivered) through a dedicated online portal » The actual training under FoSTaC is delivered offline/in classroom modules through empanelled trainers. » FSSAI has not prescribed any fixed fee for any course, though fees are expected to be nominal since the training content and use of FoSTaC

	portal are provided free of charge by FSSAI. » However, there would still be some cost involved and this can be met by the FBOs themselves whose employees are being trained or through other Government schemes or through CSR funds of Companies etc.
Resources	» **Guidance Document :** https://fostac.fssai.gov.in/fostac/doc/fostacbook.pdf » **Website:** https://fostac.fssai.gov.in/ » **Training Partners :** https://fostac.fssai.gov.in/fostac/listoftrainingpartner » **Supplementary resources :** Training manuals along with their translated versions are available at https://archive.fssai.gov.in/home/capacity-building/e-library/training-manual.html
For more details, contact:	fostac@fssai.gov.in

PROGRESS THUS FAR ....

In 2 years, more than 2000 trainers have been trained and 12000 training programmes conducted. 3,00,000 plus Food Safety Supervisors including standalone food vendors have been trained and certified so far under FoSTaC. To ensure training at scale, 242 Training Partners have been empanelled by FSSAI on a pan-India basis.

There are millions of food businesses in the unorganised sector (street food vendors, fruit and vegetable markets, meat and sweet shops and even restaurants and caterers).

Relying solely on training or on punitive action to ensure food safety and hygiene for this segment will not lead to a sustainable change in habits and practices - what is needed is a more comprehensive approach through structured schemes and projects that help to first identify, and then systematically address the gaps in their food safety ecosystem, while simultaneously creating an economic incentive to sustain the change.

One of the biggest challenges in ensuring food safety and hygiene in India is posed by the huge number of food businesses in the unorganised sector.

FSSAIs comprehensive Benchmarking and Certification Schemes are a systematic, step-by step approach involving a gap analysis and corrective actions based on pre-defined checklists for each kind of business, to ensure safe and hygienic food. The checklists are comprehensive, including inter alia personal hygiene, surrounding hygiene, basic infrastructure etc. The benchmarking and certification give recognition to food clusters and boosts livelihood through creating positive consumer perceptions.

Empanelled Training Partners and Audit Agencies bring in the necessary professional expertise to FSSAIs Benchmarking and Certification schemes, that operate at two levels:

- For Clusters.
- For Individual Outlets.

BENCH MARKING AND CERTIFICATION FOR CLUSTERS

For petty food vendors and hawkers, a cluster approach is adopted. A **cluster** is an aggregation of vendors located in a given geographical area with similar kind of business; for e.g. an aggregation of around 50 street food vendors is a cluster and can be certified as a **Clean Street Food Hub.** A structured process of defining benchmarks, gap analysis, filling infrastructure gaps, training, capacity building and certification is adopted in a cluster. This is a systematic way to ensure compliance to food safety standards and helps to organize hawkers and petty food vendors to improve food safety and hygiene. It is also an important convergence point, with local municipal authorities taking a lead in setting up clusters (e.g., clean street food hubs, vegetable and fruit markets etc) and with other government programs like Swachh Bharat Abhiyan (for cleanliness drives) and Jal Jeevan Mission (for potable water supply).

Cluster certification model has five simple steps.

Step 1 :

Cluster Identification : The State FDA, in association with the local bodies (Panchayat, municipalities, municipal corporations etc) will identify geographical areas with an aggregation/cluster of vendors and ensure they are licensed/registered as a first step.

Step 2 :

Pre-Audit : Benchmarks and checklists have been defined by FSSAI covering parameters like location, facilities, personal hygiene etc. to be followed by the FBO, based on Schedule 4 requirements. The State FDA, representatives from local bodies and an FSSAI empanelled auditing agency will conduct a pre-audit to identify gaps against the benchmarks, through a

physical visit to the cluster.

Step 3 :

Training and Infrastructure improvement : After the pre-audit, training of Food Safety Supervisors will be conducted under the FoSTaC programme. The trainer will focus on the gaps identified during pre-audit. Further, for non-compliance due to infrastructural issues, the local FDA/municipalities/concerned state department/funding partner would help to plug the gaps; the trainer or training partner may guide the FBOs with suitable solutions. In certifying any given cluster, the audit agency and training partner will be two different entities to avoid conflict of interest.

Step 4 :

Final Audit and certification : The final audit has to be conducted within **six months** of the pre-audit, by the same audit agency that did the pre-audit. The report will be submitted to the concerned state FDA and if the benchmarks as prescribed are met, FSSAI and the State FDA will jointly issue a certificate with a plaque to the cluster, which will be prominently displayed. The plaque will help to assure consumers that the cluster meets food safety and hygiene standards, thereby increasing business and enhancing livelihood of the vendors.

Step 5 :

Sustenance & Renewal of Certificate : The certificate will be valid for (two years). In these two years, certified clusters will be routinely inspected and samples drawn and tested by the State FDA in accordance with FSSR, 2011. For renewal, an audit is to be conducted by an empanelled agency/State FDA one month prior to the expiry date of the certificate. On receiving approval from State FDA, the certificate will be renewed for the next 2 years.

Currently, cluster initiatives include:

- Clean Street Food Hubs
- Clean and Fresh Fruits and Vegetable Markets
- BHOG (Blissful Hygienic Offering to God) - Places of Worship
- Eat Right Station

CLUSTER INITIATIVE 1 : CLEAN STREET FOOD HUB (CSFH)

Objective : This initiative aims at raising the quality of street food vending to the level of food courts and established hotels and restaurants. It also aims to upgrade food streets and build trust among consumers about enjoying safe and hygienic local eating experiences.

About CSFH : A Clean Street Food Hub (CSFH) may be defined as a hub or cluster of vendors/shops/stalls selling popular street foods, 80 per cent or more of which represent local and regional cuisines and meet the basic hygiene and sanitary requirements, excluding fine dining.

STANDARD OPERATING PROCEDURE

SUCCESS STORIES

Role of Stakeholders	**State FDA -** has the most crucial role since they will act as a catalyst by pulling all stakeholders together. They would coordinate with local bodies, street food vendor association, audit & training partner etc. to get the certification done. **Local self-government [Panchayat/Municipality/MC]** – Since local bodies are directly regulating aspects such as cleaning of street food vending area, managing waste, providing potable water, drainage, maintaining infrastructure etc they are indispensable to the whole process. **Street Food Vendors Committee -** Street food vendors located in particular area/lane are managed by some association or committee. Such bodies are the real stakeholders and are responsible for implementation and sustenance. **Audit & Training Partner -** FSSAI empanelled audit agency and training partner will play the role of mentor. While an auditor will identify the gaps, the trainer will handhold each one of them so that FBOs can mitigate those gaps. **Funding Partner -** Entire certification process involves some cost which can be borne by business houses out of their CSR funds, government bodies, local bodies or the street food Committee/Association themselves. Funding partners contribution could be acknowledged on the Plaque/website etc.
Steps for Implementation	The 5 steps for cluster certification listed above are to be followed. Compliance to suggestions given during initial inspection to be done within 30-60 days, which is to be confirmed by concerned State FDA official. The cluster will be delisted from potential hub list if final audit is not conducted within six months of pre-audit. FSSAI will certify the cluster as a "Clean Street Food Hub" and reward the hub with a plaque after the final audit if 80% compliance is achieved. If 80% compliance is achieved in the pre-audit, the cluster may be certified as "Clean Street Food Hub" post pre-audit.

Resources	**Guidance Documents :** Implementation guidelines ***https://fssai.gov.in/CleanStreetFood/assets/docs/Guidance%20Document_Clean%20Street%20Food%20Hub.pdf*** **Flyer :** ***http://fssai.gov.in/CleanStreetFood/assets/docs/CSF%20hub_Flyer.pdf*** **Website :** ***https://fssai.gov.in/CleanStreetFood/indexhome*** **Partners :** Auditing agency ***http://fssai.gov.in/CleanStreetFood/assets/docs/List%20of%20Auditing%20Agencies.pdf*** **Training partners :** ***http://fssai.gov.in/CleanStreetFood/assets/docs/CSF%20hub_Flyer.pdf*** **Funding partners :** Companies through CSR like HUL, Nestle, Jubilant Food Works, Herbalife etc have supported. Both food and non-food companies can support. **Supplementary Resources :** Food safety and hygiene checklist for audit under CSFH ***http://fssaigov.in/CleanStreetFood/question.jsp***
For more details, contact:	csfhfssai@gmail.com

The project has seen great enthusiasm from several states, and so far 20 have been certified covering Gujarat, Maharashtra, Madhya Pradesh, Punjab, Tamil Nadu, Chandigarh and Chattisgarh; another 19 locations are in the pipeline. The CSFH have been inaugurated by CMs/other dignitaries in the states of Maharashtra and Gujarat. CSR support has been extended by various top leading pharmacauticals & FMCG companies.

One of the first Clean Street Hubs to be certified was in Kankariya, Ahmedabad. Other iconic Street Food Hubs which have been certified as Clean Street Food Hubs include Juhu Chowpatty and Girgaon Chowpatty (Mumbai), Chappan Dukaan (Indore), Urban Chowk (Ahmedabad), Sector 8 market (Chandigarh) etc. These hubs took several measures to improve hygiene and food safety standards. Food handlers started wearing gloves, mask, caps etc. in the correct manner. They made a policy for procurement of raw and packed products from FSSAI licensed/registered suppliers only. Products started being tested randomly at frequent interval of time. They replaced non-food grade disposables with food-grade disposables for serving, which is healthy for consumer and environment too. Cast iron and wood utensils have been replaced with the stainless steel. Now proper arrangements for

storage of raw food and semi-cooked food have been made. They have also started use of potable water for washing of utensils and demarcated a common pot washing area. The Municipality is taking care of timely disposal of waste. Proper hand washing points/stations have been made available to consumers. License/Registration along with Food Safety Display Boards is prominently displayed in each vendor's stall.

CLUSTER INITIATIVE 2 : CLEAN & FRESH FRUIT & VEGETABLE MARKET

Objective : This initiative aims at ensuring that safety standards are maintained in fruit and vegetable retail.

About Clean and fresh fruit & vegetable market : A Clean and Fresh Fruit & Vegetable Market may be defined as a cluster of vendors/stalls selling fruits and vegetables. These mandis will also be a hub for consumer awareness with respect to fruits and vegetables.under this cluster certification initiative, an entire 'Sabzi Mandi" will be audited, trained and certified. It is expected that the fruits & vegetable shops in such certified Mandis will follow food safety standards individually and collectively.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**Local self government [Panchayat/Municipality/MC] –** Since local bodies are directly regulating other aspects such as cleaning of the market area, managing waste, providing potable water, drainage, maintaining infrastructure etc, therefore local bodies are indispensable in the whole process. **Market Committee -** Every market is managed by a market association or committee. Such bodies are the real stakeholders and are responsible for implementation and sustenance. **State FDA -** The role of State FDA is the most crucial one since they will act as a catalyst by pulling all stakeholders together. However, responsibility of ensuring food safety is with state FDA. They therefore have to coordinate with the local bodies, market association, audit & training partner to get the certification done. **Audit & Training Partner -** FSSAI empanelled audit agency and training partner will play the role of mentor. While an auditor will identify the gaps, the trainer will handhold each one of them so that FBOs can mitigate those gaps. **Funding Partner -** Entire certification process involves some cost which can be borne by any business houses out of their CSR funds, government bodies, local bodies or the market association themselves.

Steps for Implementation	All the 5 steps for cluster certification listed on page 293 and 294 are to be followed. The market will be delisted from potential market list if final audit is not conducted within six months of pre-audit. After proper examination post the final audit, FSSAI will certify the market as a "Clean and fresh fruit & vegetable market" and reward the market with a plaque.
Resources	Guidance document on Implementation of Clean and Fresh Fruit & Vegetable Market Flyer on the scheme Website (http://fssai.gov.in/cleanvegetablemarket)
For more details, contact:	cleanfreshfruitvegmarket@gmail.com

SUCCESS STORIES/ PROGRESS THUS FAR ....

This is a relatively new initiative, but already seven markets have been identified and are at various stages of completion-five are in Delhi, one in Uttarakhand and one in Goa. Final audit is pending in all the cases.

CLUSTER INITIATIVE 3 : BLISSFUL HYGIENIC OFFERING TO GOD (BHOG)

Objective : BHOG is an initiative to encourage places of worship to ensure the health and welfare of the pilgrims, by educating food handlers in the premises & vendors in the surrounding area about proper food safety and hygiene.

About BHOG : Under this initiative, places of worship where offerings are cooked/handled are identified, audit conducted and basic training imparted to food handlers. Display of food safety messages and Food Safety Display Boards at prominent places in the place of worship to encourage adoption of safe and hygienic food habits by the devotees is an important element of this initiative. After successful completion of all the steps, identified place of worship is recognized/certified.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**State FDA -** has the most crucial role since they will act as a catalyst by pulling all stakeholders together. They would coordinate with the local bodies, Temple Authorities/ Association, audit & training partner to get the certification done.

