

TRAINING MANUAL FOR FOOD SAFETY REGULATORS

Vol II - FOOD SAFETY REGULATIONS & FOOD SAFETY MANAGEMENT

2010



THE TRAINING MANUAL FOR FOOD SAFETY REGULATORS WHO ARE INVOLVED IN IMPLEMENTING FOOD SAFETY AND STANDARDS ACT 2006 ACROSS THE COUNTRY

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TRAINING MANUAL FOR FOOD SAFETY OFFICERS

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The Act provides for consolidation of laws relating to food and to establish the Food Safety and Standards Authority of India for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import, to ensure availability of safe and wholesome food for human consumption. Some of the salient features of the Act are:

- Movement from multi-level and multi-department control to a single line of command
- FSSAI as a single reference point for all matters relating to Food Safety and Standards, Regulations and Enforcement
- Integrated response to strategic issues like Novel foods, Health Foods, Nutraceuticals, GM foods, international trade etc.
- Decentralisation of licensing for manufacture of food products
- Achieve high degree of consumer confidence in quality & safety of food
- Effective, transparent and accountable regulatory framework within which the industry can work efficiently
- Investors friendly regulatory mechanism with emphasis on self regulations and capacity building
- Emphasis on gradual shift from regulatory regime to self compliance
- Consistency between domestic and international food policy measures without reducing safeguards to public health and consumer protection
- Adequate information dissemination on food to enable consumer to make informed choices.
- Compounding and Adjudication of cases – to reduce Court's workload and expedite the disposal of cases
- Graded penalty depending upon the gravity of offences
- Adequate representation of government, industry organizations, consumers, farmers, technical experts, retailers etc.
- enforcement of the legislation by the State Governments/ UTs through the state Commissioner for Food Safety, his officers and Panchayati Raj/Municipal bodies

The Act, inter alia, incorporates the salient provisions of the Prevention of Food Adulteration Act, 1954 and is based on international legislations and instrumentalities. In a nutshell, the Act takes care of international practices and envisages a overreaching policy framework and provision of single window to guide and regulate persons engaged in manufacture, marketing, processing, handling, transportation, import and sale of food. The Act is contemporary, comprehensive and intends to ensure better consumer safety through Food Safety Management Systems and setting standards based on science and transparency as also to meet the dynamic requirements of Indian Food Trade and Industry and International trade.

New Provisions in the Act

- Covering Health Foods, supplements, nutraceuticals
- Issuing Licenses within a time frame of 2 months
- Provision of Improvement Notice by Designated Officers
- Prosecution, if to be launched, should be within 1 year time frame
- Special Courts for summary trials
- Compensation to Victims (for any case of Injury/ Grievous injury/ Death)
- Reward to informer (informing about the violators – adulteration etc.) by State Govt.
- One composite license for unit(s) falling under one area

- Training and Awareness programmes for Food Business Operators as well as Regulators;
- Encouraging Self regulation through introduction of Food Recall Procedures
- No License for small food business operators; only registration is mandatory
- Central licensing from Authority.

The Major deviations from the existing regulations and the implications of Change

A. Changes in definitions

a. FSSA- Adulterant

Any material which is or could be employed for making the food unsafe or sub-standard or mis-branded or containing extraneous matter;

Misbranded

Means an article of food with

- i) False, misbranding or deceptive claims either on the label of the package, or through advertisement,
- ii) If the article is sold as an imitation of, or is a substitute for, or is likely to deceive, or
- iii) The package bears statement, design or device regarding the ingredients or the substances contained therein, which is false or misleading or
- iv) Manufacturers name and address is false or
- v) Contains any artificial flavouring, colouring or chemical preservative and is not labelled properly as per the requirements of the law or

Substandard

An article of food shall be deemed to be sub-standard if it does not meet the specified standards but does not render the food unsafe;

Unsafe

Means an article of food which is injurious to health:-

- i) by the article itself, or its package thereof, or
- ii) consists wholly or in part, any filthy, putrid, rotten, decomposed or diseased animal substance or vegetable substance; or
- iii) is processed unhygienically or the article of food has harmful substance in it or is infected or infested with worms, weevils or insects; or
- iv) has been substituted by inferior or cheaper substance whether wholly or in part; or
- v) uses a substance directly or as an ingredient or as additive which is not allowed under the law; or
- vi) by virtue of its being prepared, packed or kept under unsanitary conditions; or
- vii) by virtue of its being mis-branded or sub-standard or food containing extraneous matter; or
- viii) by virtue of containing pesticides and other contaminants in excess of quantities specified by regulations.

b. Advertisement

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 any notice, circular, label, wrapper, **invoice or other documents;**

c. Food

Any substance, whether processed, partially processed or unprocessed, which is intended for human consumption and includes primary food i.e. all raw produce except those in hands of the grower, farmer, fisherman etc., 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 medical 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;

d. 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 an includes food services, catering services, sale of food or food ingredients;

e. Food business operator

Means a **person by whom the business is carried on or owned** and is **responsible for ensuring the compliance** of this Act, rules and regulations made there-under;

f. 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;

g. Manufacturer- FSSA

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;

B. Changes in Provisions

a. Sampling and analysis (Section 47)

When a Food Safety Officer takes a sample of food for analysis, he shall-

- (a) Give notice in writing of his intention to have it analysed to the person from whom he has taken the sample and to the person, if any, whose name, address and other particulars have been disclosed;
- (b) Except in special cases as may be provided by rules divide the sample into four parts 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. If such person refuses to sign or put this thumb impression, the Food Safety Officer shall call upon one or more witnesses and take his signature or thumb impression, in lieu of the signature or thumb impression of such person;
 - (i) send one of the part for analysis to the Food Analyst under intimation to the Designated Officer;
 - (ii) send two parts of the Designated officer for keeping this in safe custody; and
 - (iii) send the remaining part for analysis to an accredited laboratory, if so requested by the food business operator, under intimation to the Designated Officer:

Provided that if the rests reports received under sub-clauses (i) and (ii) are found to be at variance, then the Designated Officer shall send one part of the sample in his custody, to referral laboratory for analysis if he feels, whose decision thereon shall be final.

(2) When a sample of any article of food or adulterant is taken, the Food Safety officer shall, **by the immediate succeeding working day**, send the sample to the Food Analyst for the area concerned for analysis and report.

(3) Where the part of the sample sent to the **Food Analyst is lost or damaged**, the Designated Officer shall, on a requisition made to him, by the Food Analyst or the Food Safety Officer dispatch one of the parts of the sample sent to him, to the food Analysis for analysis.

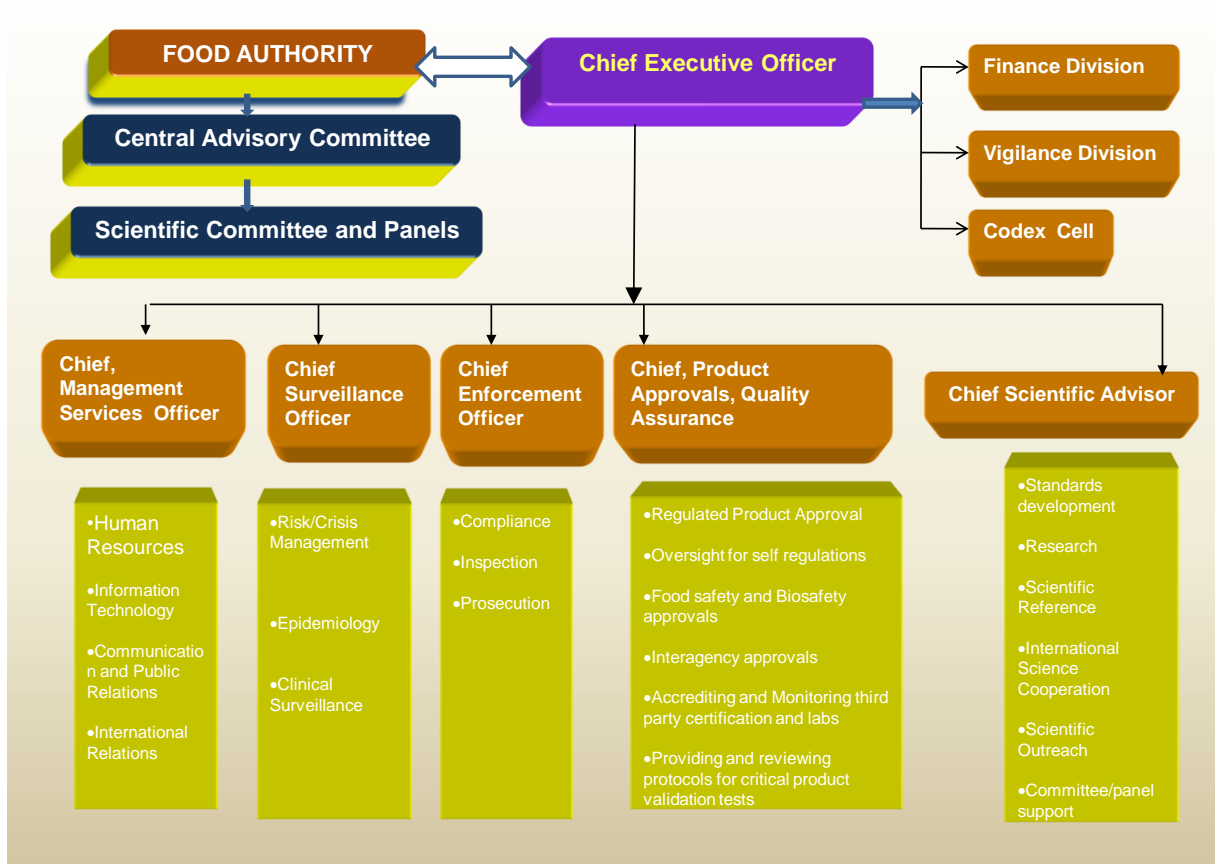
(4) In case of imported articles of food, the authorised officer of the Food Authority shall take its sample and send to the Food Analyst of notified laboratory for analysis who shall send the report within a period of five days to the authorised officer.

(5) The Designated Officer, the Food Safety Officer, the authorised officer and the Food Analyst shall follow such procedure as may be specified by regulations.

Administration at the Central Government Level

- 22 Members Authority representing various stakeholders.
- Chairperson and Chief Executive Officer
- 8 Scientific Panels and Scientific Committee.
- Central Advisory Committee.
- Separate Scientific Division
- Surveillance, Regulatory and Quality Assurance Divisions
- Referral Laboratory & Food Laboratories
- Codex cell to handle international matters
- Import Safety
- Novel Foods, Nutraceuticals, GM Foods approval
- Fixation of Standards and guidelines for food
- Labeling and Advertising norms

PROPOSED STRUCTURE OF FSSAI HEADQUARTER, NEW DELHI



New Concepts and their legal implications

A. General Principles to be followed in administration of the Act (section 18)

The Central Government, the State Governments, the Food Authority and other agencies, as the case may be, while implementing the provisions of this Act shall be guided by the following principles, namely:-

- (1)
 - a) endeavour to achieve an appropriate level of protection of human life and health and the protection of consumer's interests, including fair practices in all kinds of food trade with reference to food safety standards and practices;
 - b) carry out risk management which shall include taking into account the results of risk assessment, and other factors which in the opinion of the Food Authority are relevant to the matter under consideration and where the conditions are relevant, in order to achieve the general objectives of regulations;
 - c) where in any specific circumstances, on the basis of assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure appropriate level of health protection may be adopted, pending further scientific information for a more comprehensive risk assessment;
 - d) the measures adopted on the basis of clause (c) shall be proportionate and no more restrictive of trade than is required to achieve appropriate level of health protection, regard being had to technical and economical feasibility and other factors regarded as reasonable and proper in the matter under consideration;
 - e) the measures adopted shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health being identified and the type

of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment;

- f) in case where there are reasonable grounds to suspect that a food may present a risk for human health, then, depending on the nature, seriousness and extent of that risk, the Food Authority and the Commissioner of Food Safety shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or type of food, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk; and
- g) where any food which fails to comply with food safety requirements is part of a batch, lot or consignment of food of the same class or description, it shall be presumed until the contrary is proved, that all of the food in that batch, lot or consignment fails to comply with those requirements.