	Local self-government [Panchayat/Municipality/MC] – Since local bodies are directly regulating places of worship falling under their jurisdiction along with Local Municipality on aspects such as managing waste, providing potable water, drainage, etc, they are indispensable to the whole process. **Temple Board/Trusts/Committee/Associations -** Almost every Place of Worship is managed by Temple Board/Trusts/Committee/ Associations. Such bodies are the real stakeholders and are responsible for implementation and sustenance. **Audit & Training Partner -** FSSAI empanelled audit agency and training partner will play the role of mentor. While an auditor will identify the gaps, the trainer will handhold each FBO to help mitigate those gaps **Funding Partner -** Entire certification process involves some cost which can be borne by business houses out of their CSR funds, government bodies, local bodies or Temple Board/Trusts/Committee/Associations themselves. Funding partners contribution could be acknowledged on the Plaque/website etc.
Steps for Implementation	All the 5 steps for cluster certification listed on page 293 and 294 are to be followed.
Resources	**Resources :** ***https://fssai.gov.in/eatrightbhog/resources*** **Guidance Document :** Guidance document and flyer for Implementation of BHOG ***https://fssai.gov.in/eatrightbhog/learning-material*** **Flyer of BHOG :** ***https://fssai.gov.in/eatrightbhog/learning-material*** **Website :** ***https://fssai.gov.in/eatrightbhog/#*** **Partners :** Auditing agency ***https://fssai.gov.in/eatrightbhog/auditpartner*** **Training partners :** ***https://fostac.fssai.gov.in/fostac/listoftrainingpartner*** **Funding partners :** Temple Trust/Authorities, companies through CSR like HUL, Nestle, Jubilant Food Works etc. Both food and non-food companies can support. **Supplementary Resources :** Food safety and hygiene checklist for audit under BHOG ***https://fssai.gov.in/eatrightbhog/checklist***
For more details, contact:	bhogfssai@gmail.com

SUCCESS STORIES

Under BHOG, 30 Places of Worship are certified across the states of Gujarat, Himachal Pradesh, Chattisgarh, Tamil Nadu and Madhya Pradesh. Another 100 places of worship are identified in Tamil Nadu for implementation.

Famous Temples like **Shri Mahakal Mandir, Ujjain, M.P and Shri Ram Mandir, Raipur, Chattisgarh have implemented BHOG and shown remarkable improvement.** They made significant changes in infrastructure & lay-out, based on the gaps identified during pre-audit, to ensure unidirectional flow of food. They have started using food grade lubricants & cleaning agents that come in contact with food items and utensils. Procurement managers are ensuring food grade material only with FSSAI logo. Other good practices initiated include use of temperature monitoring devices like thermometer or digital display to make sure food is adequately cooked and safe for consumption, discontinuing use of equipment & packing material made from non-food grade plastics, newspaper, thermocol etc., testing of water and maintaining test reports and proper documentation on procurement, maintenance, personal hygiene, medical certificates, pest control, visitors and trainings.

CLUSTER INITIATIVE 4 : EAT RIGHT STATION

Objective : Railway Stations in India house several petty food vendors/stalls and see heavy footfalls. **The Eat Right Station initiative is designed to ensure that safe and wholesome food is served to passengers, visitors to railway stations and railway officials.**

About Eat Right Station : Under this initiative, all food vendors on the railway station will be audited, trained and certified. Railway Stations that fulfil benchmark criteria will then be recognized as "Eat Right Station" through plaques and/or certificate of excellence, which they would display prominently to enhance customer confidence.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**Indian Railways/IRCTC/IRSDC :** Conduct Self-Assessment as per the checklist; Overall support in identification, implementation and sustenance, mobilizing resources to become a certified 'Eat Right Station'. **FSSAI :** Overall implementation and identification of railway stations; verification of self-assessment report and final audit report and recommendation for declaring 'Eat Right Station' **Corporates/Funding Partners :** Adopting railway stations for Eat Right Station certification, promote awareness, use CSR funds for training, printing and translation of training material etc. **Training Partners :** (www.fostac.fssai.gov.in) : Mobilizing participants and conducting FoSTaC Food Safety Supervisor (FSS) trainings, translation of training material in local languages. **Third Party Auditing Agencies :** (www.fssai.gov.in) : mobilizing participation, ensure timely audits, leveraging for further improvements.

Steps for Implementation	All the 5 steps for cluster certification listed at page 293 and 294 are to be followed. Display of food safety messages and Food Safety Display Boards (FSDBs) at prominent places in the station is to be done. Based on final audit score & recommendation by auditor, station complex will be declared as "Eat Right Station" with ratings from three star (least score) till five star (max score) by FSSAI with a validity up to 2 years. Half-yearly assessment of performance as per given checklist will be conducted by the Eat Right Fellow nominated by FSSAI. The score will be considered in renewal of the certificate. All food service establishments in the railway stations are to adopt Hygiene Rating.
Resources	Eat Right Station flyer **Checklists :** Developed and shared once proforma is received **Training Partners :** ***https://fostac.fssai.gov.in/fostac/listoftrainingpartner*** **Auditing Agency :** Third Part Audit agencies empanelled with FSSAI
For more details, contact:	eatrightstation@gmail.com

SUCCESS STORIES

This is a recent initiative, but already 3 stations have been certified through the active involvement of the concerned Railway Authorities.

The first railway station to be certified was Mumbai Central Railway station; subsequently Chhatrapati Shivaji Terminus Railway Station, Mumbai and Anand Vihar Terminal Railway Station, Delhi have also been certified. At these stations significant changes were made in infrastructure & lay-out, based on the gaps identified during pre-audit. Kitchen managers are ensuring purchase of ingredients with FSSAI logo. Other good practices initiated include use of temperature monitoring devices like thermometer or digital display to make sure food is adequately cooked and safe for consumption, discontinuing use of equipment & packing material made from non-food grade plastics, newspaper, thermocol etc, testing of water and maintaining test reports and proper documentation on procurement, maintenance, personal hygiene, medical certificates, pest control and trainings.

Benchmarking and Certification of Clusters can lead to a virtuous circle. For the vendor, since the certification is backed by robust processes of gap analysis, audit and systematic capacity building, they are empowered to ensure self-compliance. For the consumer, the Plaque and Certificate are a visible symbol of food safety and good hygiene practice and can lead to higher demand, thereby creating an economic incentive to sustain proper food safety management systems and practices.

BENCHMARKING AND CERTIFICATION FOR INDIVIDUAL OUTLETS

HYGIENE RATING CERTIFICATION

Hygiene rating (HR) is a technology-enabled, user-friendly scheme where individual food service establishments are given a rating for their hygiene and food safety compliance. Establishments participating in the scheme are awarded a consolidated "Star Rating" (between 1 to 5) based on the level of their compliance to multiple safety and hygiene parameters prescribed by FSSAI through a simple checklist.

The Hygiene Star Rating is a powerful visual symbol that allows consumers to make informed choices by finding out how hygienic and safe food preparation is at any of the star rated premises, while also boosting the business of the establishment. Moreover, it encourages businesses to improve their hygiene standards and reduce the incidence of food borne illnesses.

Hygiene Rating can be implemented in standalone food establishments such as restaurants (even those present in food courts or hotels), cafes, caterers, sweet shops, bakeries and meat shops etc. These food establishments can be located in a market, mall, tourist spots, airport, highways, institutes, hospitals, etc. **The Hygiene Rating Certification is valid for 2 years.**

FSSAI has introduced "Hygiene Rating Scheme" for:

- Restaurants and Catering Establishments
- Meat Shops
- Mithai and Namkeen Shops

HYGIENE RATING INITIATIVE 1 : RESTAURANTS AND CATERING ESTABLISHMENTS

Hygiene rating implies that a restaurant, including cafes, diners, eating joints and caterers is compliant to Schedule 4, FSS (Licensing and Registration of Food Busineess) Regulations, 2011. Once a Hygiene Rating certificate is earned by a FBO, it can be displayed prominently in their premises. This would boost their business as a safe place to eat by helping consumers to make informed choices.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**Food Businesses :** The actual implementation of this scheme will be carried out by eligible food establishments and audit agencies. Food establishments need to comply with the pre- requirements (ensuring valid License/registration and completing FoSTaC training) before applying for the scheme. **Audit Agencies :** FSSAI recognized Audit Agencies play an important role of assessing /verifying the level of food safety compliance in a food establishment. **Training Partners :** Training partners ensure the food establishment understands the food hygiene and safety practices to be adopted by training the food safety supervisor. **Food Safety Department of State/UTs :** Food Safety Departments will be responsible for mobilising FBOs to participate and overall monitoring of the implementation. **Restaurant Associations :** Associations can support State/UTs Food Safety Department in implementation of this scheme by reaching out to members, organizing workshops, etc.
Steps for Implementation	The 3-step procedure for Hygiene Rating mentioned at page159 is to be followed.
Resources	**Guidance document :** ***www.fssai.gov.in/hygieneRating/resources/pdf/guidance_doc_new.pdf*** **Website** : ***www.fssai.gov.in/hygieneRating*** **Partners :** **AuditAgencies :** ***www.fssai.gov.in/hygieneRating/resources/pdf/auditingagency.pdf and www.fssai.gov.in/upload/uploadfiles/files/Food_Safety_Auditing_Agencies_Lists_13_11_2019.pdf*** **TrainingPartners :** ***www.fostac.fssai.gov.in/fostac/tpdashboarddata*** **Supplementary Resources :** **Checklist :** ***www.fssai.gov.in/hygieneRating/SelectOption?callFrom=hygeineCheckList***
For more details, contact:	servesafe@fssai.gov.in

SUCCESS STORIES

More than 3600 food establishments (including leading hotels, international and

national restaurant chains and traditional restaurants) have voluntarily opted for Hygiene Rating scheme in the states of Maharashtra, Tamil Nadu, Delhi, Gujarat, etc. This scheme gave an opportunity to food businesses to understand the gaps in implementation of Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP) mentioned in Schedule 4 of FSS (Licensing and Registration of Food Businesses) Regulation, 2011. FoSTaC training of staff supported them in finding solutions to fill the gaps identified. **GRT Grand Hotels reported that in comparison to many international food safety certification programmes, FSSAI's hygiene rating scheme had better impact since the initial step of self-assessment ensured higher involvement of managers and the checklist criteria was apt for local conditions with more workflow orientation.**

Jubilant Foodworks Ltd. reported that this scheme has helped us build confidence amongst consumers as well as business partners, as it is comes from the apex food regulator of the country.

HYGIENE RATING INITIATIVE 2 : CLEAN AND SAFE MEAT SHOPS

Meat Retail Shops sell meat products after minor processing or no processing at all. They are considered a high risk retail sector, and must comply with licensing and food safety requirements, have a trained Food Safety Supervisor and ensure safe and hygienic practices.

FSSAI has advised Food Safety Department of States/UTs to conduct Third Party Audit of 1350 meat shops across India (50 shops in each state and 20 in each UT). Hygiene Rating will also be awarded to these shops by the audit agency,

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**Food Safety Department of State/UTs :** Food Safety Departments will be responsible for overall monitoring of the implementation. **Meat Retail Shops :** The actual implementation of this scheme will be carried out by meat retail shops and audit agency. It is essential for meat retails shops to comply with the requirements and apply for the scheme. **Audit Agencies :** Hygiene Rating Audit Agencies play an important role of assessing and verifying the level of food safety compliance in a food establishment. **Training partners :** Training partners ensure the food establishment understands the food hygiene and safety practices to be adopted by food establishment by training the food safety supervisor.

Role of Stakeholders	**Associations :** Associations can support State/UTs Food Safety Department in implementation of this scheme by reaching out to members, organizing workshops, etc.
Steps for Implementation	Identify and mobilise participation of meat retail shops and their association in the district with support of the Food Safety Department of State/UT. Organize an awareness drive along with food safety officers and audit agencies for meat retail shops to sensitize and draw a plan for implementation (with timelines) of this scheme. Follow the 3-step procedure for Hygiene Rating mentioned at Page 159. Regular monitoring of the progress of implementation of the scheme to identify challenges faced by stakeholders and provide support in overcoming them. Ensure that hygiene rated meat retail shops display the rating certificate prominently in the food premises.
For more details, contact:	servesafe@fssai.gov.in

HYGIENE RATING INITIATIVE 3 : CLEAN AND SAFE MITHAI SHOPS

Mithai (sweets) are an essential part of Indian cuisine and culture. Food Establishments involved in preparation and/or sale of dessert items (majorly traditional Indian sweets) prepared mainly from milk, milk products, cereals, pulses and nuts. Sweet shops handle high risk food products such as milk and milk products (where common issues of adulteration, use of artificial colours and food hygiene are common issues). It is essential that these establishments comply with licensing and food safety requirements stated under FSSA, 2006.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**Food Safety Department of State/UTs :** Food Safety Departments will be responsible for overall monitoring of the implementation. **Sweet Shops :** The actual implementation of this scheme will be carried out by mithai (sweet) shops and audit agency. It is essential for mithai (sweet) shops to comply with the requirements and apply for the scheme. **Audit Agencies :** Hygiene Rating Audit Agencies play important role of assessing and verifying the level of food safety compliance in a food establishment.

Role of Stakeholders	**Training partners :** Training partners ensure the food establishment understands the food hygiene and safety practices to be adopted by food establishment by training the food safety supervisor. **Associations of sweet manufacturers :** Association(s) can support State/UTs Food Safety Department in implementation of this scheme by reaching out to members, organizing workshops, sensitising about the scheme, etc.
Steps for Implementation	Identify mithai (Sweet) shops and their association in the district with the support of the Food Safety Department of State/UT. Organize an awareness drive along with food safety officers and audit agencies for mithai (Sweet) shops to sensitize and draw a plan for implementation (with timelines) of this scheme. Conduct a licensing drive and trainings to meet the prerequisite requirements of hygiene rating (if not fulfilled already). Ensure Hygiene Rating of shops by following the 3-step procedure for Hygiene Rating mentioned at para page 159. Regularly monitor the progress of implementation of the scheme to identify challenges faced by stakeholders and provide support in overcoming them. Ensure that hygiene rated mithai (Sweet shop) display the rating certificate prominently in the food premise.
For more details, contact:	servesafe@fssai.gov.in

To ensure that the FSMS practices are implemented effectively, FBOs are subject to periodic inspections by Central and State Licensing Authorities. Further, a system of Third Party Audits through empanelled auditors is in place through the Food Safety and Standards (Food Safety Auditing) Regulations, 2017. The Regulation stipulates that select food categories prescribed by the Food Authority will be subject to mandatory Food Safety Auditing. Food businesses not subject to mandatory food safety auditing will be encouraged to voluntarily opt for and meet the audit parameters. FBOs who participate in the benchmarking and certification schemes or voluntary audit may be subjected to reduced frequency of inspections by Central or State licensing authorities (needs confirmation).

DEMAND SIDE INITIATIVES: EMPOWERING CONSUMERS

Empowering citizens to make informed choices in favour of safe and wholesome food creates a demand-pull; so if each citizen of India, young or old, is a **"Food Smart**

Consumer," FBOs will have no choice but to put in place systems to ensure that they deliver as per demand.

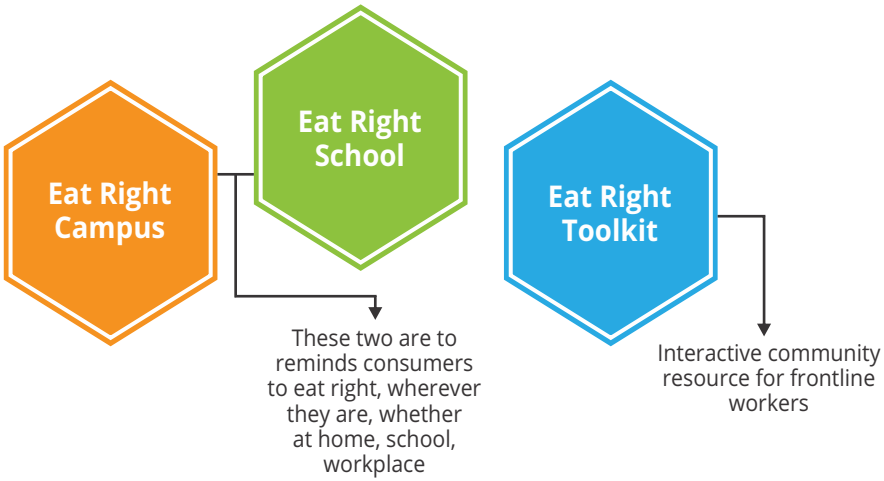
The Demand Side initiatives of FSSAI aim at large-scale social and behavioural change by engaging consumers and educating them on eating right. They work on three major focus areas as follows:

- Building Consumer awareness
- Combating adulteration
- Enabling Healthy Choices

BUILDING CONSUMER AWARENESS

Nudging consumers to eat right calls for a slew of measures that not only create awareness, but constantly reiterate the importance of 'mindful' eating to ensure a sustainable change in habits. Since food is consumed not only at home, but also at the workplace, in schools/colleges etc, there are opportunities in every space to promote safe and wholesome food habits. Home food choices can be influenced by targeting consumers directly through various IEC and awareness campaigns. Food choices in schools, workplaces or other campuses can be influenced by creating visible symbols/logos/ratings for a campus, based on compliance to a set of well-defined benchmarks that go beyond mere safety and hygiene, to include aspects of healthy and responsible food consumption.

THREE PILLARS OF CONSUMER AWARENESS



The Eat Right Campuses and Eat Right Schools would serve to remind consumers to eat right, wherever they are, whether at home, school, workplace etc.

The Eat Right Toolkit is a community resource, delivered at the grassroots level by frontline health workers and other community resource persons, with informative content and simple reiterative messaging to remind consumers to be aware, be cognizant and demand safe and nutritious food.

These initiatives focus on bringing about social and behavioural change around food safety, hygiene, healthy diets and responsible consumption and should become a powerful tool available to every citizen-hence every stakeholder must play their part to ensure their Pan-India implementation.

PILLAR 1 : EAT RIGHT CAMPUS (ERC)

The Eat Right Campus initiative has a two fold objective:

- It helps to create an environment of safe food and healthy eating for residents and visitors in various campuses through compliance to a set of well-defined parameters; and equally importantly,
- It continuously reiterates the message of "mindful eating habits" in places that are part of our daily routine e.g. at people's workplaces, colleges, institutes or any other campus.

The ERC initiative can be taken up in any of the following campuses:

- Workplaces/Corporates
- Colleges/institutes/ universities
- Jails
- Hospitals/health institutions
- Tea Estate

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**State/UT's FDA :** Overall implementation and Identification of campus; Verification of self-assessment report and final audit report and recommendation for declaring eat right campus. **Training partners :** (www.fostac.fssai.gov.in): Mobilizing campuses to participate, Training Food Safety Supervisors; Creating trainer's pool, Translation etc.

Role of Stakeholders	**Auditing agencies :** (www.fssai.gov.in): Mobilizing participation, ensure timely audits, hand holding for further improvements. **Corporates/Funding Partners :** Adopting campuses for ERC certification; promote awareness, use CSR funds for training, printing and translation of training material, etc. **Academic Institutions/Colleges/Universities :** Conduct self-assessment as per the checklist; Overall support in identification, implementation and sustenance; mobilizing resources to become a certified ERC.
Steps for Implementation	Identification of campus and submission of enrolment form. Self-assessment/Pre-audit on a clearly defined checklist to identify gaps. Food Safety Training & Certification through FSSAI empanelled Training Partners. Rectification of gaps by campus authority. Final audit by FSSAI empanelled third party auditing agency for certification & rating of the campus. **The certificate will be valid for 2 years.** **Sustenance :** Designate a staff/student as ERC Fellow, who will be trained for periodic internal audits. Local FSO will draw sample randomly as per the risk involved.
Resources	**Guidance Document :** The Orange Book (I &II) : A handbook on Eat Right Campus : ***https://fssai.gov.in/book-details.php?bkid=14*** **Website :** ***https://eatrightindia.gov.in/EatRightCampus/*** **Partners :** **Audit Agencies :** ***www.fssai.gov.in/hygieneRating/resources/pdf/auditingagency.pdf and www.fssai.gov.in/upload/uploadfiles/files/Food_Safety_Auditing_Agencies_Lists_13_11_2019.pdf*** **Training Partners :** ***www.fostac.fssai.gov.in/fostac/tpdashboarddata*** **Supplementary Resources :** The Pink Book : A guide to eating safe, healthy and sustainably at home. ***https://fssai.gov.in/knowledge hub.php?hubname***=Book,Report,Manuals **Brochure :** ***https://www.eatrightindia.gov.in/EatRightCampus/images/pdf/flyer.pdf*** AV film ***https://www.eatrightindia.gov.in/EatRightCampus/videoGallery***

Resources	**Posters, Standee :** *https://www.eatrightindia.gov.in/EatRightCampus/communicationKit*
For more details, contact:	eatrightcampus@gmail.com

SUCCESS STORIES

Eat Right Campus has been gaining momentum since its launch in 2019. On the first World Food Safety Day, 7th June 2019, seven campuses were awarded Eat Right Campus certification by Dr. Harsh Vardhan, Hon'ble Minister of Health and Family Welfare at FSSAI. The following campuses were recognized for their exemplary standards-**IIT Gandhinagar, IIT** Roorkee, LBSNAA, Mussourie, Unilever, Bengaluru, Wipro, Bengaluru, HCL Noida and Genpact, Gurugram.

One of the first Eat Right Campuses to be recognized is the Lal Bahadur Shastri National Academy of Administration (LBSNAA), Mussourie. They have not only got the Hygiene Rating of their canteen done but have taken additional steps such as replacing plastic bottles with personalised glass bottles for probationers, introducing healthy snacks such as sprouts/channa instead of fried items, adopting a healthy menu, putting posters on healthy habits in the premises and conducting sessions with nutritionists for officers in the institute.

PILLAR 2 OF CONSUMER AWARENESS : EAT RIGHT SCHOOL

Poor eating habits impact not only the physical, but also the mental and cognitive development of children, lower their immunity and can have serious implications on learning outcomes. Schools are well poised to influence dietary practices and promote lifelong healthy habits, as students spend an average of 7-8 hours per day in school and are strongly influenced by peers and teachers. Moreover, most of our food habits are established at a young age. Hence as a special focus, FSSAI has put together the Eat Right School Campaign, at the heart of which lies the creation of Eat Right Schools.

Eat Right School is designed to help school children inculcate the habit of eating safe, eating healthy and eating sustainably through an interactive learning model. The Yellow Books I & II that have been developed specifically for school children from grades 1-8 with age appropriate and scientifically credible content on healthy habits. Schools may also create Health and Wellness Teams, certified by FSSAI, to drive this programme in the school. Further, a comprehensive matrix has been created for schools that include curricular and extracurricular activities based on which points are awarded. Based on the score received on the matrix, a school may be certified as an Eat Right School.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**Individual Schools/School Foundations or Trusts :** Implementing the Eat Right School programme. **Central and State Education Departments and School Boards :** To increase outreach, create regionalised content, integrate & to facilitate adoption of school programme. **MHRD – DIKSHA :** Learning & certification platform for teachers & students with curated learning material on all topics. Diksha platform and Project Management Unit will aid dissemination of content & certification of Health & Wellness Ambassadors under health and wellness track in all states. Outreach of 30 lac teachers in 28 states. **NIOS –** MoU signed with National Institute of Open Schooling to integrate the Eat Right principles into the curriculum of the largest open schooling board in India with an outreach of over 5 lakh students. **Anemia Mukt Bharat & UNICEF :** Joining hands to spread awareness among school children across India. **Publishing Houses/Corporates :** To integrate content from the Yellow Books into text books, for outreach as well as printing/distribution of Yellow Books. **Implementation partners such as NGOs, CSOs :** Integration of Eat Right Schools into mainstream curricular & co-curricular activities. **Domain experts :** Lending expertise to create credible content and dissemination through SNF Fellows.
Steps for Implementation	**A School can register online on the School Portal :** www.fssai.gov.in/eatrightschool–A user friendly and comprehensive online portal has been created for school registration, creation of Health & Wellness teams, and access to many activities under Eat Right School. **Create and Certify Health and Wellness Ambassadors (HWA) :** School teachers and/or parents can be nominated as Health and Wellness Ambassadors/Health and Wellness teams. They would be certified by FSSAI by undertaking an online certification program at **www.fssai.gov.in/eatrightschool.** and drive the Eat Right School programme. **Conduct Eat Right Activities :** Schools will create an activity calendar and conduct activities around eating right such as organizing 'Eat Right Carnival' and 'Healthy recipe day', include eating safe and healthy food as a

	part of SUPW activities, organise sessions with mothers for healthy & tasty snacks, identify 'Master & Miss Sehat' from each class on a weekly/monthly basis, create school kitchen gardens, paint a wall, participate in theatre, puppet activities based on Eat Right Themes etc. The evidence of these activities must be uploaded on the school website. **Monitoring and Evaluation :** Schools will use the Eat Right Matrix available on the website **www.fssai.gov.in/eatrightschool** to monitor and evaluate the programme. **Eat Right School Certification :** Suitable reward and recognition will be given to the schools on the basis of their performance.
Resources	**Guidance Document :** ***https://fssai.gov.in/eatrightschool/learning-books.php*** **Yellow Books :** These are available in 11 languages (English, Hindi, Punjabi, Gujarati, Marathi, Telugu, Tamil, Malayalam, Kannada, Bengali & Assamese on ***www.fssai.gov.in/eatrightschool***. The English version also available on DIKSHA - National Teacher's Platform, created by MHRD for teachers across India. **Activity Book :** A fun-filled activity book has been designed to teach and reinforce the message of safe and nutritious food. **Training Manual :** A teacher training manual has also been developed to give an in-depth understanding of the concepts on food safety and nutrition. **Website :** ***www.fssai.gov.in/eatrightschool*** **Supplementary Resources :** **The Pink Book :** A guide to eating safe, healthy and sustainably at home.https://fssai.gov.in/knowledge- **The DART Book :** A guide to Detecting Adulterants with Rapid Testing (DART) at home : **https://fssai.gov.in/knowledge-hub.php?hubname=Book,Report,Manuals**
For more details, contact:	snfatschool@fssai.gov.in

SUCCESS STORIES

Over 33,000 schools across the country have enrolled in SNF @ School through an online portal www.fsssai.gov.in/eatrightschool. Going forward, these schools will now be certified as Eat Right Schools on the basis of their performance.