(2) The Food Authority shall, **while framing regulations or specifying standards under this Act-**

- a) Take into account **prevalent practices and conditions in the country** including agricultural practices and handling, storage and transport conditions;
- b) Ensure that there is **open and transparent public consultation**, directly or through representative bodies including all levels of panchayats, except where it is of opinion that there is an urgency concerning food safety or public health to make or amend the regulations in which case such consultation may be dispensed with:

Provided that such regulations shall be in force for not more than six months;

- c) Ensure **protection of the interests of consumer** and shall provide a basis for consumers to make informed choices in relation to the foods they consume;
- d) Ensure prevention of-
 - i) Fraudulent, deceptive or unfair trade practices which may mislead or harm the consumer; and
 - ii) Unsafe or contaminated or sub-standard food.

(1)

B. The New Provisions

1. Special purpose foods (Section 22)

Save as otherwise provided under this Act and regulations made there under, 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. Separate regulations for each of them are being framed for this category.

2. Provisions relating to import (Section 25)

All imports of articles of food to be subjected to this Act.

- (1) No person shall import into India-
 - i) any unsafe or misbranded or sub-standard food or food containing extraneous matter;
 - ii) any article of food for the import of which a license is required under any Act or rules or regulations, except in accordance with the conditions of license; and
 - i) Any article of food in contravention of any other provision of this Act or of any rule or regulation made there under or any other Act.
- (2) The Central Government shall, while prohibiting, restricting or otherwise regulating import of articles of food under the Foreign Trade (Development and Regulation) Act, 1992, follow the standards laid down by the Food

Authority under the provisions of this Act and the rules and regulations made there under.

- (3) All imports will come under Central Licensing and an existing importer also needs to be registered under the Central Authority and all imported products will be screened for safety parameters by an IT enabled Food Safety System as a new initiative under FSSA.

3. Responsibility of Authorities for Enforcement of the Act (Section 29)

Enforcement of the Act will be done through Commissioner, Designated Officer and Food Safety Officers.

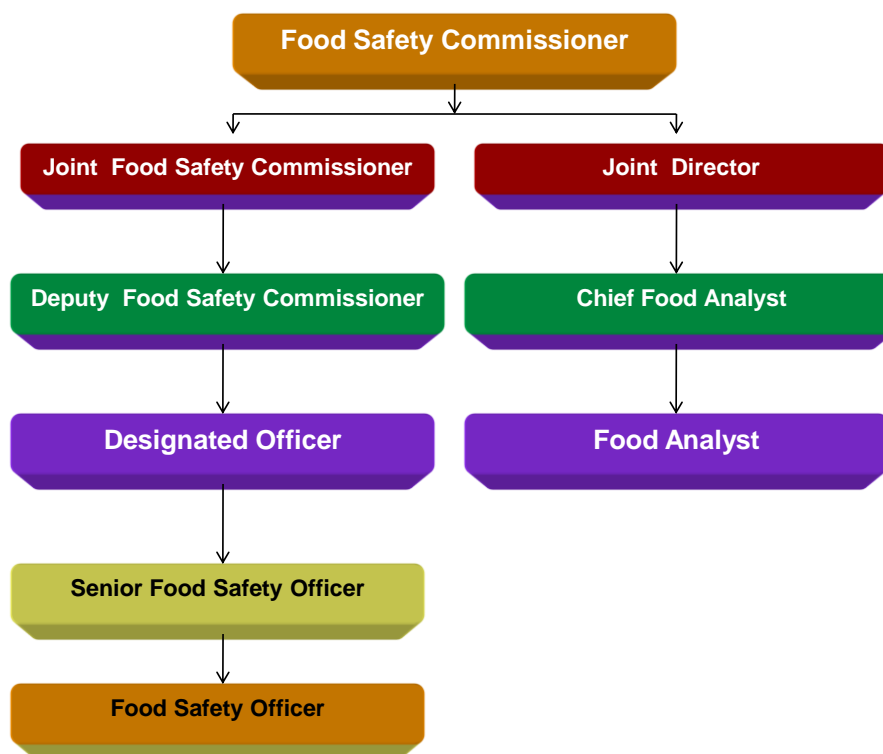
- a) The Food Authority and the State Food Safety authorities shall be responsible for the enforcement. They shall monitor and verify that the requirements of law being fulfilled by the FBO at all stages of Food Business.
- b) Authorities shall maintain a system of control and other activities as appropriate to the circumstances including public communication on Food Safety and risk. Food safety surveillance and monitoring covering all stages of food business.
- c) FSOs shall enforce and execute within their area the provisions of this Act with respect to which the duty is not imposed expressly or by necessary implication on some other authority.
- d) The regulations under this Act shall also specify which of the Food Safety officers are to enforce and execute them generally or in relation to cases of a particular description or particular area.

Administrative set up at State Level

The enforcement of the Act would be through the state commissioner of Food Safety (CFS) and his officers (viz. Designated Officer, Food Safety Officer) and Panchayati Raj / Municipal bodies.

It is also proposed that Food Analysts, Chief Food Analyst, and Joint Director may be posted at District Level, Zonal Level, and State Level Offices in rotation with their posting in the laboratory. These officers will act as co-ordinators between Enforcement Officers and Laboratory. These officers will assist Food Safety Commissioner in identification food laboratories and research institutions for testing and calibration or any other accreditation agency to be notified by the Food Authority for the purpose of carrying out analysis of samples. These officers will also play a role in policy making, formation of schemes related to development of laboratories including infrastructure , well qualified staff, training of existing staff and may be entrusted with any other work related to food safety management viz. Food surveillance, Food recall/ incident reporting, Food Terrorism and Rapid Alert System as directed by Food Safety Commissioner.

PROPOSED SET UP AT STATE LEVEL



Functions, Duties & Responsibilities of food safety regulators

- **Functions of the Commissioner (Section 30):**

The commissioner of the food safety shall not be below the rank of the commissioner and Secretary to the State Government.

- i) Prohibit in public health interest the manufacture, storage, distribution or sale of any article of food in the whole of the state within a maximum time of one year.
- ii) Survey of the industrial units engaged in the process of manufacture of food in that state for compliance.
- iii) Organise and conduct training programmes for the personnel of the office of the Commissioner and on a wider scale, different segments of food chain for generating awareness on food safety.
- ii) Ensure an efficient and uniform implementation of the standard and the other requirements and also ensure a high degree of objectivity, accountability, practicability, transparency and credibility.
- iii) Sanction prosecution for offences punishable with imprisonment and also
- iv) Perform other functions as the State Government may in consultation with the Food Authority prescribed.

- **Functions of the Designated Officer (Section 36):**

- i) Shall be a whole time officer, not below the rank of Sub divisional Officer or Equivalent.
- ii) Appointment shall be done by Commissioner of Food Safety and each district will have at least one Designated Officer who has the power to issue or cancel license.

- iii) Prohibit sale of any article of food in contravention with the provisions of the Act and the rules.
- i) Receive report and samples of articles from Food Safety Officer under his jurisdiction and get them analyzed.
- ii) Recommended cases to Commissioner for sanction to launch prosecution, in case the contravention is punishable with imprisonment.
- iii) Sanction or launch prosecution in case of contravention punishable with fine or recommended the case to Commissioner for punishment with imprisonment.
- iv) Maintain record of all inspections made by Food Safety Officer and the actions taken by them, etc.

- **Functions of Food Safety officer (Section 38):**

A full time officer having a degree in food or Dairy technology or Agricultural Science or Veterinary Sciences or Bio Chemistry or Microbiology or degree in Science or Chemistry as one of the subjects from a recognized university or Possess any other qualification notified by the Central Government or is a graduate in medicine and has received training in Food Safety, sampling and surveillance or

Has successfully completed the training, for a specified period in Food Safety, Food Inspection and Sampling under an institute or institution approved for the purpose by the Food Authority.

Appointment shall be done by Commissioner according to the need and through issuance of notification. The State Government may authorize any officer of the State Government having the prescribed qualifications to perform the functions of a Food Safety Officer.

Major functions are as follows:

- i) Take sample of food or other substances intended for human consumption for analysis purpose.
- ii) Article of food or substance to be produced as evidence.
 - i) Seize any article of food in contravention of the Act or rules and may keep the same in the safe custody of the FBO after taking the sample and send the same to Food Analyst of the local area for analysis and report generation. He may require the FBO to execute a bond for a sum of money equal to the value of the article seized with one or more sureties as he deems fit.
 - ii) Enter and inspect any place of food manufacturing, storing for sale or storing for manufacture of any other article of food or exhibited for sale and where any adulterant is manufactured or stored and take samples for analysis. If the article is of perishable nature and the FSO feels that it is unfit for human consumption, he can, after giving notice in writing to the FBO destroy the same.
 - iii) Inspection of a premise shall follow as far as possible the provisions of Code of Criminal Procedure, 1973, relating to search or inspection by a police officer executing a search warrant issued under the code.
 - iv) To inspect as frequently as prescribed by the designated officer all food establishments for having license for manufacture, handling, packing or selling of foods within area of his jurisdiction.
 - v) Maintain a data base of FBO in the area assigned to him and check compliance with the conditions of license and report to the Designated Officer.
 - vi) Investigate complaints in respect to any contravention of the provisions, if any.

- vii) Issue improvement notices and record all inspections including taking of samples and seizure of stocks.
- viii) Stop and inspect any suspected vehicle and recommend to Designated Officer giving specific grounds the violence done by the licensee.
- ix) Carry out Food Safety surveillance, respond to food poisoning and facilitate food safety plans for Panchayats/ Municipalities as per the guidelines.

- **Functions of the Food Analyst (Section 45)**

He would be responsible for carrying out the required analysis of the sample as instructed by the Food Safety Officer along with the test method. The various steps to be taken are as follows:

- i) Compare and note down the conditions of the seal of the container and the outer cover containing the sample.
- ii) He may ask for the second sample if the first sample is found to be in broken condition or unfit for analysis and inform the DO about the same within seven days time and also send a requisition for the second part of the sample retained by DO.
- i) He will then analyze, prepare report and send to DO for copies of report indicating the method of sampling and analysis within 14 days time.
- ii) Where the purchaser wants the food to be analyzed, then the report shall be sent to that purchaser with a copy to the DO.

Note: Appeal against reports from Food Analyst shall be done before the DO and if he feels refer the matter to the Referral laboratory as may be notified by the Food Safety Authority.

- **Adjudicating Officer:** The State Government will notify adjudicating officer for adjudication of food related cases. He will perform all or any of the following functions:

- The Adjudicating Officer will have the powers of a civil court and all the proceedings before him shall be deemed to be judicial proceedings within the meaning of sections 193 and 228 of the Indian Penal Code.
- The Adjudicating Officer while adjudging the quantum of penalty shall have due regard to the following
 - (a) the amount of gain or unfair advantage (wherever possible to quantify) due to contravention
 - (b) the amount of loss caused or likely to cause to any person due to contravention
 - (c) the repetitive nature of contravention
 - (d) whether contravention is knowingly or unknowingly
- may issue direction to person found guilty of an offence, for taking corrective action to rectify the mistake or destruction of such article of food.
- may direct offender to pay compensation to victim or representative of victim in case of injury or death of consumer.
- may order for cancellation of license, re-call of food from market, forfeiture of establishment ad property
- issue prohibition orders

Synergizing Consumers, Industry and Local Bodies:

Multiplicity of food laws, standard setting and enforcement agencies for different sectors of food has created a state of confusion in the minds of consumers, traders, manufacturers and investors. Standards are rigid and non-responsive to scientific advancements and modernization and varied Quality/Safety standards were proving restrictive in innovative food products. Thin spread of manpower, poor laboratories infrastructure and other resources were conducive to effective fixation of standards and their enforcement. Regulatory Mechanism was investor adversary and there was poor Information dissemination level to consumer level.