Schools like Gyan Mandir Public School, Delhi Public School R K Puram and Mt Abu School have trained Health and Wellness Ambassadors and use resources such as Yellow Books and Activity Book in the curriculum. They conduct competitions/melas such as Healthy recipes that are available and accessible to parents, Eat Right carnival, student exhibits, full day events and design of paper bags by students to make the campus plastic free. Students also identify and train petty vendors around the campus selling food to ensure safety of food.

Eat Right Creativity Challenge was launched by FSSAI from 14Nov'18 – 10Jan'19 to unleash creative talent of our young people and engage, excite and enable them to inculcate healthy eating habits. 75,137 Children from 3621 schools across numerous States/UTs participated in 'On the Spot Poster' Competition, Wall Art Competition and Digital Creative Competition. The winners were awarded cash prizes & appreciation certificates in a grand award ceremony in New Delhi on 29 Jan'19.

PILLAR 3 : EAT RIGHT TOOLKIT

Bringing about large-scale social and behavioural change to promote right eating habits at the grassroots level calls for 2 critical elements:

- ***Simple, powerful and reiterative messaging through engaging content.***
- ***The services of resource persons who are trusted and recognised by the local community to deliver the content.***

The Eat Right Toolkit is an interactive training kit that has been designed to be integrated with the existing training modules of frontline health workers such as Anganwadi workers (AWW), ASHA workers, ASHA Sangini, Multi-Purpose Worker-Females (MPW-F), Community Health Officers (CHOs)/Mid-Level Health Providers (MLHPs), Medical Officer (MBBS) at Health and Wellness Centres. The Toolkit has been co-developed by FSSAI, National Health Systems Resource Centre (NHSRC) and Voluntary Health Association of India (VHAI). It has a training manual as well as useful tools in the form infotainment videos, posters, activity cards flyers, and interactive games to educate people about safe and healthy diets in a simple, clear and engaging manner.

Through this toolkit, community members would learn about eating safe by following safe food practices (including personal and surrounding hygiene) and combating food adulteration. They would also learn about eating healthy (i.e. balanced diet, fortified foods, avoiding foods high in salt, sugar and fat, and eliminating trans fats).

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**State Governments :** Facilitate procurement and placement of the 'Eat Right Toolkit' in HWCs as well as training of trainers at state and district level and frontline health workers. **State Food Safety Departments :** Facilitate trainings and provide Food Safety on Wheels (Van) on the day of training. Identify other government programmes for integration of Toolkit. **National Health Systems Resource Centre (NHSRC) :** This is the nodal body for integrating the 'Eat Right Toolkit' in Health and Wellness Centres under Ayushman Bharat. Training of the trainers (at national, state and district level) along with FSSAI and Voluntary Health Association of India (VHAI). Training of frontline health workers and contextualization of the toolkit into regional languages. **NetProFaN :** Members from NetProFaN will lend expertise to create a pool of master trainers at National/State level and integrate the toolkit/ components from the toolkit in their community outreach efforts. **MHRD :** Training of the Nodal Officers of the Mid-Day Meal Programme. Integration of Eat Right toolkit into school curriculum and/or as co-curricular activities. **Frontline workers at HWC [ASHA, CHO/MLHP, MPW (F)] :** On ground implementation of toolkit.
Steps for Implementation	The Eat Right Toolkit is available online on the Eat Right India website and will be soon available on Government e-Marketplace portal for direct procurement by stakeholders. The toolkit is also being translated in regional languages to be used across India. It has been included in state PIPs (programme implementation plan) by Ministry of Health and Family Welfare (MoHFW). » Training of the National trainers and followed by training of the State and district trainers to create a pool of Master Trainers. » Master trainers will then train frontline health workers by integrating the toolkit in their existing training programmes as an additional module. » Printing/Procurement of Toolkits for placement in Health and Wellness Centres across the country, by states in a phased manner. » Frontline health workers to use the toolkit to educate their respective target audiences to educate them about eating right.

Steps for Implementation	» **Convergence with other Ministries :** Ministries, with frontline worker force [Anganwadi workers – MoWCD; Agriculture extension workers–Ministry of Agriculture and Farmers Welfare; Swachhta Preraks–Ministry of Drinking Water and Sanitation; Community Resource Persons–Ministry of Rural Development] can integrate the 'Eat Right toolkit' in their respective outreach programmes.
Resources	**Guidance Document :** Eat Right Toolkit Handbook ***https://eatrightindia.gov.in/EatRightIndia/rbook/?rf=spice&viewFilePath=file/Eat%20Right%20Toolkit%20Handbook2020_English.pdf#rbook/*** **Website :** Eat Right India: ***https://eatrightindia.gov.in/outreach.jsp*** **Partners :** NHSRC, VHAI, members from NetProFaN, state food safety department **Supplementary resources :** » E-Course in Eat Right for Frontline Workers Videos (15 Videos series) ***https://fssai.gov.in/erfw*** » Weblink for Eat Right Toolkit ***https://eatrightindia.gov.in/outreach.jsp*** » Government E-Marketplace portal link for procurement : ***https://gem.gov.in/***
For more details, contact:	Eatright.toolkit@gmail.com

SUCCESS STORIES

Eat Right Toolkit orientation master class was held in December 2018 at Delhi for ASHA, Auxiliary Nurse Midwife (ANM), AWW and Nodal officers of the mid-day meal programme. The toolkit was well received by the audience and around 700 ASHA & ANM, 600 AWW and 600 teachers, who were the Nodal officers of the Mid-Day Meal Programme, actively participated in the masterclass.

Pilot training of the Eat Right toolkit was conducted at Regional Health & Family Welfare Training Centre (RHFWTC), Meerut, Uttar Pradesh. The training was attended by a diverse group of 42 participants-members of SHC-HWC and PHC-HWC [ASHAs, ASHA Facilitators (ASHA Sangini), Multi-Purpose Worker-Females (MPW-F), Community Health Officers (CHOs)/Mid-Level Health Providers (MLHPs), MO-MBBS, Pharmacist, Lab Technician and Staff Nurse].

COMBATING ADULTERATION

Food adulteration must be addressed through a holistic approach of strengthening lab testing infrastructure; training of lab personnel; and guiding the consumer about common adulterants and the need to be vigilant. Further, in view of the increasing incidence of fake news that spreads rapidly in today's social media world and causes undue panic, it is equally critical to address 'perceptions' about adulteration through informing and educating consumer.

With these objectives in mind, FSSAIs initiatives to address adulteration are as follows:

- Strengthening Food Testing Labs
- FSW, DART Book, Food Safety Magic Box
- Consumer Guidance Notes and Myth Buster
- Periodic surveys/surveys in hotspots

All resources created for the initiatives above are available for use by States/UTs, Food Businesses, Consumers, Consumer Organizations, Schools, Colleges and others.

To combat adulteration effectively, every stakeholder is strongly encouraged to access these resources and ensure they are used extensively and disseminated through multiple channels.

COMBATING ADULTERATION BY STRENGTHENING FOOD TESTING LABORATORIES

FSSAI is implementing a Central Sector Scheme for "Strengthening of Food Testing System in the Country Including Provision of Mobile Food Testing Labs" (SOFTeL). The scheme has been formulated for effective implementation of the Food Safety and Standards Act 2006 in a uniform and transparent manner in the country.

One of the components of the scheme is strengthening of State Food Testing Labs atleast one in each State/UT and two in larger States. Under this component, a grant of Rs. 10 crore (approx.) is admissible for each State Food Testing Laboratory (SFTL), subject to the readiness of the concerned SFTL. This grant facilitates the creation/renovation of infrastructure for housing high-end equipment (HEE), procurement of 3 high end equipment viz. LC-MSMS, GC-MSMS and ICP-MS (alongwith consumables, CRMs, accessories, maintenance and associated manpower to run these equipments). An additional grant for setting up of microbiology laboratory is also admissible under this component. In addition to this, the North East States have been endowed with a grant of Rs. 3 crore each for setting up new food testing laboratory in these States.

This would enable the States/UTs to analyse the regulatory and surveillance samples drawn by the FSO within the shortest possible time frame; to analyze the safety parameters in food samples such as Heavy metals, Pesticide residues, Antibiotic and drug residues and Naturally occurring toxic substances along with Microbiological tests; to reduce the time taken from sample collection to sample analysis; to ensure compliance of FSSAI standards on food; to enable the laboratory to achieve NABL accreditation within 2 years from the date of release of final instalment; to become a resource point for training and facility up-gradation for other existing Government / Public Food testing laboratories in the State; and to introduce online laboratory data management system through Laboratory Information Management System (LIMS). This would benefit all stakeholders in ensuring safety and quality of food products.

For more details State/UTs may contact : Quality Assurance Division, FSSAI (Email: labs@fssai.gov.in)

COMBATING ADULTERATION : FOOD SAFETY ON WHEELS (FSW), DART BOOK, FOOD SAFETY MAGIC BOX

A series of innovative tools including mobile testing labs, portable testing kits and guidance booklets to empower consumers to deal with adulteration have been created by FSSAI and are available for wide dissemination across the country.

FOOD SAFETY ON WHEELS (FSW)

Reaching testing facilities to remote areas is a challenge. To address the issue of lack of food testing infrastructure in remote areas and cater to basic analytical needs of consumers, FSSAI has set-up mobile food testing laboratories called Food Safety on Wheels (FSW) that are being provided to States/UTs on first-come-first serve basis, depending upon their readiness.

Food Safety on wheels performs 3 key functions – Testing, Training and Awareness generation. The mobile labs are equipped with basic testing infrastructure plus training facilities including an LED screen and awareness material in the form of videos/audios/flyers and manuals. FSW are also being used for cold chain logistics for movement of regulatory/ surveillance samples, as offsite wings of Labs, a handy tool for training street food vendors, providing information and support for licensing and registration, training and/or awareness programs for plantation workers about food safety, as a module for communicating IEC materials in vernacular languages and as a tool for creating awareness during any pandemic or epidemic.

Information related to FSW and the soft copy of manuals is available on the website of FSSAI and can be freely downloaded and printed without changes by any individual or company or publisher for individual use or widespread dissemination.

For more details on Mobile lab - *https://fssai.gov.in/cms/mobile-labs.php*

DETECT ADULTERANTS WITH RAPID TESTING (DART)

To tackle economically driven adulteration, a booklet titled "Detect Adulteration with Rapid Test (DART) has been co-created with domain experts. DART is a compilation of common quick tests that consumers can conduct themselves at home, for detection of common food adulterants. The booklet depicts differences between pure and adulterated food products through pictorial representations. It covers more than 50 quick tests that can be performed easily for detection of food adulterants with the help of water and simple solutions like tincture of iodine in various food products like Milk & Milk Products, Oils and Fats, Sugar & Confectionary, Food Grains and its products, Spices & Condiments, etc. These tests also include sensory evaluation of food for establishing authentication of food product.

The soft copy of DART booklet is available on the website of FSSAI. The Food Safety Department of States/UTs are using this booklet as a tool to spread awareness for combating adulteration by downloading and printing free of cost in regional languages. Some States/UTs are making videos based on DART for demonstration purposes to public. Schools/colleges use DART for demonstrating and teaching students in their labs on these simple tests. This booklet is available in the form of pocket size booklet, keychain and in a smaller size for better distribution and wider dissemination of information.

To access resources :

- **DART Book**
  https://fssai.gov.in/upload/knowledge_hub/1878035b34b558a3b48DART%20Book.pdf

- **Videos for testing common adulterants in food items**
  https://www.youtube.com/playlist?list=PLe_cE1UOQ6EZOx0O0kSMbSSkWV7W4YZpM

FOOD SAFETY MAGIC BOX

The Food Safety Magic Box is a self-contained portable food testing kit, useful as a pedagogical tool for school children, in primary health centres, for frontline health-workers etc. The Magic Box is a small-sized, light-weight box that contains a few basic chemicals, small instruments and safety gadgets. It also has a companion guidance book that illustrates testing across various food products in a very simple way through pictures.

A total of 102 very simple tests can be performed with the Magic Box, including tests to determine adulterants like water, urea, detergents, starch, pulverised soap etc in milk; starch and artificial colours in spices and condiments; mineral acid in beverages, adulteration in sugar and honey.

Institutions/State Authority/Schools can buy the reasonably priced Food Safety Magic box from Government e-Marketplace portal (https://gem.gov.in/) Further, the soft copy of Food Safety Magic Box Companion Book is available on the website of FSSAI and can be freely downloaded and printed without changes by any individual or company or publisher for personal use or widespread dissemination. The Companion Booklet for the Magic Box can act as a standalone resource, wherein hands-on experiments can be done at school labs using materials available readily in their science laboratory.

To access the Food Safety Magic Box Companion Book -
https://fssai.gov.in/upload/knowledge_hub/1089415e550a12c9d0bBook_Food_Safety_Magic_Box_25_02_2020.pdf

COMBATING ADULTERATION : CONSUMER GUIDANCE NOTES AND MYTH BUSTERS

CONSUMER GUIDANCE NOTES

In order to keep citizens informed about the latest developments in food safety, nutrition, food sustainability and related areas and clarify their doubts and queries, FSSAI releases consumer guidance notes from time to time and circulates them through social media as well as through its website.https://fssai.gov.in/cms/guidance-notes.php

The topics of these consumer guidance notes range from safety and quality of milk, concerns about pesticides in food to stickers on fruits and vegetables. These guidance notes provide credible information vetted by scientific experts associated with FSSAI. They provide

complete and correct information on topics particularly about which there is a lot of misinformation.

MYTH BUSTERS

It has been observed time and again that various fake news articles are circulated through social media channels such as YouTube, WhatsApp, Facebook etc which have a wide reach among masses. These fake news messages are not based on scientific facts and create panic among citizens. With all the false and misleading information propagated through these media, FSSAI in consultation with the subject experts issues clarification on these fake news items from time to time under the 'Myth Busters' section on its website and through social media. https://fssai.gov.in/cms/myth-buster.php

These myth busters serve to provide citizens with clear and correct information and reassure them of the safety of food they are consuming.

COMBATING ADULTERATION : FOOD SAFETY SURVEILLANCE-SURVEYS IN HOTSPOTS / PERIODIC SURVEYS

FSSAI undertakes periodic food surveys to build trust of consumers in safety and quality of food products, in association with other relevant government departments, throughout the country. The surveys may be conducted based on factors like hotspot areas, high-risk food products, increased seasonal demand as well as public perception. The survey may be conducted through state machinery or with help of third party. The hot spot areas and other risk-factors thus identified would help in stringent enforcement/surveillance activities. Also, the evidence-based results would dispel wide spread perception that food in the country is largely adulterated/unsafe.

STEPS FOR IMPLEMENTATION

1. Identification of product/commodity and area for survey
2. Consultation with other departments/bodies dealing with the commodity wherever available, for knowledge sharing
3. Formulation/revision/strengthening of standards for product under consideration
4. Formulation of survey guidelines
5. Sample collection, testing and results
6. Findings and outcomes
7. Guidelines/action plan/guidance document for further action

ROLE OF STAKEHOLDERS

- **FSSAI :** Identification of product and area for survey, Formulation/revision/ strengthening of standards for product under consideration, Formulation of survey guidelines, Guidelines/action plan/guidance document for further action.
- **Other departments/bodies dealing with the commodity :** Sharing of knowledge and experience, Other collaborations.
- **State governments :** Identify target areas, Undertake/facilitate on ground sample collection.
- **Third party agencies :** Sample collection, testing and results, Findings and outcomes.
- **Producers/Manufacturers :** Follow Guidelines/action plan/guidance document for further action.

ENABLING HEALTHY CHOICES

FSSAI's mandate is to ensure both "safe" as well as "wholesome" food for human consumption. To nudge consumer demand towards healthier food choices, FSSAI has prioritised the following focus areas for enabling healthy choices: -

- Food Fortification
- Reduction of Salt, Sugar and Fat
- Trans-fat Free India@75 by 2022

FOCUS AREA 1 : FOOD FORTIFICATION

While a balanced diet and dietary diversification is always the primary source for fulfilling nutritional requirements, food fortification is a useful supplementary strategy to address the widespread micronutrient deficiencies in our country. It involves adding small amounts of vital micronutrients to staple foods, for which FSSAI has defined standards of fortification. Fortification fills the gaps in nutrition without any change in taste, texture or flavour of food, thereby making it easy to adopt without calling for behaviour change.

An enabling ecosystem for large scale adoption of food fortification is now in place. FSSAI has gazette notified the Food Safety and Standards (Fortification of Foods) Regulation dated 2nd August, 2018 on fortification of food in key staples like Oil and Milk (with Vitamin A and D), Wheat Flour and Rice (with Iron, Folic Acid and Vitamin B 12), and Double Fortified Salt

(with Iodine and Iron). The Logo (+F) for fortified foods, has created a rallying point for the industry to adopt fortification, placing fortification firmly on the national agenda. Various advisories for premix supplier, endorsement of +F logo, and Scientific Health Claims for label declaration of fortified foods approved by the Scientific Panel on Nutrition and Fortification were also released.

Stakeholders (including States/UTs as well as FBOs) can thus systematically adopt fortification by following the standard operating procedure.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**States/UTs/Line Ministry Departments –** Overall implementation and scaling up fortification in their States. **Food industry –** Provide fortified products for open market and government safety net programmes. **Development Partners –** To provide technical know-how and support to scale up fortification by mobilizing the state officials and food industry. **Food Safety Department –** Can encourage open market availability by guiding the FBO through the +F endorsement process. Supporting State government by supply chain alignment of fortified staples.
Steps for Implementation	Coordination by an appointed nodal officer among line departments of ICDS/MDM/PDS to discuss the current progress of fortification in the state and next steps. FDA department to ensure that the FSOs are sensitized and trained towards food fortification. Trained FSOs to hold a meeting with the food businesses and encourage them to adopt fortification. For any technical assistance, FFRC may be approached. Once the businesses adopt fortification, ensure the +F endorsement of fortified products through the FoSCoS system of FSSAI. Provide the list of businesses or connect the businesses to ICDS/MDM/PDS departments, along with sample tender documents for procurement of fortified staples. Conduct mass awareness activities to generate awareness and increase consumption of fortified staples. Once the city/district is progressing on fortification, provide the information to FSSAI and FFRC.

Resources	**Guidance Document :** Sample tender documents - *https://ffrc.fssai.gov.in/snp* **FSO guidebook by FFRC -** *https://ffrc.fssai.gov.in/mpublication?mreq=books-references* Books and other publications *https://ffrc.fssai.gov.in/mpublication?mreq=books-references* **Directives issued by line ministries -** *https://ffrc.fssai.gov.in/snp* **Directives issued by FSSAI -** *https://ffrc.fssai.gov.in/order-advisory* **FFRC brochures -** *https://ffrc.fssai.gov.in/brochure* **Website -** *www.ffrc.fssai.gov.in* **Partners -** *https://ffrc.fssai.gov.in/partners* **Supplementary Resources** **Training videos -** *https://ffrc.fssai.gov.in/mgallery?mreq=video* **Danglers/Posters/Standees** *https://ffrc.fssai.gov.in/advocacy-comm?mreq=standee* **TVC and other videos -** *https://ffrc.fssai.gov.in/mgallery?mreq=tvc* **Radio spots -** *https://ffrc.fssai.gov.in/mgallery?mreq=tvc* **Social media -** *https://ffrc.fssai.gov.in/*
For more details, contact:	fortification@fssai.gov.in

SUCCESS STORIES

114 large as well as MSME companies are offering ~ 157 fortified products across commodities. There has been tremendous traction in the oil and milk industry, with 47 percent of top ten players of packaged refined edible oil industry and 36.6 percent of the organized milk industry fortifying as per FSSAI standards.

19 States (Odisha, Karnataka, Haryana, Gujarat, Uttar Pradesh, Himachal Pradesh, Madhya Pradesh, Maharashtra, Jharkhand, Rajasthan, Tamil Nadu, Tripura, West Bengal, Kerala, Bihar, Chhattisgarh, Andhra Pradesh and Delhi) and 5 UTs (Dadra and Nagar Haveli, Daman & Dui, Andaman & Nicobar Islands, Chandigarh) have adopted fortification of several commodities in the government safety net programmes (SNP) namely ICDS, MDM and PDS.

FOCUS AREA 2 : REDUCTION OF SALT, SUGAR AND FAT

The exponential increase in the consumption of High Fat Sugar and Salt (HFSS) foods is leading to grave consequences in the form of diet related non-communicable diseases (NCDs) like diabetes, hypertension, heart diseases etc. Children are particularly vulnerable, with childhood obesity increasingly co-existing with micronutrient deficiencies, causing irreversible harm to their physical, cognitive and mental health. Unfortunately, the extent of damage to health by excessive consumption of such foods is not widely understood.

As food habits (dietary behaviour) cannot change overnight, FSSAI has initiated a 2 pronged approach to nudge both consumers and producers to address the issue. A nation-wide media campaign - "Aaj Se Thoda Kam" to encourage consumers to make dietary modifications by gradually decreasing the consumption of fat, sugar and salt has been launched. The renowned bollywood actor Mr Raj Kumar Rao is the face of the campaign, and a series of short videos (with subtitles in 12 languages) have been created and supported with flyers, banners, audio clips and an Eat Right India website with useful inputs on gradually reducing HFSS foods consumption. Simultaneously, manufacturers are being encouraged and supported to reformulate their food products to healthier options. To recognize the contribution of food companies and individuals towards "Aaj Se Thoda Kam" campaign, Institutional and Individual "Eat Right Awards" have been instituted under various categories. The success of the campaign depends on the widest possible dissemination and reiteration of the simple message, and a standard operating procedure is in place to enable large-scale participation by various stakeholders.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**State/UT governments :** Initiation and implementation of the campaign in their jurisdictions. **Food industry/Vendors :** Produce, reformulate and promote foods low in fat, sugar and salt, responsible advertising of foods. **Health, Food and Nutrition Associations/Organizations (IDA, NSI, NetProFaN, NetSCoFAN, IFCA, IMA, AFSTI, etc) :** Create awareness on adverse health effects of foods high in fat, sugar and salt and ways to reduce them in the diet. **Media (print, electronic and social media) :** Effective messaging
Steps for Implementation	The "Aaj Se Thoda Kam" campaign content is available online at FSSAI's website/You Tube to all stakeholders including States/UTs, FBOs, Consumer Organisations, the Medical and Professional Community, Educational and Training Institutes etc. for wide dissemination and reiterative messaging which can be done as follows:

Steps for Implementation	» Use the material for creating awareness by playing the video at various events like conferences, seminars, workshops, trainings, Eat Right Melas etc along with distribution of posters, flyers and other education material on the importance and ways to reduce fat, sugar and salt. » Connecting with food businesses like hotels, restaurants, *dhabas*, sweet shops, bakeries, etc. to reformulate the recipes. » Creating awareness and engaging street food vendors to use less fat, sugar and salt. » Engaging members from Network of Professionals of Food and Nutrition (NetProFaN) and Network for Scientific Co-operation for Food Safety and Applied Nutrition (NetSCoFAN) to create awareness on reduced fat, sugar and salt. » Funding Opportunities - From State exchequer funds, NHM funds for IEC activities, CSR or voluntary funds from businesses / organizations. Funding partners contribution could be acknowledged on the plaque/website etc.
Resources	**Guidance Document :** Health concerns with High Fat, Sugar and Salt (HFSS) consumption URL: ***https://fssai.gov.in/cms/guidance-notes.php*** **Website :** Eat Right India **URL :** ***https://eatrightindia.gov.in/EatRightIndia/index*** **Partners :** NetProFaN & NetSCoFAN **Supplementary resources** **Videos :** Aaj Se Thoda Kam, featuring Rajkummar Rao ***https://www.youtube.com/watch?v=Ue39uvSQI4s*** Plus-Minus rule, featuring Virat Kohli ***URL:https://www.youtube.com/watch?v=xUsFYbaMKVg*** Eat Right Quick Tips URL : ***https://fssai.gov.in/knowledge-hub.php?hubname=Video,Audio,Photos*** **Posters/Flyers :** ***https://eatrightindia.gov.in/EatRightIndia/IECMaterial.jsp*** Food Safety and Standards (Advertising and Claims) Regulations, 2018 : ***https://www.fssai.gov.in/upload/uploadfiles/files/Gazette_Notification_Advertising_Claims_27_11_2018.pdf***
For more details, contact:	***hfss.eri@gmail.com***