The Food Safety and Standards Act, 2006 has kept all the above factors into consideration and is an attempt to have single reference point for all matters relating to Food Safety and Standards, regulations and Enforcement. Suggested for effective, transparent and accountable regulatory framework with investors friendly regulatory mechanism with emphasis on self regulations and capacity building. More responsibility has been left on the part of Food Businesses to ensure safe and quality food for the consumers. The Act has empowered the consumers by more emphasis on adequate information dissemination on food to enable consumer to make informed choices and achieve high degree of consumer confidence in quality & safety of food. Local Panchayat and Municipalities are also considered to be involved in the implementation of Act to have the spread of concept of food safety up to grass root level.

Food regulations are mandatory and must be complied with by the processor and enforced by the food safety regulatory authorities in all cases, because violations constitute offences. Failure by the food safety officers or other food safety authorities to enforce regulations at all times, besides being illegal, defeats the purpose of having a food safety system and promotes non-compliance across the industry by example. It would be unfair to demand compliance from one processor and not from others. The food safety regulator's primary responsibility is to protect the consumer by ensuring compliance with food safety laws and regulations, given that the public's well-being is the ultimate objective of a national food safety system. Producers and processors, in contrast, are in business to make a profit and that priority may well impair their perception of accountability to society. Therefore, it is also the food safety regulator's duty to remind producers and processors of their responsibility to produce safe foods. This message can be made more relevant by explaining to food producers and processors that the safety of their products not only fulfils their responsibility towards society – something that may seem idealistic and ethereal – but may also be determinant in developing their business. For example, the adverse effect of bad publicity and the use of favourable publicity as a marketing tool could be described. Compliance with guidelines and voluntary standards, on the other hand, depends on the good will and disposition of the processor and should be strongly encouraged by the food safety regulatory authorities.

Special responsibilities of Food Business Operator (Section 26)

- **Every food business operator shall ensure that the articles of food satisfy the requirements of this Act and the rules and regulations** made there under at all stages of production, processing, import, distribution and sale within the businesses under his control.
- No food business operator shall employ any person who is suffering from infectious, contagious or loathsome disease.
- No food business operator shall sell or offer for sale any article of food to any vendor unless he also gives a guarantee in writing in the form specified by regulations

about the nature the nature and quality of such article to the vendor: Provided that a bill, cash memo, or invoice in respect of the sale of any article of food given by a food business operator to the vendor **shall be deemed to be a guarantee – Replacing the provision of Warranty under PFA**

- Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, **it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment within a specified time**, it is found that the rest of the batch, lot or consignment is unsafe: Provided that any conformity of a food with specific provisions applicable to that food shall be without prejudice to the competent authorities taking appropriate measures to impose restrictions on that food being placed on the market or to require its withdrawal from the market for the reasons to be recorded in writing where such authorities suspect that, despite the conformity, the food is unsafe.

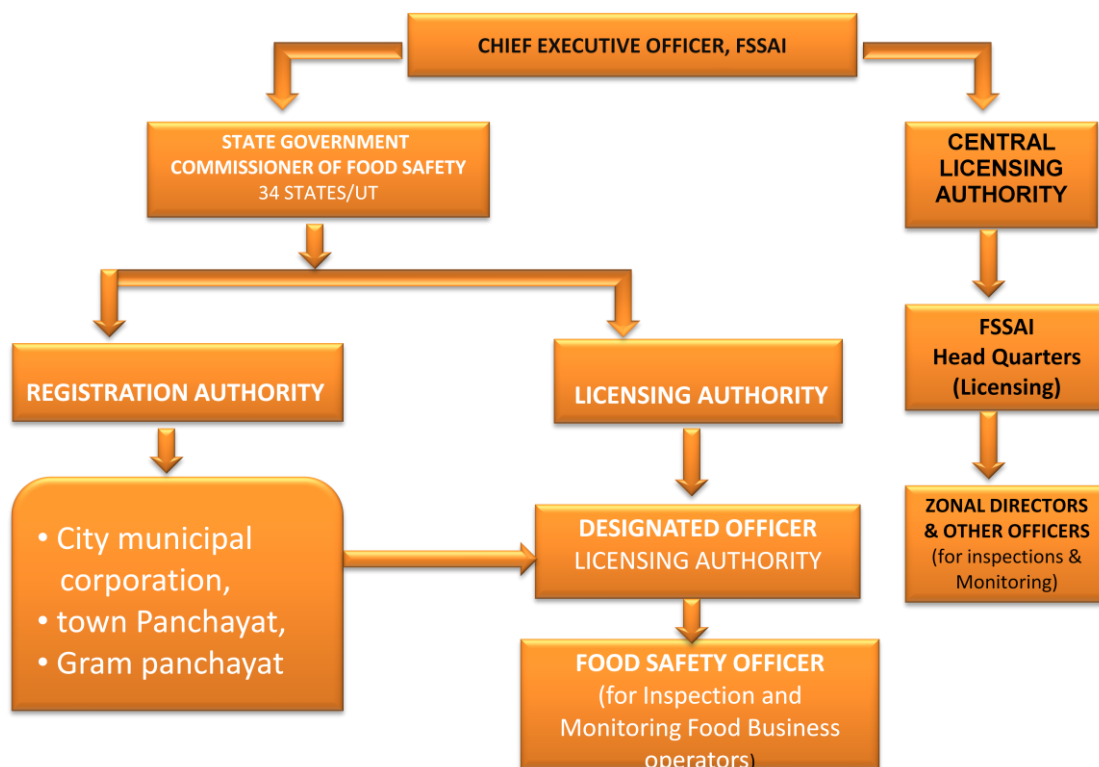
Under the Article 31 of FSS Act, 2006 (Food Safety and Standards (Licensing/Registration of Food Businesses) Regulations, 2009, lays down Licensing and Registration conditions which are compulsory for any food business. Any person desirous to commence or carry on any food business shall make an application to grant of a License to the Designated Officer alongwith fees. In case a license is not issued within two months from the date of making the completed application or his application is not rejected, the applicant may start his food business after expiry of the said period. The provision of obtaining a licence for carrying on any food business shall not apply to a petty retailer, hawker, itinerant vendor or a temporary stall holder or small scale or cottage or such other industries relating to food business or tiny Food Business Operator. But they shall have to register themselves with the registering authority.

Licensing procedures have been unified under the FSS Act 2006, to be implemented by the Food Safety and Standards Authority, Food Safety Commissioner in the States and the officers working under the Commissioner. Common application forms and procedures have been laid down to bring out uniformity of the food standards in the country as mandated by the Food Safety and Standards Act.

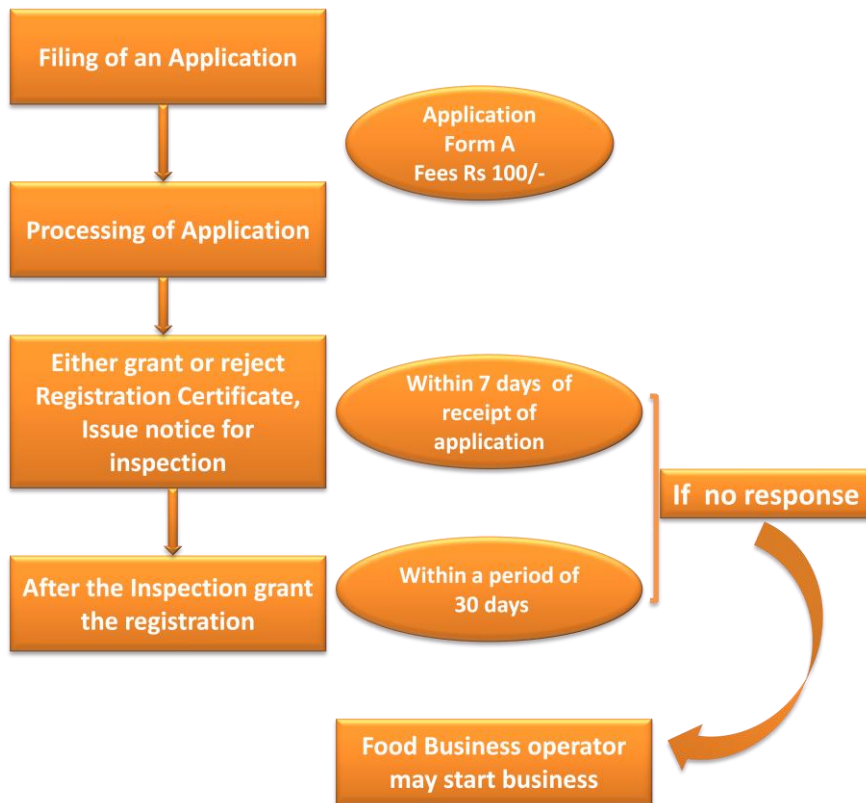
As mandated by the Act, a distinction has been introduced between 'registration' and 'licensing'. Cut off limits for registration and licensing have been proposed. Food sub-sectors which are currently under the control of the Government of India have been retained and unified. In addition, sectors which have high potential for food contamination and hazard have been brought under central licensing. This includes food service establishments under the various organs of the Government of India and interstate operations of large food businesses.

Set of Safety, Sanitary and Hygiene conditions have been laid down for registration/licensing according to the potential for food related hazards.

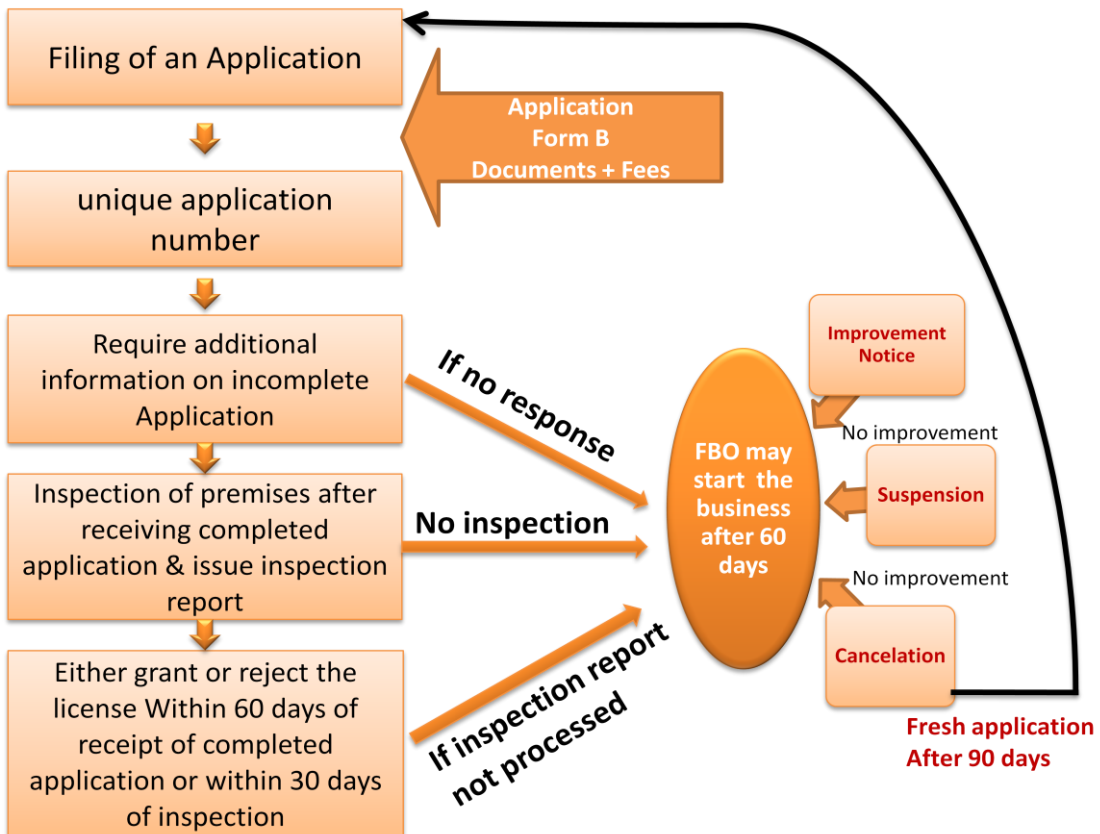
PROPOSED ENFORCEMENT STRUCTURE OF REGISTRATION & LICENSING



PROPOSED PROCEDURE FOR REGISTRATION OF FOOD BUSINESSES



PROPOSED PROCEDURE FOR GRANT OF LICENSE TO FOOD BUSINESS



Introduction of Unified Licensing / Registration under FSSAI

All the food Business Operators in this country shall be either registered (Petty food business) or licensed (depending the scale and volume of business as laid down in Licensing & Registration Regulations 2010).

Registration will be under State Food Safety Authority; however, licensing for major food business operator and for sectors which are prone to contamination shall remain under Central Licensing.

Single license for one or more articles of food and for different establishment or premises in the same area.

Mandatory safety, sanitary and hygienic conditions are laid down (Schedule 4) for both registered and Licensed operators on the basis of potential for food related hazards.

Pre inspection of the premise shall be mandatory for License applicants which may be followed by improvement notices, if so required before granting license.

Regular inspection of premises for enforcing compliance towards food safety shall be done for both registered and licensed.

For new license applicants the term will be for one to five years and will be renewed afterwards within one month before expiry.

Existing registration/ license holders under various orders and Acts (to be repealed once this regulation comes into force) shall inform the License/ Registration Authority through an application upon expiry of the validity of the existing registration/ license.

However, FBO holding registration/ license under any Act or order without any specific validity or expiry date shall have to apply and obtain a Registration/ License by paying applicable fees within one year from the date of notification of this regulation.

Registration required for the Food Business Operator, who –

- a.** manufactures or sells any article of food himself or a petty retailer, hawker, itinerant vendor or temporary stall holder; or
- b.** such food business including small scale or cottage 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.** production or procurement or collection of milk is up to 100 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 than that

Licenses to be granted by Central Licensing Authority

Schedule 1

[See Regulation 5 (4)]

- (i) Dairy units including milk chilling units equipped to handle or process more than 50 thousand litres of liquid milk/day or 2500 MT of milk solid per annum.
- (ii) 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.
- (iii) 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
- (iv) Meat processing units equipped to handle or process more than 500 kg of meat per day or 150 MT per annum
- (v) All food processing units other than mentioned under (i) to (iv) including relabellers and repackers having installed capacity more than 2 MT/day except grains, cereals and pulses milling units.
- (vi) 100 % Export Oriented Units
- (vii) All Importers importing food items for commercial use.

(viii) All Food Business Operators manufacturing any article of Food which does not fall under any of the food categories prescribed under these regulations or deviates in any way from the prescribed specification for additives therein.

(ix) Retail chains operating in three or more states

(x) Food catering services in establishments and units under Central government Agencies like Railways, Air and airport, Seaport, Defence etc.

State Licensing Authority

License for commencing or carrying on food business, which are not covered under Schedule 1, shall be granted by the concerned State Licensing Authority.

License for food business (Existing Licenses granted under diff. Food Orders)

Subject to Regulation 4, no person shall commence any food business unless it possesses a valid license under these Regulations.

Provided that any person or Food Business Operator carrying on food business on the date of notification of these Regulations, under a license, registration or permission, as the case may be, under the Acts or Orders mentioned in the Second Schedule of the Act shall get their existing license/ registration converted in to the license/ registration under these regulations following an application made by the Food Business Operator to the Licensing/ registering Authority on the expiry of the period for which such registration/ license is valid. No license fee will have to be paid for the remaining period of the validity of the earlier license or registration granted under any of the said Acts or Orders. Non-compliance with this provision by a Food Business Operator will attract penalty under section 55 of the Act.

Provided further that any Food Business Operator holding Registration/ license under any other Act/Order as specified under schedule 2 of FSS Act, 2006 with no specific validity or expiry date and otherwise entitled to obtain a license under these regulations shall have to apply and obtain a registration/ license under these regulations within one year from the date of notification by paying the applicable fees.

Notwithstanding the provisions contained in section 5(1) above or in any of the registration or license certificates issued under existing Acts or Orders mentioned in the second schedule of the Act, the Licensing Authority, if it has reason to believe that the Food Business Operator has failed to comply with all or some of the conditions of the existing registration or license or the safety requirements given in schedule 4, may give appropriate direction to the Food Business Operator to comply with.

License for commencing or carrying on food business, which falls under Schedule 1, shall be granted by the Central Licensing Authority. For Food Business Operators importing any type of food items shall have to obtain a license from the Central Licensing Authority, in addition to the license taken as per the Regulations herein for any other food business that he may be engaged in.

Provided that Food Authority may through notification may make such changes considered necessary or modify the list given in the Schedule I.

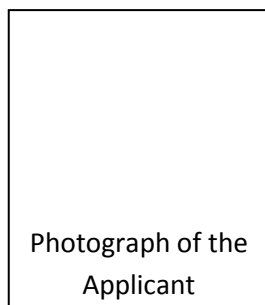
DOCUMENTS/ FORMATE REQUIRED FOR REGISTARTION/LICENSING

Schedule 2

Form 'A'

Application for Registration / Renewal of Registration under Food Safety and Standards Act, 2006

[See Section 31 and Regulation 4 & 10]



Kind of business:

- Itinerant / Mobile food vendor
- Hawker
- Home based canteens/dabba wallas
- Petty Retailer of snacks/ tea shops
- Permanent/ Temporary Stall holder
- Manufacturer/Processor
- Re Packer
- Religious gatherings, food stalls in fairs etc
- Milk producers (who are not member of dairy co operative society)/ milk vendor
- Dhabha
- Fish/ meat/ poultry shop retailer
- Other(s), please specify:_____

(a). Name of the Applicant/Company: _____

(b). Designation or Capacity:

- Individual
- Partner
- Proprietor
- Secretary of co-operative society.
- Others (Please specify)

(c). Proof of photo Identity of applicant: _____

[Note: Please submit a copy of photo ID like Driving License, Passport, Ration Card or Election ID card]

(d). Correspondence address:

Tel No.:_____ Mobile No.:_____

Fax No.:_____ Email:_____

[Note: In case the number(s) are a PP or common number(s), please specify the name of the contact person as well]

(e). Area or Location where food business is to be conducted/Address of the premises:

(f). Description of the food items to be Manufactured or sold:

S.No.	Name of Food Category	Description

Please attach separate sheet if required

- (g). Total Annual turnover from the food business, if existing, alongwith any supporting Document(s) showing proof of income (*in case of renewal*):

- (h) In case of new business - intended date of start: _____

- (i) In case of seasonal business, state the opening and closing period of each year: _____

- (j) Source of water supply:

Public supply

Private supply

Any other source

- (k) Whether any electric power is used in manufacture of the food items:

Yes

No

If yes, please state the exact HP used or sanctioned Electricity load: _____

- (l) I/We have forwarded a sum of Rs.....towards registration fees according to the provision of the Food Safety and Standards (Licensing and Registration) Regulations, 2009 vide:

Demand Draft no. (payable to -----)

Cash

(Signature of the Applicant)

Form 'B'

Application for License / Renewal of license under Food Safety and Standards Act, 2006

[See Section 31 and Regulation 5, 6 & 10]

Kind of business (Please tick more than one, if applicable):

- Manufacturing/Processing including sorting, grading etc.
- Milk Collection/chilling
- Slaughter House
- Solvent extracting
- Solvent extracting plant equipped with pre cleaning of oil seeds or pre expelling of oil.

- Solvent extracting and oil refining plant.
- Packaging
- Relabeling (manufactured by third party under own packing and labelling)
- Import
- Storage/Warehouse/Cold Storage
- Retail Trade
- Wholesale Trade
- Distributor/Supplier
- Transporter of food
- Catering
- Dhabha or any other food vending establishment
- Club /canteen
- Hotel
- Restaurant
- Other(s), please specify:_____

1. Name of the Company: _____
2. Registered Office Address: _____
3. Address of Premise for which license is being applied _____

4. Name, qualification and address of technically qualified person in charge of operations as required under Regulation

Name:

Qualification:

Address:

Telephone Number(s):

Mobile no:

Email:

Photo Identity card no and expiry date

5. Name Address and contact details of person responsible for complying with conditions of license (if different from 4 Above):

Name:

Address:

Telephone Number(s):

Mobile no

Email:

Photo Identity card no and expiry date

6. Correspondence address (if different from 3 above)

7. Tel No.:_____ Mobile No.:_____
 Fax No.:_____ Email:_____

8. Food items proposed to be manufactured:

S.No.	Name of Food Item	Description/ Installed production capacity

If required attach separate sheet

If already having valid license- mention annual quantity of each food product manufactured during last three years

9. Installed Capacity food product wise (per day)_____

10. For Dairy units

(i) Location and installed capacity of Milk Chilling Centers (MCC) / Bulk Milk Cooling Centers (BMCs) owned or managed by the applicant.

S.No.	Name and address of MCC/BMC	Installed Capacity

If required attach separate sheet

(ii) Average Quantity of milk per day to be used/handled in

a. in lean season_____

b. in flush season_____

11. For Solvent –Extracted Oil, De oiled meal and Edible Flour

(i) Details of proposed business

Name of Oil bearing material	From seed or nut or cake	Solvent –Extracted Oil, De oiled meal and Edible Flour						Vegetable Oil
		Crude	Neutralized	Neutralized & Bleached	Refined	De-oiled meal	Edible Flour	

If already having valid license- mention annual quantity of each product manufactured during last three years

ii) Name and address of factory or factories used by the miller or solvent extractor for processing oil bearing material produced or procured by him or for refining solvent extracted Oil produced by him.

12. Sanctioned electricity load or HP to be used _____

13. Whether unit is equipped with an analytical laboratory

If yes the details thereof:_____

14. In case of renewal or transfer of license granted under other laws as per proviso to Regulation 5(1) - period for which license required (1 to 5 years) _____

15. I/We have forwarded a sum of Rs._____ towards License fees according to the provision of the Food Safety and Standards (Licensing and registration) Regulations, 2009 vide:

Demand Draft no (payable to)

(Signature of the Applicant/Authorized Signatory)

Annexure I.

Declaration

I, Mr./Ms./Mrs. _____ S/o / D/o Mr. _____, R/o _____ do hereby solemnly affirm and declare that all information and particulars furnished here by me are true and correct to the best of my knowledge. I further declare that the food business conducted or proposed to be conducted by/through me conforms/shall conform to the Food Safety and Standards Act, Regulations/Bye-laws enacted thereunder, and specifically to the Guidelines on Hygiene and Sanitary Practices provided under Schedule 4 of the Registration and Licensing Regulations published by the Food Safety and Standards Authority of India or any person authorized on its behalf from time to time.

Dated:

(Signature)

Annexure-2

Documents to be enclosed with new application for license to State/Central Licensing Authority

1. Form-B duly completed and signed (in duplicate) by the proprietor/ partner or the authorised signatory
2. Blueprint/layout plan of the processing unit showing the dimensions in metres/square metres and operation-wise area allocation.
3. List of Directors with full address and contact details
4. Name and List of Equipments and Machinery along with the number, installed capacity and horse power used.
5. Photo I.D and address proof issued by Government authority of Proprietor/Partner/Director(s)/Authorised Signatory.
6. List of food category desired to be manufactured (in case of manufacturers).
7. Authority letter with name and address of responsible person nominated by the manufacturer along with alternative responsible person indicating the powers vested with them viz assisting the officers in inspections, collection of samples, packing & dispatch.
8. Analysis report (Chemical & Bacteriological) of water to be used as ingredient in food from a recognised/ public health laboratory to confirm the potability indicating the name of authorised representative of Lab who collected the sample and date of collecting sample.
9. Proof of possession of premises. (Sale deed/ Rent agreement/ Electricity bill, etc.)
10. Partnership Deed/Affidavit/Memorandum & Articles of Association towards the constitution of the firm.
11. NOC from manufacturer in case of Re-labellers
12. Food safety management system plan or certificate if any
13. Source of milk or procurement plan for milk including location of milk collection centres etc in case of Milk and Milk products processing units.
14. Source of raw material for Meat and Meat processing plants

15. 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
16. Recall plan, if any
17. NOCs from Municipality or local body and from State Pollution Control Board except in case of notified industrial area.