SUCCESS STORIES

- The Aaj Se Thoda Kam campaign has been run in cinema halls, social media platforms like PVRs, TV channels (Doordarshan and Food Food), Facebook, Twitter, Youtube, etc. The campaign was effectively run and reached a larger population during Swasth Bharat Yatra across India including the remote areas and Eat Right Melas in Delhi, Tamil Nadu (Chennai), Assam (Barpeta) and Madhya Pradesh (Indore). Additionally, NetProFaN through its 22 chapters and professional associations like IDA, NSI, IMA, IFCA, AFSTI, disseminated the messages of the campaign to various stakeholders by means of conferences, workshops, trainings, etc. Around 2 lakh posters, tent cards and piano folds have been circulated for sensitizing doctors and patients; restaurants and hotel staff and customers; airlines staff and travellers.
- Fifteen major food companies (Britannia, Bikanervala, Bagrry's, Del Monte, Haldirams, ITC, MTR, Nestle, Patanjali, Kellogg's, Marico, Weikfield, HUL, Mapro, Kraft Heinz) have taken voluntary pledge to reformulate packaged foods to reduce the level of fat, sugar and salt.
- Three food services establishments (Bikarnervala, Haldirams's and Jubilant foods) took voluntary pledges to provide healthier food options and introduce menu labelling.
- Nine major food retail players (Amazon, Sanpdeal, Zomato, Spencers's Retail, Kendriya Bhandar, Big Basket, Cloudtail, ANI technologies pvt ltd and New Modern Bazaar) including e-commerce players pledged to promote healthier food options and responsible retail practices.
- FSSAI organized a 'Salt Challenge' for medical and nutrition professionals, students, chefs etc. across India in November 2019 inviting simple, practical and easy to use suggestions/tips for reducing salt content in home cooked and restaurant prepared meals/snacks. Overwhelming response was received from all over the country and 45 winners were awarded certificates.

FOCUS AREA 3 : TRANS-FAT FREE INDIA@75 BY 2022

We aim to eliminate industrially produced trans-fat from the food supply chain in India by 2022, a year ahead of the global target of 2023 by the World Health Organization (WHO), thus making India trans-fat free in its 75th year of Independence.

Poor lifestyle and diet along with consumption of trans fat; especially industrially produced (IP) trans fat has emerged as a major risk factor for cardiovascular diseases. Trans

fats are usually found in partially hydrogenated vegetable oils (PHVOs)-vanaspati, margarine, bakery shortening and food products which are prepared using PHVOs like bakery products (biscuits, fan, cakes), fried foods (bhatura, samosa), etc. Small amount of trans fats also get generated when the same cooking oil is used for repeated frying.

Currently, FSSAI Regulations limits the Trans Fatty Acids (TFA) content to not more than 5% of total fats in various PHVOs, including interesterified vegetable fats, vanaspati, bakery shortening and bakery and industrial margarine. In 2018, a draft amendment in the regulation was issued stating that all edible oils and fats shall limit the trans fat content to not more than 3% by weight, on and from 1st January, 2021 and not more than 2% by weight, on and from 1st January, 2022. Additionally, in 2019, a draft notification was published to expand the regulation (not more than 2% trans fat) to food products which use edible oils and fats as an ingredient.

FSSAI has adopted a multifaceted approach to make India trans-fat free. Apart from regulatory steps, FSSAI has also run various campaigns to eliminate trans-fat. One such campaign called "Heart Attack Rewind" was launched on 30th November, 2018 in the form of a Public Service Announcement (PSA) aimed to create awareness about the harmful effects of trans fat. This 30-second video is available in 17 languages and has been disseminated through various media and social media platforms. To ensure maximum visibility and spread awareness about the fatal effect that trans-fats can have, standard operating procedures have been put in place for ease of sharing the content through various forums.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**State/UT governments :** Initiation and implementation of the campaign, surveillance and regulatory actions related to transfat. **Edible oil industries :** Produce and promote trans-fat free oils/fats. Responsible advertising of fats/oils. **Food industry/vendors/retailers :** Produce, reformulate and promote trans fat free foods. Responsible advertising of foods. **Health, Food and Nutrition Associations/Organizations :** Create awareness on adverse health effects of trans fat and ways to eliminate it from the diet. **Media (print & electronic and social media) :** Effective messaging on trans fat.

Steps for Implementation	Conduct conferences, seminars and workshops to create awareness on trans fats among citizens and the food industry. Engage members from Network of Professionals of Food and Nutrition (NetProFaN), Network for Scientific Co-operation for Food Safety and Applied Nutrition (NetSCoFAN) to support this initiative by providing technical inputs to the food industry and creating awareness among citizens. Engage street food vendors, food businesses like hotels, restaurants, *dhabas*, sweet shops, bakeries and Chefs to use trans fat free fats/oils. Conduct surveillance and enforcement drives for adherence to the trans fat regulation. Support analytical laboratories for upgrading their facility for high quality trans fat analysis in fats/oils and foods. Conduct trainings for capacity building of laboratory staff for accurate analysis of trans fat in fats/oils and foods. Support partially hydrogenated vanaspati oil (PHVO) manufacturers in technology transfer to trans fat free fat/oil.
Resources	**Guidance Document :** Eliminate trans fat form your diet ***https://fssai.gov.in/cms/guidance-notes.php*** **Website :** ***https://eatrightindia.gov.in/EatRightIndia/index*** **Partners :** NetSCoFAN and NetProFaN : ***https://fssai.gov.in/NetProFaN/*** **Supplementary resources :** **Videos :** Heart Attack Rewind- Public Service Announcement on Trans Fat ***(https://eatrightindia.gov.in/hfss.jsp)*** In Conversation with Dr Tom Frieden, President & CEO of Resolve to **Save Lives :** www.youtube.com/watch?v=eb8KOVkFJAY&t=211s **Digital Trans Fat Free logo :** ***https://eatrightindia.gov.in/EatRightIndia/hfss.jsp*** **Posters/Flyers :** ***https://eatrightindia.gov.in/EatRightIndia/IECMaterial.jsp#*** **Regulations :** ***https://www.fssai.gov.in/upload/uploadfiles/files/Gazette_Notification_Advertising_Claims_27_11_2018.pdf*** ***https://fssai.gov.in/upload/advisories/2019/07/5d3b01c07b950Letter_TransFat_24_07_2019.pdf***

	https://fssai.gov.in/upload/uploadfiles/files/Gazette_Notification_TFA_28_08_2015.pdf
For more details, contact:	transfat.eri@gmail.com

SUCCESS STORIES

The "Heart Attack Rewind" PSA reached a large audience (approx. 34,900,000) through digital/social media and radio spots.

Voluntary commitments to create awareness and phase out trans fats by 2022 [India@75 - Freedom from trans-fats by 2022] was signed by edible oil industry (Indian Vanaspati Producers' Association, The Solvent Extractors' Association of India, The Vanaspati Manufacturers' Association of India), bakery associations (Indian Bakers Federation, Society of Indian Bakers, Assocom Institute of Bakery Technology & Management, Wheat Products Promotion Society, Federation of Biscuits Manufacturers of India), Halwai association and professional associations like the Nutrition Society of India (NSI), Indian Dietetics Association (IDA), Association of Food Scientists and Technologists (India) and Indian Medical Association(IMA) of India.

Ten bakeries were felicitated by Dr. Harsh Vardhan, Honorable Union Minister of Health and Family Welfare at the 8th International Chefs Conference, organized by Indian Federation of Culinary Associations (IFCA) in New Delhi for adopting methods/techniques to gradually eliminate trans-fat from their food products or who commit to do so in near future.

SUSTAINABILITY INITIATIVES : RESPONSIBLE PRODUCTION AND CONSUMPTION

There is a symbiotic relationship between our food, our health and our planet - one cannot grow at the expense of the other. Unfortunately, unsustainable practices in production and consumption of food (that seem to have become the global norm) have grave environmental consequences like land degradation, water and air pollution, and biodiversity loss, thereby threatening our very survival.

We need to adopt responsible production and consumption practices with a sense of extreme urgency, starting NOW.

To encourage and support responsible production and consumption, FSSAI is spearheading the following initiatives:

- Jaivik Bharat
- Save Food, Share Food

- Safe and Sustainable Packaging in Food and Beverage Sector
- Repurpose Used Cooking Oil (RUCO)

SUSTAINABILITY INITIATIVE 1 : JAIVIK BHARAT

Organic Foods are grown in a system of agriculture without the use of chemical fertilizers and pesticides with an environmentally and socially responsible approach. India is becoming a growing market for organic foods and to maintain consumer's trust, there is a need to ensure genuineness of foods claimed as 'Organic' for which a regulatory mechanism backed by a robust certification system is required.

Under Section 22 of Food Safety Standards Act, 2006, FSSAI has the mandate to regulate manufacture, distribute, sell or import organic foods. Food Safety and Standards (Organic Food) Regulations, 2017 have been notified in the Gazette of India, as per which all the Food Business Operator were required to comply with the provisions of these Regulations by 1st July, 2018.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	» The Agricultural & Processed Food Products Export Development Authority (APEDA) is implementing National Programme for Organic Production (NPOP). » Integrated Nutrient Management (INM), Division of the Department of Agriculture, Cooperation and Family Welfare (DAC & FW) through National Centre of Organic Farming is implementing Participatory Guarantee System for India (PGS-India). » Accredited Certification Bodies under NPOP are Accredited Certification Agencies authorized under the programme to certify organic producers. » Regional Councils under PGS-India are authorized by PGS-NAC to coordinate, monitor and approve certification decisions of Local Group under PGS-India organic Guarantee programme » The FBOs to ensure that they (i) get the organic food certified as per PGS-India or NPOP (ii) have valid FSSAI license for organic foods (iii) comply with labeling, quality and food safety requirements of FSSAI in addition to certification under NPOP or PGS- India. » State Food Safety Commissioners ensure that (i) all the organic foods sold in the market bear "Jaivik Bharat" logo besides all mandatory labeling requirements for conventional foods (ii) Organic food is displayed separately from conventional foods in the retail outlets.

Steps for Implementation	» The FBO has to get registered for certification under PGS-India or NPOP for the appropriate category i.e. Producer/Processor/Trader. For PGS-India, they may contact the nearest Regional Council. The details of the Regional Councils can be had from the PGS-India website -https://pgsindia-ncof.gov.in. For NPOP, they may contact any of the Certification Body accredited under NPOP. The details of Accredited Certification Bodies are available at the APEDA website – ***https://apeda.gov.in*** » The FBO should have valid FSSAI licence for organic foods. He can also get the existing licence endorsed for organic foods. » The FBOs will ensure that the organic food products bear "Jaivik Bharat" logo, carry certification or quality assurance mark of NPOP or PGS-India and are displayed separately from conventional foods in the retail outlets. » The FBOs/Regional Councils/Accredited Certification Bodies to ensure that organic foods comply with the requirements of product standards as provided in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011 and with limits of contaminants specified in Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 » State Food Safety Commissioners to ensure that all the organic foods sold in the market bear "Jaivik Bharat" logo besides all mandatory labeling requirements for conventional foods. They shall also ensure that organic foods are displayed separately from conventional foods in the retail outlets.
Resources	**Guidance Document :** Food Safety and Standards (Organic Foods) Regulations, 2017. The Regulations can be accessed at (www.fssai.gov.in). **Website :** » "Indian Organic Integrity Database Portal", a repository of Organic Food Business Operators certified under NPOP and PGS-India and would help consumers verify the authenticity of organic foods. ***(https://jaivikbharat.fssai.gov.in/).*** » For PGS- India related issues ***: https://pgsindia-ncof.gov.in*** » For NPOP related issues : ***https://apeda.gov.in***
For more details, contact:	advisor@fssai.gov.in

SUSTAINABILITY INITIATIVE 2 : SAVE FOOD, SHARE FOOD

About Save Food, Share Food: It seems illogical, not to mention unethical, that huge quantities of usable surplus food are thrown away/wasted, even as the underprivileged are unable to afford just 1 square meal a day. The 'Save Food, Share Food' initiative aims to tackle the problem of surplus food wastage by bridging the gap between food business operators, surplus food distribution organizations and those in need. It is also geared towards encouraging food donation amongst food businesses and adopting robust practices to reduce food loss and food waste in the supply chain.