During renewal or transfer of license from other laws existing prior to these Regulations

1. Any change in documents or information provided during grant of previous application
2. Certificate or Plan of Food Safety Management system being adopted (for units under Central Licensing it has to be a certificate from accredited agencies)
3. Recall plan and/or policy for at least one step forward and backward traceability.
4. List of workers with their medical fitness certificates.
5. Name, qualification and details of technical personnel in charge of operation.

Annexure 3

Conditions of License

All Food Business Operators shall ensure that the following conditions are complied with at all times during the course of its food business.

Food Business Operators shall:

1. Display a true copy of the license granted in Form C shall at all times at a prominent place in the premises
2. Give necessary access to licensing authorities or their authorised personnel to the premises
3. Inform Authorities about any change or modifications in activities
4. Employ at least one technical person to supervise the production process. The person supervising the production process shall possess at least a degree in Science with Chemistry/Bio Chemistry/Food and Nutrition/ Microbiology or a degree or diploma in food technology/ Dairy technology/ dairy microbiology/ dairy chemistry/ dairy engineering /oil technology /veterinary science /hotel management & catering technology or any degree or diploma in any other discipline related to the specific requirements of the business from a recognized university or institute or equivalent.
5. Furnish periodic annual return 1st April to 31st March.
6. Ensure that no product other than the product indicated in the license/ registration is produced in the unit.
7. Maintain factory and workers Hygiene as specified in the Schedule – 4.
8. Maintain daily records of production, Raw materials utilization and sales in separate register (whichever is applicable).
9. Ensure that the source and standards of raw material used are of optimum quality.
10. Food Business Operator shall not manufacture, store or expose for sale or permit the sale of any article of food in any premises not effectively separated to the satisfaction of the licensing authority from any privy, urinal, sullage, drain or place of storage of foul and waste matter.

11. Ensure Clean-In-Place systems (wherever necessary) for regular cleaning of the machine & equipments.
12. Ensure testing of all chemical and microbiological contaminants in food products through own or NABL/recognized labs atleast once in a month.
13. Ensure that required temperature is maintained throughout the supply chain from the place of procurement or sourcing till it reaches the end consumer including chilling, transportation, storage etc.

Other conditions

1. Proprietors of hotels, restaurants and other food stalls who sell or expose for sale savouries, sweets or other articles of food shall put up a notice board containing separate lists of the articles which have been cooked in ghee, edible oil, vanaspati and other fats for the information of the intending purchasers.
2. Food Business Operator selling cooked or prepared food shall display a notice board containing the nature of articles being exposed for sale
3. 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, 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 manufactory or place of business, and shall present such register for inspection whenever required to do so by the licensing authority.
4. No producer or manufacturer of vegetable oil, edible oil and their products shall be eligible for license under this Act, unless he has his own laboratory facility for analytical testing of samples.
5. Every sale or movement of stocks of solvent-extracted oil, 'semi refined' or 'raw grade I', edible groundnut flour or edible coconut flour, or both by the producer shall be a sale or movement of stocks directly to a registered user and not to any other person, and no such sale or movement shall be effected through any third party.
6. Every quantity of solvent-extracted oil, edible groundnut flour or edible coconut flour, or both purchased by a registered user shall be used by him in his own factory entirely for the purpose intended and shall not be re-sold or otherwise transferred to any other person:
Provided that nothing in this sub-clause shall apply to the sale or movement of the following:-
 - (i) karanjia oil; (ii) kusum oil; (iii) mahuva oil; (iv) neem oil; (v) rice-bran oil; (vi) tamarind seed oil. (vii) edible groundnut flour bearing the I.S.I. Certification Mark (viii) edible coconut flour bearing the I.S.I. Certification Mark
7. No Food Business Operator shall sale or distribute or offer for sale or dispatch or deliver to any person for purpose of sell 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.

FORM 'C'

(See Regulation 7 (6))

Government of India

Food Safety and Standards Authority of India

License under FSS Act, 2006

License No _____

1. Name and Registered Office address of licensee _____

2. Address of authorized premises _____

3. Kind of Business _____

4. Details of location with address and capacity of - Milk Chilling Centers (MCC) / Bulk Milk Cooling Centers (BMCs) owned by the holder of licensee/RC in case of Milk processing and details of Raw material suppliers in other cases -

5. Category of License:

This license is granted under and is subject to the provision of FSS Act, 2006 all of which must be complied with by the licensee.

Place:

Date:

Stamp and signature of Designated Officer

Food Safety and Standards Authority of India

Validation and Renewal

Renewal Date	Period of validity	License fee paid	Items of Food products with capacities authorized to Manufacture/ Re-pack/ Re-label	Signature of Designated Officer

FORM 'D'

Return to be filed

(See Regulation 17)

1. Name and address of Licensee:-
2. Address of the authorized premises for the manufacturing / Re-packing / Re-
Labelling of food products:
3. License No.
4. Statement showing quantities of food products manufactured and exported in
Tonnes

Name of the food product	Size of can / bottle/any other package (like PP) or bulk package	Quantity in MT	Value	Quantity exported/imported in Kg	Name of the country or port of Export	Value	Remarks
1	2	3	4	5	6	7	8

'FORM 'D'

Returns to be filed

(See Regulation 17)

Part 1

Monthly Return

For the month of the year

1. Name and address of Licensee:-

2. Address of the authorized premises for the manufacturing/re-packing/re-labelling of food products:

3. License No.

4. Milk Procurement

Type of Milk	Total Qty (Tonnes)	Av. Price (Rs/ kg of milk)	Price (Rs./kg of fat)	Price (Rs./kg of SNF)	Remarks, if any

Rs/kg - Rupees per kilogram

5. Details of Receipts, Sale and Stocks of Products

Product Name	Opening stock (tonnes)	Receipts		Product sold(tonnes)	Closing Stock (tonnes)
		Produced (tonnes)	Purchased (tonnes)		

1. Fresh milk

- Standardized
- Toned
- Double toned
- Whole
- Skimmed
- Others (Specify)

2. Milkfat products

- Butter
- Ghee
- Butteroil

3. Dried milks

- Skimmed
- Whole

4. Other milk products

Place

Date

Signature of the Licensee

A register detailing the above information shall be maintained by each licensee for inspections.

Part 2

Yearly Return

For the year

1. Name and address of Licensee:-

2. Address of the authorized premises for the manufacturing/re-packing/re-labelling of food products:

3. License No.

4. Statement showing quantities of food products manufactured and exported in Tonnes with their sale value during the period

Procurement

Type of milk	Total Qty MT	Total fat MT	Total SNF MT	Price Rs / kg of milk	Price Rs/kg of fat	Price Rs/kg of SNF
1	2	3	4	5	6	7
Cow						
Buffalo						
Mixed						
Products						

Reconstitution

<u>Utilized for making liquid milk or milk products</u>	Whole milk powder (tonne)	Skimmed milk powder (tonne)	Butter oil (tonne)	White butter (tonne)
All liquid milks for sale <ul style="list-style-type: none">• In lean season (Apr-Sep)• In flush season (Oct-Mar) Other milk products <ul style="list-style-type: none">• In lean season (Apr-Sep)• In flush season (Oct-Mar)				

Annexe details regarding name, location etc.

Stocks

Product Name	Opening Stock (Tonnes)	Closing Stock (Tonnes)
<u>1. Fresh milk</u> <ul style="list-style-type: none">• Standardized• Toned• Double toned• Whole• Skimmed• Others (Specify) <u>2. Milk fat products</u> <ul style="list-style-type: none">• Butter• Ghee• Butter oil <u>3. Dried milks</u> <ul style="list-style-type: none">• Skimmed• Whole <u>4. Other milk products</u>		

Date:

Signature of the Licensee

A register detailing the above information shall be maintained by each licensee for inspections. ‘

SCHEDULE - 3

FEE FOR GRANT/ RENEWAL OF LICENCE

REGISTRATION / LICENCE FEE PER ANNUM IN RUPEES

1. <u>Fees for Registration</u>	Rs 100
2. <u>Fees for License issued by Central Licensing Authority:</u>	Rs 7500
3. <u>Fees for License issued by State Licensing Authority:</u>	
1. <u>Manufacturer /Miller</u>	
(i) Above 1MT per day Production or 10,001 to 50,000 LPD of milk or 501 to 2500 MT of milk solids per annum	5000/-
(ii) Below 1 MT of Production or 101 to 10,000 LPD of milk or 51 MT to 500 MT of milk solids per annum	3000/-
2. Hotels – 3 star and above	5000/-
3. All Food Service providers including restaurants/boarding houses, clubs etc. serving food, Canteens (Schools, Colleges, Office, Institutions), Caterers, Banquet halls with food catering arrangements, food vendors like dabba wallas etc.	2000/-
4. Any other Food Business Operator	2000/-

The fees paid by any applicant for a licence shall not be refundable under any circumstances.

Issue of Duplicate registration or License

- (1). Where a registration certificate or license is lost, destroyed, torn, defaced or mutilated, the applicant may apply for a duplicate copy of the registration certificate or license during the validity period, accompanied with a fee amounting to 10% of the applicable License fee.
- (2). On receipt of such an application, the Licensing Authority shall grant a duplicate copy of the registration certificate or license, as the case may be to the applicant with the word “Duplicate” appearing prominently thereon.

INSPECTION REPORTS/ NOTICES

1. On receiving the completed application the concerned licensing authority shall direct the Food Safety Officer or any other person specially designated for such functions to inspect the premises to verify the suitability of licensing as per the requirements of the act.
2. The Licensing Authority may issue a notice to the applicant, if he deems fit, guiding him on necessary steps to be taken or changes or alteration to be made in the premises in order to adhere to general safety, hygiene and sanitary conditions laid down under the rules and regulations.
3. During the Inspection the various points to be considered by the inspecting officer and prescribed inspection procedure to be followed as explained in Chapter **Inspection of food establishments and Inspection of Spl. Establishemnts.**
4. By considering the appropriate points a detailed Inspection Report to be prepared by the officer as per the format **A.** copy of the same has to be handed Over to the applicant suggesting compliance for improvements if any. After confirming that all requirements have been complied with the requirements a licence will then be issued by the Licencing Authority in format C provided under Schedule 2 of the licensing and registration Regulations, 2009.
5. The Food Safety Officer or any other person specially designated for such functions shall with a view to securing a compliance with this order:-
 - a) To get investigated any complaint which may be made in writing in respect of any contravention of the provisions of this order and the rules and regulations made there under.
 - b) enter upon, inspect the processing and the storage premises of any licensee or manufacturer and make routine Inspection Report as per the format **B** at any time with a view to satisfying himself whether the Sanitary and **Hygienic requirements are** being followed as per the requirements of the act or not.
 - c) Verify the following documents: (In case of routine Inspection after issuing license)
 1. File which includes original licence, previous inspection report and the compliance thereon, all letters corresponding with the Food authority, production statement form -D,
 2. Daily Production register and stock register in the form of Form 'D' and 'E' in respect of different raw materials, their consumption in the manufacture of food and disposal of the processed foods.
 3. Medical examination and vaccination report of permanent workers.
 4. Lab testing records batch wise and date wise in case of small scale and large scale factories.
 5. Food safety management system plan, if any
 6. Recall plan, if any

- d) Follow, as far as may be, the provisions of the code of Criminal Procedure, 1973 (2 of 1974) relating to the search or inspection while exercising the powers of entry upon, and inspection of any place under this section.
- e) on giving a proper receipt (Annexure C), seize or detain any food manufactured , marketed, packed or labeled otherwise than in accordance with the provisions of the act or suspected in contravention of the provisions of this act and keep it in the safe custody of the Food Business Operator after taking the sample.

Provided that where 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.

- f) destroy any article of food seized which is perishable nature and is so deteriorated that it is unfit for human consumption after giving notice in writing to the Food Business Operator.
- g) Inspect any books or other documents of a licensee relating to the manufacture and disposal of fruit products.
- h) Seize or detain, on giving proper receipt, raw materials, documents, account books or other relevant evidence connected with manufacture of food products in respect of which he has reason to believe that a contravention of the act has taken place.

Provided that no such books of account or other documents shall be seized by the food Safety Officer except with the previous approval of the authority.

- i) To prohibit the sale of any food products which is in contravention of the provision of this act and rules and regulations made there under.
- j) Dispose of all food products of raw materials, so seized or detained in such a manner as he deems fit.
- k) Collect, on payment, samples of food products intended or exposed for sale or sold or under dispatch or delivery to any dealer, agent or broker for the purpose of sale, and have such samples analysed at a laboratory selected for the purpose by the Licensing Officer.
- l) Collect, from the licensee of manufacturer, its cost calculated at the rate at which the article is usually sold to the public, on giving a proper receipt, samples of any food products or any chemical, dye or any other ingredients used in the preparation of such food products from the premises of such licensee of manufacturer, in respect of which he has reason to believe that a contravention of the act has taken place.

INSPECTION REPORT FOR NEW APPLICANTS (F&VP) (A)

DATE OF INSPECTION: - / /

1. Name and Address of the factory :

2. Products for which license applied :

3. Category of license applied for :

4. Location of the factory :

5. (a) Fly proof area of the manufacturing premises
 - 1.
 - 2.
 - 3.(b) Finished goods
(c.) Raw material stores
(d.) Area of laboratory :

1. (a) Nature of construction & type of ceiling viz. R.C.C. corrugated asbestos or iron sheets. :

- (b) Factory hygiene :
 - (1) Fly Proofing :
 - (2) Flooring :
 - (3) Drainage :
 - (4) Ventilation :
 - (5) Lighting :
 - (6) White Washing :
- (c) Whether walls up to the height of 5 ft. from the floor have been impervious. If, so with what material. :

- (d) No. of urinals for each sex and their distance from the manufacturing hall :
- (e) No. of wash basins provided :

7. (a) Machinery & equipments installed

- (8) Whether whole time or part time food technologist/chemist employed

- (9) Source of supply of water whether chemicals and bacteriological analysis was carried out with what results and on what date :

- (10.). Arrangement for cooking :

(11.) Worker's health hygiene.

GENERAL OBSERVATION AND SUGGESTION

Signature of the applicant

Food safety Officer with seal

ROUTINE INSPECTION REPORT (F&VP) (B)

Date of Last Inspection _____

Date of Inspection _____

1. **Name and address of the Factory** :

2. (a) Licence No.:
(b) Category:

3. **Products for which licensed** :

4. **Licence Fee paid** for 200_
(a)-whether licence for 200_ renewed:
(b)-Reason for non-renewal of licence:

5. (a)-**Location of the factory**
 1. Residential-whether independent composite building or
Part of the building with independent approach :
 2. Commercial;
 3. Industrial :(b) Surroundings:
(c) Approach :
(d) Arrangement for disposal of effluents and waste :

6. (a)-**Fly proof area of the manufacturing premises**
 - I- Number of rooms with dimensions of each Length/ :
Breadth/Height
 - (b)-I-Address of godown, if located outside the factory :
premises
 - II-Area of the godowns-R M Stores/F G Stores :
 - (c)-I-Area of Laboratory with list of equipments etc. :

7. (a)-**Nature of construction and type of ceiling of factory and Godown**

(b)-**Factory hygiene;**
 - I- Fly proofing
 - II- Flooring
 - III- Drainage
 - IV- Ventilation
 - V- Lighting
 - VI- Whitewashing
(c)-**Moisture proofing of walls up to 5 ft height**

(d)-**No. of urinals for each sex and distance from manufacturing hall**
(e)-**Whether any repugnant item manufactured**

8. (a)-**Machinery any Equipment installed with H.P.** :
(b)-**Installed capacity per h hour shift** :

9. **(a)-Source of supply of water, if non-municipal date of water:
Analysis for water's potability**
(b)-Quantity of water available per 8 hrs. :
10. **Arrangement for cooking**
(a)-Whether boiler is installed details:
(b)-No. of gas or Kerosene burners:
(c)-I-No. of bhattis:
II-Arrangement for outlet of smoke:
11. **Workers hygiene**
(a)-Medical:
(b)-Vaccination, Inoculation:
(c)-Aprons/Headwear:
(d)-Soaps, detergents, nail cutters, towels:
12. **Production and disposal records**
(a)-Maintenance of forms D & E:
(b)-Submission of Form-C:
(c)-Quantity manufactured:
(d)-Value:
(e)-Exports:
13. **Whether labels and closures are approved-when?**
14. **Average No. of workers**
(a)-Permanent-skilled/unskilled:
(b)-Temporary:
(c)-Contract:
15. **Sample details**

Sl.no	Name of the product	Batch and code no.	Quantity	Remarks

General Remarks

Signature of the Licencee

Food Safety Officer with seal

**Under FSS ACT, 2006 Affidavit on Non-Judicial Court Stamp Paper of Rs. 20/-
Duly Attested Public Notary for a Relabeller's Licence.**

I/We-----
----do hereby state on solemnly affirmation as under: -

I/we have applied for a Relabeller's Licence under FSS ACT, 2006, I am/We are fully aware of the provisions of the said Order and confirm that this does not include buying of fruit and vegetable products in bulk and repacking them into either bulk or small containers and that I am/we expected to buy and relabel fruit and vegetable products only from bonafide licensees manufactured by them in their own authorized premises.

That I/we shall not utilize the said licence for any other purpose other than that for which the licence has been issued under FSS Act, 2006.

That I am/we are also aware that I am/are required to maintain necessary records to substantiate my/our relabeling activity including the purchase and sales of such items. I we confirm that I/we will not undertake any repacking or manufacturing activity under this licence.

I/we further undertake to surrender the said relabeller's late or non-submission of the same for renewal for the terms subsequent to one for which it is valid. I/we shall not retain illegally such invalid licence.

That I/we hereby undertake to comply with all the provisions of FSS Act, 2006.

Deponent

VERIFICATION: -

Verified at _____ on this _____ that the content of the affidavit are correct and true to the best of my knowledge and belief.

Deponent

CONSENT LETTER FOR RELABELLING

1) I/We ----- Proprietor/Director/Partner of firm
M/s -----
----- which is licensed under FSS Act, 2006 having License No.-----
---Category ----- Renewed upto year -----
-----& licensed items are -----

2) I/we are ready to supply fruit & veg. Products of various varietie in different
packes to M/s-----

3) I/we shall have no objection if the products supplied by us are Relabelled and
marketed under the Brand/Trade name of M/s -----

Date: -

**Signature of manufacturer
With address**

Inspection Memorandum for Grant of Licence (MEAT & MEAT PRODUCTS)

1. Name of the Unit

2. Address of the Unit

(a) Distance from the nearest
Airport

(b) Is there any provision for
Expansion in future

3. External Inspection

1. Whether situated adjacent to
Residential area (Clean/Unclean
Surroundings)

2. Whether situated near obnoxious industries
Like fish canning, tanneries chemical
Plants fertilizer plants releasing
Hydrogen sulphide, sulphur etc.

3. Condition of service road

4. Whether boundary wall or barrier provided
To avoid unauthorised entry of human
Being or animals

5. (i) Is the surrounding area free from
Cesspools, ponds, rat wholes etc.

(ii) Presence of birds, crows, vultures
Etc., if any

6. Whether the entry restricted to
Unauthorised person

7 (i) Whether incinerator or burial pits
For disposal of condemned carcasses
Wastes exists

(ii) Whether rendering plant exist

8. Condition of the drainage system
Whether open or permanently installed
Underground (Adequate/Inadequate)

9. Arrangement of disposal of
Waste material

10. Source of water supply
Whether identifying marks have been applied
To the pipelines for easy identification
Of potable and non potable supply

11. Condition of animal house, holding Pen, quarantine pens (Hygienic/ Unhygienic) and their approximate Distance from the processing plants
12. Whether wash and change rooms for The worker provided. If provided whether Clean toilet facilities exists
13. Whether idle/condemned equipment Or machineries have been stored Properly to avoid harbouring of rodents, flies, insects etc.
14. Whether the external walls are properly Plastered and free from crevice, Holes, dampness
15. Whether separate loading docks for Edible and inedible products are Provided and whether the loading Socks are covered to avoid exposure of Material to vulture, dropping of birds, Flies and rough weather
16. Whether the entry is restricted; The entries and exits with double doors Having fly proofing and self closing Device provided
17. Whether the windows are fly proof
18. Whether the smoke chimney is at Sufficient height
19. Whether antiseptic/disinfectant foot Bath is provided at the entrance

4. Internal Inspection

1. Whether the unclean and clean departments Are partitioned adequately; whether the walls And ceilings are properly whitewashed
2. Whether the floor, walls and ceilings are Properly plastered with impervious material Like cement
3. Fissures, holes and crevices, dampness (present / absent)
4. Condition of the floodwalls (Clean/Unclean)
5. Whether the walls are tiled up a

Sufficient height. Whether the windows are at
Sufficient height and away from working
Platform, tables, cooking vats to avoid
Contamination with dust, accidentally broken
Glass parts etc.

6. Whether the raw meat department fishing
Department and cooked meat department
Are partitioned adequately

7. Whether separate entry and exits to
Above departments exists

8. Whether adequate foot operated combination
Only faucets with hot and cold water supply
provided along with liquid soap containers
at each entry point

9. Whether sufficient care is being exercised
To ensure that each worker washes his
Hands properly before entering and leaving
The factory (**Note:** It is preferable to provide
Antiseptic solution for hand washes also)

10. Whether sufficient sign boards indicating
“NOT TO SPIT/SMOKE” in the premises
Are displayed

11. Whether artificial/natural lighting is
adequate and the bulbs/tube light are
away from the working equipment to
avoid accidental falling of broken glass
pieces in the meat products

12. Whether exhaust fan provided

5. Condition of Stores

Whether the spices, additives, curing agents
Etc., are properly labelled and packed to avoid
access and contamination by the rodents
and insects. Whether pesticides, rodenticides,
antiseptics disinfectants are properly labelled
and kept under lock and key

6. Drainage System

1. Whether adequate and sufficient
2. Whether the two systems i.e., (i) sanitary
Lines carrying the waste from toilet and
Dressing rooms and (ii) line which picks up
And remove the liquid waste of the plant
Are independent of each other to avoid
Backing up of waste from sanitary system
In to edible products department should

A blockage or choking occur

7. Water Supply

Source: Municipal/Well/bore well

1. Whether adequate potable water supply with Pressure is provided along with steam line, Coloured green and white respectively in Each department (to avoid accidental burns)
2. Whether hose pipe are provide, if provided Is that separate for each department

8. Personnel

1. Whether the staff is periodically examined for Medical fitness, if in affirmative what is the Periodicity when was the last examination done
2. Name, qualification and address of the doctor And hospital to which attached
3. Whether regularly vaccinated against cholera, Typhoid, Tuberculosis etc.
4. Whether nails and hair are properly trimmed (use of nail polish to be prohibited).
5. Whether clean uniforms, caps and gum boots Provided
6. Whether educated to observe personal Hygiene and not enter the clean department If employed in unclean department and Vice-versa to avoid contamination
7. Whether mouth mask provided in cooking And filling departments
8. Whether informed that talking, sneezing, Spitting in the factory premises while Working is prohibited

9. Meat

Source of Supply

- i) From Municipal Slaughter House
 - ii) Slaughter done in the factory
 - iii) Other sources, if any
2. a) Whether adequate ante/post/mortem examination Facilities exist, where slaughtering is done
 - b) Whether the carcasses from municipal slaughter-house are brought in refrigerated vans