A network of Surplus Food Distribution Organizations known as 'Indian Food Sharing Alliance' (IFSA) has been created along with a technology platform (website and application) to scale up safe and hygienic food donation (pre-packaged, fresh, cooked food), reduce food waste and ensure safe food collection and distribution through registered agencies. Awareness generation about food loss and food waste amongst citizens through behaviour change strategies is also taken up.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**Surplus Food Distribution Agencies :** These agencies constitute IFSA network and are the nodal point of this initiative. They are responsible for the core activity of food collection and distribution. **Food Businesses and their Associations :** Hotels and restaurants, retailers (perishables and packaged foods) and food processing industries which produce and handle food. Food businesses should be encouraged to adopt practices to reduce food waste and donate surplus food to the needy. **Beneficiaries :** Orphanages, Slums, Shelter homes, etc. are the end consumers who will receive the food from food distribution agencies. **State and Central Food Safety Departments :** Responsible for hand holding these agencies to get FSSAI registration and organizing food hygiene and safety training for IFSA team. **All Businesses :** Can support in development of proper food safety management system in the supply chain for these agencies by providing refrigerators/ deep freezers/vans etc. through their CSR funds. **Government Departments :** Human Rights, Consumers, MoFPI etc. can help in spreading awareness about these initiatives to scale up the effort.

Steps for Implementation	**Identification of food distribution agencies :** FSSAI (central and state departments) identify and connect new agencies with existing IFSA teams. **Training cum Workshop :** State Food Safety Department should conduct workshops for surplus food distribution agencies and their volunteers where the key agenda will be: » FSSAI Registration of food distribution agencies » Food Safety Awareness training for food distribution agencies and volunteers » Sensitization about Save Food Share Food Initiative, its campaigns and Food Safety and Standards (Recovery and Distribution of Surplus Food) Regulations, 2019. Connect agencies with food businesses such as leading hotels, companies and their associations in the district/city. Consumer awareness drives should be conducted at public events/State Department Events, food donation drives etc.
Resources	**Guidance Documents :** » Food businesses - ***https://sharefood.fssai.gov.in/regulation-food-business.html*** » citizens - ***https://sharefood.fssai.gov.in/regulation-guidance-citizens.html*** and » Food distribution agencies - ***https://sharefood.fssai.gov.in/regulation-recovery-agency.html*** **Website :** ***www.sharefood.fssai.gov.in*** **Partners :** Food Collection Agencies: **Supplementary Resources :** » **Flyer :** ***https://sharefood.fssai.gov.in/resource.html*** » **Video :** ***https://www.youtube.com/watch?v=XdQgnibrAa0***
For more details, contact:	savefood.sharefood@gmail.com

SUCCESS STORIES

At present, 82 food distribution agencies are part of IFSA network. These agencies are collecting surplus food and feeding the underprivileged in more than 100 districts. Over 50 million meals have been donated by these agencies so far. FSSAI was awarded SKOCH Platinum award for this initiative in year 2018.

SUSTAINABILITY INITIATIVE 3 : SAFE AND SUSTAINABLE PACKAGING IN FOOD AND BEVERAGE SECTOR

Safety and sustainability of food packaging (especially plastics) has become a subject of vital importance to all businesses due to its impact on health and environment. FSSAI has taken a lead in addressing these concerns by taking out advisories on alternative food packaging materials and awareness programmes towards plastic waste management.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**Food Businesses :** The food businesses to pledge to reduce the packaging/plastic footprint and to develop infrastructure and systems for its segregation/recycling. **Food Safety Departments of States/UTs :** These departments may create awareness and educate the public on use of alternatives to plastics, proper plastic disposal and litter management. **Consumers :** Consumers may responsibly segregate waste and properly dispose of packaging materials to ease collection and recycling. **Regulators :** FSSAI has constituted a Scientific Panel on Packaging to deal with the challenges in the area and to address them accordingly in the regulations. The food authority has also linked various eminent research organizations working in the same field and constituted a Network for Scientific Co-operation for Food Safety and Applied Nutrition (NetSCoFAN), namely the safer & sustainable packaging group to provide necessary scientific research, data and knowledge.
Steps for Implementation	Many Food businesses have pledged to eliminate single-use plastic in the coming years; develop environmental friendly substitutes and also adopt an efficient plastic collection and recycling/disposal system. This may be taken up appropriately during food inspection/audits etc by the field offices. In alignment with the Swachhata Hi Seva Campaign, various awareness generation and collection drives were organized to free our houses, offices and workplaces from single use plastic. FBO's may be asked to organize such activity and this could be made a part of the social responsibility system.
Resources	**Guidance Notes :** Advisories ***https://www.fssai.gov.in/upload/advisories/2019/09/5d6e4cd671207Letter_Bamboo_Food_Material_03_09_2019.pdf***

	https://www.fssai.gov.in/upload/advisories/2019/09/5d766553bfdacOrder_Paper_Sealed_Glass_Bottle_09_09_2019.pdf *https://www.fssai.gov.in/upload/advisories/2020/02/5e3d4cdfba1ebDirection_Antinomy_limits_Packaged_Drinking_Water_07_02_2020.pdf* **Website :** *https://fssai.gov.in/cms/eatrightindia.php*
For more details, contact:	advisor@gov.in

SUCCESS STORIES

In September 2019, 22 of the top food companies including multinational companies committed themselves to effectively manage plastic waste in their operations and reduce their plastic footprint in the coming years in the presence of Minister of Health and Family Welfare Dr. Harshvardhan. They also signed a voluntary pledge that includes the commitment from food businesses for reduction of plastic footprint in the coming years.

A plastic collection drive organised by FSSAI from 12th Sep – 19th Sep 2019 led to collection of approx. 305 Kgs of waste including PET bottles, Poly propylene pouches, Low/High density polythene, Hard plastic and Multi-layered plastics.

Cricket legend Shri Virat Kohli, who is a powerful influencer, joined hands with FSSAI and reached out to millions of fans through his social media accounts to spread awareness around plastic waste free India.

SUSTAINABILITY INITIATIVE 4 : REPURPOSE USED COOKING OIL (RUCO)

Food Business Operators (FBOs) often use the same cooking oil for repeated frying. The consumption of Used Cooking Oil (UCO) poses adverse health effects since total polar compounds (TPC) are formed during frying. These compounds are associated with several diseases such as hypertension, atherosclerosis, Alzheimer's disease, liver diseases amongst others. Used cooking oil is either not discarded at all or disposed off in an environmentally hazardous manner choking drains and sewerage systems. Also, UCO from organised Food Business Operators reportedly finds its way to small restaurants/dhabas and road-side vendors.

In a perfect example of repurposing, Used Cooking Oil has the potential to be used as a feedstock for manufacturing biodiesel. To harness this potential at scale, FSSAI has launched Repurpose Used Cooking Oil (RUCO), an ecosystem to enable the collection and conversion of used cooking oil to biodiesel, which is good for the health of people and the planet.

STANDARD OPERATING PROCEDURE

Role of Stakeholders	**Ministry of Petroleum and Natural Gas :** Monitoring and administrative matters for conversion of UCO to biodeisel **Pollution Conservation Research Association :** Research and technical support for conversion of UCO to biodeisel **Food Business Operators :** Providing UCO to biodeisel manufactureres/collection agencies instead of using it repeatedly **Oil Marketing Companies :** Ultimate suppliers of the biodiesel manufactured from UCO. **Biodiesel Manufacturers :** Collection of UCO and its conversion to biodiesel **Biodiesel/Biofuel Boards :** Provide administrative support for conversion of UCO to biodiesel. **Biodiesel Association of India :** Onboarding Biodiesel manufacturers to use UCO as feedstock and in turn help in creating an ecosystem to convert UCO to biodiesel and facilitating collection of UCO. » **FSSAI Role :** » Issuance of guidelines, SOPs, Checklist, Sticker etc. » Provisional enrolment of biodiesel manufacturers for collection of UCO from FBOs. The enrolment is *valid only till one year from the date of issue or until the registration mechanism* in States/UTs gets devised as per clause (xiv) of the Gazette Notification dated 30th April 2019 Vide No. P-13039(18)/1/2018-CC(P-26825) issued by Ministry of Petroleum and Natural Gas, whichever is earlier. » **State FSCs role :** » Ensure compliance that FBOs whose consumption of edible oil frying capacity is more than 50 litres per day are maintaining usage records. » Award of RUCO sticker as per SOPs & Checklist to RUCO compliant FBOs.
Steps for Implementation	State FDA to sensitise the FBOs who are involved in repeated frying of foods to sensitise them about the adverse health effects of used cooking oil using the content provided and available on FSSAI website. State FDAs to ensure that FBOs with consumption of more than 50 liters of cooking oil per day mandatorily maintain UCO disposal records as per the directions issued by FSSAI at https://fssai.gov.in/ruco/direction.php

Steps for Implementation	FSSAI to enroll eligible biodiesel manufacturers and update the same on RUCO website. The guidelines for collection of UCO from FBOs by biodiesel manufacturers are at ***https://fssai.gov.in/ruco/guidelines_for_collection.php.*** Also FSSAI to update the list of collection agencies who will collect UCO from FBOs on behalf of biodiesel manufacturers so that the FBOs can contact them for giving their UCO for conversion to biodiesel. The list of enrolled biodiesel manufacturers is available at ***https://fssai.gov.in/ruco/enrolled-biodiesel-manufacturers.php.*** State FDAs to implement and monitor on regular basis to make it sustainable. FSSAI to keep record of status of implementation in all states in order identify the gaps and assist States to address it. FSSAI and State FDAs through its various social media platforms to conduct mass awareness among the citizens about the health hazards of UCO and about the RUCO initiative and by activities using posters, flyers, videos by playing them in public places or sticking posters in high visibility areas at ***https://fssai.gov.in/ruco/picture.php.*** FBOs to sign a pledge to not use cooking oil having developed TPC of 25%. Sample pledges are available at ***https://www.fssai.gov.in/ruco/pledge.php***.
Resources	**Guidance Document :** » Guidelines for UCO collection ***https://fssai.gov.in/ruco/guidelines_for_collection.php.*** Directions for food businesses ***https://www.fssai.gov.in/ruco/direction*** » Guidance Note for consumers: ***https://www.fssai.gov.in/ruco/guidance-note*** **Website :** ***https://www.fssai.gov.in/ruco*** **Partners :** List of biodiesel manufacturers: ***https://fssai.gov.in/ruco/enrolled-biodiesel-manufacturers.php*** **Supplementary resources :** » Gazette Notification : ***(https://www.fssai.gov.in/ruco/gazette-notification)*** » Posters, Flyers on RUCO : ***(www.fssai.gov.in/ruco -> Resources)*** » Sample Pledge : ***https://www.fssai.gov.in/ruco/pledge*** » Videos on RUCO : ***https://fssai.gov.in/ruco/video***
For more details, contact:	enforcement1@fssai.gov.in

SUCCESS STORIES

RUCO was formally inaugurated in the state of Gujarat on 4 September 2018 in association with the Gujrat State Food and Drug Control Administration. At the launch programme, the stakeholders undertook a pledge to collect at least one crore litres of UCO each year for the generation of biodiesel from the state.

Within a short span of launch of this initiative, FSSAI has so far empanelled 16 Biodiesel Manufacturers across the country for collection of used cooking oil and its conversion into biodiesel. These Biodiesel Manufacturers have so far collected around 55 lakh kg of used cooking oil and manufactured around 39 lakh kg of biodiesel.

In Haryana, an entrepreneur buys over 5,000 kg UCO from over a thousand restaurants in Delhi/NCR every day and converts it into biodiesel. It has sold over 10 million litres of biodiesel within the first year of its plant operations. This company is receiving huge demand from existing and new customers thereby cutting imported crude oil dependence, fighting pollution, managing illegal discharge of oil into drainage systems and checking edible oil adulteration.

CITIZEN CONNECT

Consumers are the key stakeholders for every business. During the course of consumption, the consumer may have a grievance towards the food product and needs to be redressed either by the FBO or the regulatory Authorities. To facilitate the consumers in getting their grievances redressed, FSSAI has developed a robust grievance redressal mechanism with varied consumer interfaces. FSSAI wishes to bring each citizen on board to share their concerns regarding food safety violations. The *Food Safety Connect* portal allows a consumer to share their concerns, know their rights, track Food Business Operators license/registration certificate authenticity and view related articles/videos on food safety.

A grievance/Compliant is defined as any communication that expresses dissatisfaction about an action or lack of action, about the standard of service/deficiency of service of a product for prompt redressal.