3. Whether the carcasses/processed meat is stored at recommended temperature and Relative Humidity (R.H.)

10. Equipment

1. Condition of the working table, cooking vats, stirrers, mincers, blenders, fillers, retorts etc., (Good/Worn out)

2. Are the equipment so placed as to permit easy Cleaning and are at a sufficient height to check For any leftover of meat products

3. Whether clean and sufficient drums or receptacles, Provided for storing the glands, waste, tissues, bones Blood clots etc. separately in each department (Slaughter hall, boning, cooking and filling departments)

4. Whether trolleys suitable arrangements provided for Quick transportation /removal of the above material

5. Whether the storage receptacle/trolleys are properly marked as slaughter department, boning department cooking department, packing department etc. to avoid cross contamination and easy identification

6. Whether the Cooking / processing equipments are equipped with safety devices

11. LABORATORY

Whether laboratory is provided inside the unit if so what is the capacity

2. Person in-charge of the laboratory

12. STORAGE OF CARCASSES

1. Whether adequate cold storage refrigeration facilities exists with thermometer and hygrometer to record the

- i) Temp
- ii) Relative Humidity, if not what is the arrangement

2. Whether the carcasses are quickly transported to the cold storage

3. Condition of cold storage

- i) (clean/unclean)
- ii) meat properly stored or not

4. Whether separate cold storage provided for

- i) Raw material
- ii) cooked meat

13. Packing : (Storage to be damp proof, free from Pests, rodents etc.)

- 1) Type of products: Canned/raw/cooked mutton /pork/beef/chicken corned/curried/chunks/ Keema /sausage/ cured/ham streak/smoked/soup/ products etc.
- 2) Mode of packing: tin cans, alufoil, poly packs etc
- 3) Condition of the packing material
- 4) Size of packing
- 5) Code used (Whether easy to decode)
- 6) Whether date of manufacture is being indicated
- 7) Whether the labels are true and correct in Representation
- 8) Storage at wholesale/ retail outlets

14. Suggestions for Improvement

15. Time limit prescribed for carrying out compliance of suggestions

16. Recommendations

Place:

Date:

(Signature of the Inspecting officer with Designation)

Official Veterinary Health Certificate
For Meat & Meat Products

Inspection No.

Certificate No.

Date

I. Identification of Meat & Meat Products
Products manufactured with meat from

(Animal species)

Nature of Product(s)

Nature of Packaging

Number of individual item of package

Code Number(s)
(embossed)

Gross weight

Net weight

II. Destination of Meat & Meat Products
The Meat & Meat Products will be sent from

(Place of loading)

By the following means of transport
Name and address of Consignor

Name and address of the consignee

Consignors private mark(s)

Shipping Mark(s)

Shipping Number(s)

III. Health Attestation

I, the undersigned, certify that -

a. the meat food products described above were manufactured from meat obtained from healthy animals, slaughtered in the licensed premises of M/s _____ and were subjected to ante-mortem inspections according to the procedures prescribed in the Chapter on Meat & Meat Food Products of the Food Safety & Standards Act,2006.

b. The meat has been prepared under hygienic conditions and is free from parasitic infestation and pathogenic micro organisms including salmonella;

c. The cans containing the product have been subjected to a temperature of more than 100°C for a period of more than 120 minutes during the sterilization process.

d. The products has not been treated with any chemical preservatives or additives (other than salt and sodium nitrite) and any other substances harmful to health; and

e. The product is wholesome and fit for human consumption.

IV. Additional remarks :

The Meat & Meat Products is manufactured out of meat derived from animals slaughtered according to Islamic rites.

V. Validity

The certificate is valid for _____ days from
The _____.
(date) (Month) (Year)

Signature of Inspecting Officer
(Meat & Meat Products)

Date

Name : _____
Designation : _____

GENERAL FOOD ESTABLISHMENT INSPECTION REPORT

1. Date of Inspection

2. **Company Name**

Address

City..... **State** **Zip**

4. Type of Establishment;

Limited / Private Limited / Public Sector Undertaking / Co-operative / Partnership / Proprietorship/other

Establishment Category -

Processing/Handling/Storing/Serving/Packing/Repacking/ Relabeling/ others (Specify).....

Products (Specify)

5. **Last Inspection Date**.....

6. **Inspected by**

7. **Now Inspected by**

(FSO/AO Name)

8. **FSO/AO Signature**

Sl. No.	Questions	Yes.	No.	NA	Comments
1	BUILDING AND FACILITIES				
1.1	<p>Grounds -</p> <ul style="list-style-type: none"> • Is the area within the immediate vicinity of the Production Hall properly maintained so as to avoid attracting, harboring and breeding pests? Is equipment properly stored, litter and waste removed and grass and weeds cut? • Is immediate vicinity properly maintained to avoid contamination of food by seepage, foot borne filth? • Are adequate waste receptacles provided? <p>Is waste treatment and disposal adequate?</p>				
1.2	<p>Processing Hall -</p> <ul style="list-style-type: none"> • Provides sufficient space for equipment and storage to ensure the maintenance of sanitary operations and the production of safe food? • Provides sufficient aisle and working space to allow employees to perform their duties and to prevent contamination? 				

	<p>Floors, walls and ceilings are kept clean and in good repair?</p> <ul style="list-style-type: none"> • Prevents condensation on fixtures, ducts, and pipes to contaminate food, food-contact surfaces, and / or food packaging materials? • Outside doors kept closed unless in use? • Electrical bug-killers in place? • Damaged product kept in marked Area? • Is adequate lighting provided in: <ul style="list-style-type: none"> ○ Hand washing areas? ○ Areas where food is examined, processed, and stored? ○ Areas where equipment and utensils are cleaned? • Are safety type light bulbs, skylights, and fixtures used in areas over exposed food to prevent contamination incase of breakage? • Is adequate ventilation and / or control equipment provided to minimize odors and vapors in areas where they may contaminate food? • Are fans and other air-blowing equipment located in a manner that minimizes the potential for contamination? <p>Are screens and other appropriate measures used to protect against pests?</p> <ul style="list-style-type: none"> • Floor swept and free of debris? • Floor Drains visible and clear? • Is peeling paint visible on walls / roof? • Is Cob webs visible? <p>Is adequate floor drainage provided in areas where floors are subject to flood-type cleaning, or where normal operations release of discharge water or other liquids?</p>				
1.3	<p>Warehouse –</p> <ul style="list-style-type: none"> • Finished Products Stored 18 inches away from walls? • Painted white lines for inspection aisle? • Is Peeling paint visible? • Is Cob webs visible? • Damaged product kept in marked 				

	<p>area.</p> <ul style="list-style-type: none"> • Are products stored in a manner that permits their being periodically moved or rotated. "FIRST IN FIRST OUT". <p>Are food products stored in the coolest part of available storage facilities to prevent high external temperatures, from adversely affecting product quality, safety and nutritional value?</p> <p>Cold Storage/ freezer room provided? If yes required temp Maintained?</p> <ul style="list-style-type: none"> • Ingredients properly stored in clean covered containers? <p>Cleaning Compounds Sanitizing Agents, Toxic materials stored separately?</p>				
2	FOOD OPERATIONS & CONTROL				
2.1	<p>Procurement of Raw Material</p> <ul style="list-style-type: none"> • Raw material is sourced from authorized places after quality checking • Food additives and ingredients confirms to the Regulations laid down under the FSS Act. • Records of Raw materials, additives, ingredients as well their source of procurement maintained in register. 				
2.2	<p>Time and Temperature control</p> <ul style="list-style-type: none"> • Time and temperature controlled effectively for – <ul style="list-style-type: none"> • Receiving • Processing • Cooking • Cooling • Storage • Packaging • Distribution • Food service upto consumer 				
2.3	<p>Food Packaging and labelling</p> <ul style="list-style-type: none"> • Packaging Material provides adequate protection to food product to prevent contamination, damage • Packaging space is sufficient to accommodate required labelling. • Labelling information adequate as per the requirements of FSS Act. 				
2.4	<p>Food Distribution/ Service</p> <ul style="list-style-type: none"> • Adequate supply chain maintained to minimize food spoilage during 				

	<p>transportation processed/ packaged/ ready-to-eat food.</p> <ul style="list-style-type: none"> • Adequate transportation facilities provided to avoid cross contamination of the finished products. 				
3	SANITARY OPERATIONS				
3.1	<p>Cleaning & Sanitization</p> <ul style="list-style-type: none"> • Substances use in cleaning and sanitizing, storage of toxic materials? • Are cleaning compounds and sanitizing agents: <ul style="list-style-type: none"> ○ Identified, held, used, stored, and disposed of in a manner that protects against contamination of foods, food-contact surfaces or food packaging materials? • Is the use and storage of toxic materials limited to those required for: <ul style="list-style-type: none"> ○ Maintaining clean and sanitary conditions? ○ Use in laboratory testing procedures? ○ Plant and equipment maintenance and operation? • Are cleaning and sanitizing compounds: <ul style="list-style-type: none"> ○ Free from undesirable microorganisms? ○ Safe and adequate under their conditions of use? ○ Purchased under a supplier's guarantee? <p>If insecticides and rodenticides are used, are appropriate precautions taken to prevent contamination of food, food-contact surfaces, and food packaging materials?</p> <ul style="list-style-type: none"> • Are the food-contact surfaces used in the manufacturing or holding low-moisture food: <ul style="list-style-type: none"> ○ Dry and in a sanitary condition at the time of use? ○ Sanitized and thoroughly dried before subsequent use? ○ Are the facilities, procedures and / or machines used for cleaning and sanitizing equipment and utensils effective? 				

	<ul style="list-style-type: none"> ○ Are cleaned utensils and equipment handled and stored in a location and manner that protects food-contact surfaces from contamination? • Are Food-Contact surfaces of utensils and equipment: <ul style="list-style-type: none"> ○ Corrosion resistant? ○ Made of non-toxic materials? ○ Designed to withstand the environment and chemicals associated with their intended use? ○ Maintained to protect food from becoming contaminated by any source including unlawful indirect food additives? <p>Are seams on food-contact surfaces smoothly bonded or otherwise maintained to minimize the collection of particles, dirt, and other organic matter?</p>				
3.2	<p>Water –</p> <ul style="list-style-type: none"> • Is the water that comes in contact with food or food-contact surfaces safe and of potable quality? • Is the Test Report of water available? • Is the running water of sufficient pressure, and of suitable temperature, and provided in all areas where required for processing, cleaning, and employees sanitation? • Are overhead and underground water tanks clean and properly marked to show date when last cleaned? <p>Are overhead and underground water tanks properly covered to protect against contamination.</p>				
3.3	<p>Plumbing – Plumbing shall be of adequate size and design and adequately installed and maintained to:</p> <ul style="list-style-type: none"> • Carry sufficient quantities of water to required locations through out the plant? • Whether Separate pipe lines for potable and non-potable water provided and marked to identify? • Properly convey sewage and liquid disposable waste from the plant? • Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or 				