OBJECTIVES

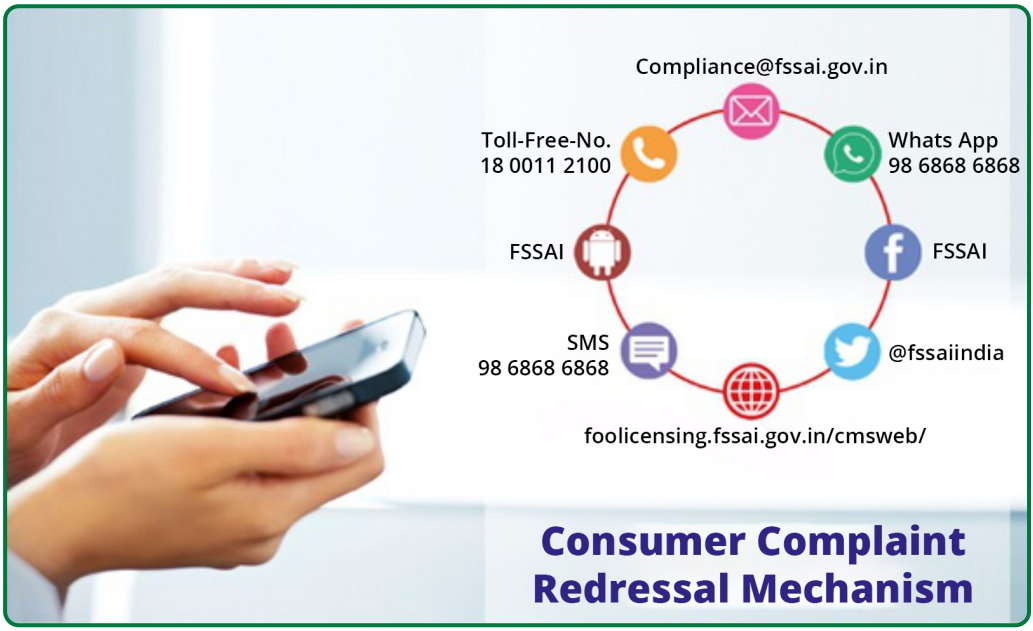
- To promptly resolve the consumer grievance in an unbiased and equitability manner.
- To provide enhanced level of consumer satisfaction or delight.
- To educate the consumer about their rights and responsibilities to safe food.
- To ensure that the consumers are responded with courtesy and in time.

- To identify the root cause of the compliant and rectify the same in order to improve quality and safety.

CONSUMER COMPLAINT REDRESSAL MECHANISM

FOOD SAFETY CONNECT

Food safety Connect is a Consumer Centric App and an online portal developed by FSSAI that offers a centralised platform to the consumers to raise concerns related to food safety and hygiene. The FSSAI, State FSO and DO and the FBOs have the access to the grievances raised by the consumers. All the concerns are filtered out for completeness and authenticity and are forwarded to concerned State Food Authorities or FSSAI HQ.



The consumer grievance redressal mechanism at FSSAI is working effectively and coordinates with State FDAs and FBOs and ensure that the consumer compliant/concerns are addressed in timely manner. The consumer can lodge the complaints/grievances through face book, twitter, WhatsApp, SMS, FSSAI App, written letters, email, or toll free number. All the complaints received through various channels are fed in "Food Safety Connect" portal.

All the complaints received in the portal are then scrutinised by the regulatory compliance division of the FSSAI for authenticity and completion. If the compliant is found to be incomplete or does not pertain to food safety the same is informed to the consumer. Upon successful feeding of the compliant in the portal a unique compliant number is generated and

shared with the consumer who can then track the status of the compliant using this unique ID.

Based on the details of the complaints, the Regulatory Compliance Division at FSSAI then forward the compliant to the Designated Officer of the State. The DO then forwards the complaint to FSO for further necessary action, who can either inspect the premises, collect sample for testing and record other evidences as per the complaint. The FBO can nominate one nodal person for handling the complaints and to coordinate with FSSAI for addressing the consumer concerns. The FBO upon receiving the compliant, are required to do a root cause analysis of the complaint, and if the compliant is genuine, the FBO will take corrective and preventive action (CAPA). Once the procedure is completed the Nodal person nominated by FBO is required to submit the CAPA report to the FSO.

The FSO will then review and submit the report to the DO, who further after analysis will submit the report to CFS or FSSAI for their interventions. The FSSAI after reviewing the action report and if satisfied may forward the same to the consumer and the complaint then is considered as redressed.

NOTES

GLOSSARY

TERMS AS DEFINED IN THE FSS ACT, 2006

- "Adulterant" means any material which is or could be employed for making the food unsafe or sub-standard or mis-branded or containing extraneous matter;
- "Advertisement" means any audio or visual publicity, representation or pronouncement made by means of any light, sound, smoke, gas, print, electronic media, internet or website and includes through any notice, circular, label, wrapper, invoice or other documents;
- "Chairperson" means the Chairperson of the Food Authority;
- "Claim" means any representation which states, suggests, or implies that a food has particular qualities relating to its origin, nutritional properties, nature, processing, composition or otherwise;
- "Commissioner of Food Safety" means the Commissioner of Food Safety appointed under section 30;
- "Consumer" means persons and families purchasing and receiving food in order to meet their personal needs;
- "Contaminant" means any substance, whether or not added to food, but which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry or veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination and does not include insect fragments, rodent hairs and other extraneous matter;
- "Designated Officer" means the officer appointed under section 36;
- "Extraneous matter" means any matter contained in an article of food which may be carried from the raw materials, packaging materials or process systems used for its manufacture or which is added to it, but such matter does not render such article of food unsafe;
- "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 para-37 below, 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.

Provided that the Central Government may declare, by notification in the Official Gazette, any other article as food for the purposes of this Act having regards to its use, nature, substance or quality;

- "Food additive" means any substance not normally consumed as a food by itself or used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or otherwise affecting the characteristics of such food but does not include "contaminants" or substances added to food for maintaining or improving nutritional qualities;
- "Food Analyst" means an analyst appointed under section 45;
- "Food Authority" means the Food Safety and Standards Authority of India established under section 4;
- "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 thereunder;
- "Food laboratory" means any food laboratory or institute established by the Central or a State Government or any other agency and accredited by National Accreditation Board for Testing and Calibration Laboratories or an equivalent accreditation agency and recognised by the Food Authority under section 43;
- "Food safety" means assurance that food is acceptable for human consumption according to its intended use;
- "Food safety audit" means a systematic and functionally independent examination of

food safety measures adopted by manufacturing units to determine whether such measures and related results meet with objectives of food safety and the claims made in that behalf;

- "Food Safety Management System" means the adoption Good Manufacturing Practices, Good Hygienic Practices, Hazard Analysis and Critical Control Point and such other practices as may be specified by regulation, for the food business;
- "Food Safety Officer" means an officer appointed under section 37;
- "hazard" means a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect;
- "Import" means bringing into India any article of food by land, sea or air;
- "Improvement notice" means a notice issued under section 32 of this Act;
- "Infant food" and "infant milk substitute" shall have the meanings assigned to them in clauses (f) and (g) of subsection (l) of section 2 of the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992(41 of 1992), respectively;
- "Ingredient" means any substance, including a food additive used in the manufacture or preparation of food and present in the final product, possibly in a modified form;
- "Label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, 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;
- "Licence" means a licence granted under section 31;
- "local area" means any area, whether urban or rural, notified by the Commissioner of Food Safety, to be a local area for the purposes of this Act;
- "Manufacture" means a process or adoption or any treatment for conversion of ingredients into an article of food, which includes any sub-process, incidental or ancillary to the manufacture of an article of food;
- "Manufacturer" means a person engaged in the business of manufacturing any article of food for sale and includes any person who obtains such article from another person and packs and labels it for sale or only labels it for such purposes;
- "Member" means Member of the Food Authority and includes the Chairperson;

- "Misbranded food" means an article of food:–

(A) if it is purported, or is represented to be, or is being:–

(i) offered or promoted for sale with false, misleading or deceptive claims either;

(a) upon the label of the package, or

(b) through advertisement, or

(ii) sold by a name which belongs to another article of food; or

(iii) offered or promoted for sale under the name of a fictitious individual or company as the manufacturer or producer of the article as borne on the package or containing the article or the label on such package; or

(B) if the article is sold in packages which have been sealed or prepared by or at the instance of the manufacturer or producer bearing his name and address but:–

(i) the article is an imitation of, or is a substitute for, or resembles in a manner likely to deceive, another article of food under the name of which it is sold, and is not plainly and conspicuously labelled so as to indicate its true character; or

(ii) the package containing the article or the label on the package bears any statement, design or device regarding the ingredients or the substances contained therein, which is false or misleading in any material particular, or if the package is otherwise deceptive with respect to its contents; or

(iii) the article is offered for sale as the product of any place or country which is false; or

(C) if the article contained in the package:–

(i) contains any artificial flavouring, colouring or chemical preservative and the package is without a declaratory label stating that fact or is not labelled in accordance with the requirements of this Act or regulations made thereunder or is in contravention thereof; or

(ii) is offered for sale for special dietary uses, unless its label bears such information as may be specified by regulation, concerning its vitamins, minerals or other dietary properties in order sufficiently to inform its purchaser as to its value for such use; or

(iii) is not conspicuously or correctly stated on the outside thereof within the limits of variability laid down under this Act.

- "Notification" means a notification published in the Official Gazette;

- "Package" means a pre-packed box, bottle, casket, tin, barrel, case, pouch, receptacle, sack, bag, wrapper or such other things in which an article of food is packed;
- "Premises" include any shop, stall, hotel, restaurant, airline services and food canteens, place or vehicle or vessel where any article of food is sold or manufactured or stored for sale;
- "Prescribed" means prescribed by rules made by the Central Government or the State Government, as the case may be under this Act;
- "Primary food" means an article of food, being a produce of agriculture or horticulture or animal husbandry and dairying or aquaculture in its natural form, resulting from the growing, raising, cultivation, picking, harvesting, collection or catching in the hands of a person other than a farmer or fisherman;
- "Prohibition order" means an order issued under section 33 of this Act;
- "Risk", in relation to any article of food, means the probability of an adverse effect on the health of consumers of such food and the severity of that effect, consequential to a food hazard;
- "Risk analysis", in relation to any article of food, means a process consisting of three components, i.e. risk assessment, risk management and risk communication;
- "Risk assessment" means a scientifically based process consisting of the following steps:

  (i) Hazard identification,

  (ii) Hazard characterisation;

  (iii) Exposure assessment, and

  (iv) Risk characterisation;
- "Risk communication" means the interactive exchange of information and opinions throughout the risk analysis process concerning risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
- "Risk management" means the process, distinct from risk assessment, of evaluating policy alternatives, in consultation with all interested parties considering risk assessment and other factors relevant for the protection of health of consumers and for the

promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options;

- "Sale" with its grammatical variations and cognate expressions, means the sale of any article of food, whether for cash or on credit or by way of exchange and whether by wholesale or retail, for human consumption or use, or for analysis, and includes an agreement for sale, an offer for sale, the exposing for sale or having in possession for sale of any such article, and includes also an attempt to sell any such article;
- "Sample" means a sample of any article of food taken under the provisions of this Act or any rules and regulations made thereunder;
- "Specified by regulations" means specified by regulations made by the Food Authority;
- "Standard", in relation to any article of food, means the standards notified by the Food Authority;
- "State Government" in relation to a Union territory means the Administrator of that Union territory appointed by the President under article 239 of the Constitution;
- "Substance" includes any natural or artificial substance or other matter, whether it is in a solid state or in liquid form or in the form of gas or vapour;
- "Sub-standard" an article of food shall be deemed to be sub-standard if it does not meet the specified standards but not so as to render the article of food unsafe;
- "Tribunal" means the Food Safety Appellate Tribunal established under section 70;
- "Unsafe food" means an article of food whose nature, substance or quality is so affected as to render it injurious to health: -

  (i) by the article itself, or its package thereof, which is composed, whether wholly or in part, of poisonous or deleterious substance; or

  (ii) by the article consisting, wholly or in part, of any filthy, putrid, rotten, decomposed or diseased animal substance or vegetable substance; or

  (iii) by virtue of its unhygienic processing or the presence in that article of any harmful substance; or

  (iv) by the substitution of any inferior or cheaper substance whether wholly or in part; or

  (v) by addition of a substance directly or as an ingredient which is not permitted; or

  (vi) by the abstraction, wholly or in part, of any of its constituents; or

(vii) by the article being so coloured, flavoured or coated, powdered or polished, as to damage or conceal the article or to make it appear better or of greater value than it really is; or 8

(viii) by the presence of any colouring matter or preservatives other than that specified in respect thereof; or

(ix) by the article having been infected or infested with worms, weevils, or insects; or

(x) by virtue of its being prepared, packed or kept under insanitary conditions; or

(xi) by virtue of its being mis-branded or sub-standard or food containing extraneous matter; or

(xii) by virtue of containing pesticides and other contaminants in excess of quantities specified by regulations.

NOTES

DISCLAIMER

This manual is meant for reference purpose only by Food Safety Officers and is in no way any substitute for FSS Act, its Rules & Regulations. In case of any discrepancy, the relevant provisions of FSS ACTs, its Rules and Regulations should be consulted.

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

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