	<p>creating an unsanitary condition?</p> <p>Provide adequate floor drainage in all areas where normal operations release or discharge water or other liquid waste on the floor?</p> <p>Provided, that there is not back-flow from, or cross- contamination between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing?</p>				
3.4	<p>Sewage and Waste Disposal –</p> <ul style="list-style-type: none"> • Whether municipal facilities are available and whether these are actually used? • Is waste and garbage collection point large enough to carry peak loads and does not contribute to contamination? • If waste is disposal off in pits whether there is any possibility of contamination of any water supply obtained from nearby wells. • Is sewage disposed into an adequate sewerage system? • Is sewage disposal is made only after it is treated in Effluent Plant? • Is Garbage collected and stored at a marked place? <p>Is Garbage removed every day to the Garbage disposal point?</p>				
3.5	<p>Toilet Facilities –</p> <ul style="list-style-type: none"> • Adequate and readily accessible to all employees? • Marked for men and women by Pictorial Sign? <p>Kept sanitary and in good repair?</p> <p>Separate workers change room provided?</p>				
3.6	<p>Hand Washing Facilities –</p> <ul style="list-style-type: none"> • Adequate and convenient? • Furnished with running water of a suitable temperature? <p>Supplied with appropriate cleaning / sanitizing preparations and disposable towels or other suitable drying devices?</p>				
4	PERSONNEL				
4.1	<p>Disease control – Are employees who have an illness, open lesion or other abnormal source of contamination, excluded from operations which could result in contamination of food, food- contact</p>				

	surfaces, or food packaging materials?				
4.2	<p>Cleanliness – Do employees who work in direct contact with food, food-contact surfaces, or food packaging materials:</p> <ul style="list-style-type: none"> • Wear appropriate outer garments? • Maintain adequate personal cleanliness? • Wash hands thoroughly before starting work and at other times as needed? • Signs supporting hand washing are posted appropriately? • Remove all jewelry and other objects that could become food safety hazards? • Maintain gloves in an intact, clean, and sanitary condition? • Wear hairnets, and beard covers? • Store clothing and personal items, eat food, chew gum, use tobacco, apply cosmetics, etc. in designated areas away from where food is exposed and where equipment and utensils are washed? 				
4.3	<p>Education & Training –</p> <ul style="list-style-type: none"> • Do employees with responsibility for identifying sanitation failures or food contamination have the necessary education and / or experience? • Have food handlers and supervisors received appropriate training in food handling techniques, food protection principles and the dangers of poor hygiene and unsanitary practices? • Are Sanitation and Safety Rules clearly posted for Employees? <p>Are Employees required to understand and agree to GHP/GMP in writing?</p>				
5	PEST CONTROL				
5.1	A documented pest control program is maintained				
5.2	Pest Control Operator is licensed, insured and certified.				
5.3	Whether Pesticides used are permissible.				
5.4	Handling procedures, Material Safety Data Sheet (MSDS) and labels are on file.				
5.5	Any evidence of INTERNAL pest activity.				
5.6	Any evidence of EXTERNAL pest activity.				
5.7	All pest control devices are located in such a manner as not to contaminate product,				

	packing materials or equipment.				
5.8	The number and placement of traps and bait stations are effective. Bait stations are secured and tamper resistant.				
5.9	All pesticides are labelled and are properly stored.				
6	FOOD TESTING FACILITIES				
6.1	Well equipped modern laboratory is maintained for Physical, Microbiological and Chemical analysis of food material in accordance to the specifications/ standards laid down under the FSS Act,2006				
6.2	Laboratory Accredited?				
6.3	In case of suspicion or possible contamination food/product is being tested before from the establishment				
6.2	Regular testing from outside accredited Laboratory/ designated laboratory are being done and records are kept.				

Signature of

Establishment Contact Person

Signature of

FSO/Authorized officer

Improvement notices (as per section 32 of FSS Act,2006)

(1) If the Designated Officer has reasonable ground for believing that any food business operator has failed to comply with any regulations to which this section applies, he may, by a notice served on that food business operator (in this Act referred to as an “improvement notice”)-

(a) state the grounds for believing that the food business operator has failed to comply with the regulations;

(b) specify the matters which constitute the food business operator’s failure so to comply;

(c) specify the measures which, in the opinion of the said Authority, the food business operator must take, in order to secure compliance; and

(d) require the food business operator to take those measures, or measures which are at least equivalent to them, within a reasonable period (not being less than fourteen days) as may be specified in the notice.

(2) If the food business operator fails to comply with an improvement notice, his licence may be suspended.

(3) If the food business operator still fails to comply with the improvement notice, the Designated Officer may, after giving the licensee an opportunity to show cause, cancel the licence granted to him:

Provided that the Designated Officer may suspend any licence forthwith in the interest of public health for reasons to be recorded in writing.

(4) Any person who is aggrieved by –

(a) an improvement notice; or

(b) refusal to issue a certificate as to improvement; or

(c) cancellation or suspension or revocation of licence under this Act, may appeal to the Commissioner of Food Safety whose decision thereon, shall be final.

(5) The period within which such an appeal may be brought shall be –

(a) fifteen days from the date on which notice of the decision was served on the person desiring to appeal; or

(b) in the case of an appeal under sub-section (1), the said period or the period specified in the improvement notice, whichever expires earlier.

(DRAFT subject to modification)

Food Safety & Standards Authority of India (FSSAI)

FDA Bhavan
Next to Rashtriya Bal Bhavan,
Kotla Road, New Delhi-110002 **India**

Date.....

IMPROVEMENT NOTICE

To,
(Name & address of the food business operator)

.....
.....
.....

Re: Case ID #.....

Dear.....

On (date).....to (date)....., the.....(Inspecting agency name) conducted an inspection of your..... (Industry type) facility located at.....This letter notifies you of the violations of the FSS Act that we found during our investigation of your operation. You can find the Act & its associated regulations on the Internet at www.fssai.gov.in

The inspections revealed significant deviations from the..... (Standards & respective section no. Or HACCP regulations or cGMP regulation of foods etc.)

The deviations observed during the inspection include:
(along with the details)

- 1) (Deviations) _____

We acknowledge your response which includes (state the lack of adequate system, test methods to follow, specify the failures & its corrective actions)

- 2) _____

The violations cited in this letter are not intended to be an all-inclusive statement of the violations that exist at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that you comply with all requirements of the Act.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, injunction. Other federal agencies may take this Improvement Notice into account when considering the award of contracts

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps, other than those already submitted, that you will take, or have taken to correct the violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction. If you no longer manufacture or market any of your..... (Product name), your response should so indicate, including the reasons that, and the date on which, you ceased production.

Please direct any correspondence to: FSSAI, at the above address. If you have any questions, please contact..... (contact person name) at..... (contact no.)

Sincerely,

Sd /- Designated Officer

Date.....

(DRAFT 2- subject to modification)

Improvement Notice

Insert Regulation Name & No.

(Name of the Food Business)IMPROVEMENT NOTICE

Reference Number:

To:.....
.....(Food Business Operator)

At:.....
.....

.....(Address of Food Business Operator)

2. I have reasonable grounds for believing that you are failing to comply with the food law because:

.....
.....
.....
.....

[Officer to insert grounds for believing that requirements of specified food law as defined in the FSSA 2006 Regulations are being breached]

in connection with your food business

.....
.....
.....(Name of Food Business)

at

.....
.....(Address of Food Business)

The matters which constitute your failure to comply are:

.....
.....
.....
.....

[Officer to insert provision(s) of specified clauses as defined in the FSSA Regulations are being breached and how]

1. In my opinion, the following measure(s) are needed for you to comply with the legal requirements specified above:

.....
.....
.....

The measure or measures that will achieve the same effect must be taken by:.....(date)

2. *It is an offence not to comply with this (Name of the Food business) improvement notice by the date stated.*

Signed:.....
.....(Authorised Officer)

Name in capitals:
.....
.....

Date:
.....
.....

Address:
.....
.....

Tel:

Fax:

E-mail:

Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.

NOTES

1. In the opinion of the authorised officer you are not complying with specified food law as that term is defined in the (Name of the Food Business & the name of Regulations) as detailed in paragraph 2 of the notice. The work needed in the officer's opinion to put matters right is described and it must be finished by the date set.
2. You are responsible for ensuring that the work is carried out within the period specified which must be at least 14 days.
3. You have a right to carry out work that will achieve the same effect as that described in the notice. If you think that there is another equally effective way of complying with the law, you should first discuss it with the officer.

YOUR RIGHT OF APPEAL

4. In accordance with regulation 32 of the FSSA, if you disagree with all or part of this notice, you can appeal to the State Food Safety Commissioner . You must appeal within 14 days of the date of the notice or the period ending with the date stated in paragraph 3 of the notice, whichever ends earlier.
5. If you decide to appeal, the time set out in the notice is suspended and you do not have to carry out the work described until the appeal is heard. However, if you are not complying with the legal requirements mentioned in the notice, you may still be prosecuted for failure to comply with those requirements.
6. When the appeal is heard, the Food Safety Commissioner may confirm, cancel or vary the notice.

WARNING

FAILURE TO COMPLY WITH THIS NOTICE IS AN OFFENCE

Offenders are liable to be fined and/or imprisoned as per the gravity of an offence.

Prohibition orders.

(1) If –

(a) any food business operator is convicted of an offence under this Act; and

(b) the court by or before which he is so convicted is satisfied that the health risk exists with respect to that food business, the court, after giving the food business operator an opportunity of being heard, may by an order, impose the following prohibitions, namely:-

(i) a prohibition on the use of the process or treatment for the purposes of the food business;

(ii) a prohibition on the use of the premises or equipment for the purposes of the food business or any other food business of the same class or description;

(iii) a prohibition on the use of the premises or equipment for the purposes of any food business.

(2) The court may, on being satisfied that it is necessary so to do, by an order, impose a prohibition on the food business operator participating in the management of any food business, or any food business of a class or description specified in the order.

(3) As soon as practicable after the making of an order under sub-section (1) or subsection (1) or sub-section (2) (in this Act referred to as a “ prohibition order”), the concerned Food Safety Officer shall-

(a) serve a copy of the order on the food business operator; and

(b) in the case of an order under sub-section (1), affix a copy of the order at a conspicuous place on such premises used for the purposes of the food business, and any person who knowingly contravenes such an order shall be guilty of an offence and be punishable with a fine which may extend to three lakh rupees.

(4) The concerned Food Safety Officer shall with the approval of the Designated Officer issue a certificate to the effect that the food business operator has taken sufficient measures justifying lifting of the prohibition order, within seven days of his being satisfied on an application made by the food business operator for such a certificate or the said officer shall-

(a) determine, as soon as is reasonably practicable and in any event within fourteen days, whether or not he is so satisfied; and

(b) if he determines that he is not so satisfied, give notice to the food business operator of the reasons for that determination.

(5) A prohibition order shall cease to have effect upon the court being satisfied, on an application made by the food business operator not less than six months after the prohibition order has been passed, that the food business operator has taken sufficient measures justifying the lifting of the prohibition order.

(6) The court shall give a direction on an application by the food business operator, if the court thinks it proper so to do having regard to all the circumstances of the case, including in particular, the conduct of the food business operator since the making of the order; but no such application shall be entertained if it is not made –

(a) within six months after the making of the prohibition order; or

(b) within three months after the making by the food business operator of a previous application for such a direction.

Emergency prohibition notices and orders.

(1) If the Designated Officer is satisfied that the health risk condition exists with respect to any food business, he may, after a notice served on the food business operator (in this Act referred to as an 'emergency prohibition notice"), apply to the Commissioner of Food Safety for imposing the prohibition.

(2) If the Commissioner of Food Safety is satisfied, on the application of such an officer, that the health risk condition exists with respect to any food business, he shall, by an order, impose the prohibition.

(3) The Designated Officer shall not apply for an emergency prohibition order unless, at least one day before the date of the application, he has served notice on the food business operator of the business of his intention to apply for the order.

(4) As soon as practicable after the making of an emergency prohibition order, the Designated Officer shall require the Food Safety Officer to –

(a) serve a copy of the order on the food business operator of the business; or

(b) affix a copy of the order at a conspicuous place on such premises used for the purposes of that business; and any person who knowingly contravenes such an order shall be guilty of an offence and shall be punishable with imprisonment for a term which may extend to two years and with fine which may extend to two lakh rupees.

(5) An emergency prohibition order shall cease to have effect on the issue by the Designated Officer of a certificate to the effect that he is satisfied that the food business operator has taken sufficient measures for justifying the lifting of such order.

(6) The Designated Officer shall issue a certificate under subsection (5) within seven days of an application by the food business operator for such a certificate and on his being not satisfied, the said officer shall give notice to the food business operator within a period of ten days indicating the reasons for such decision.

Date.....

Emergency Prohibition Notice

Insert Regulation Name & No.

(Name of the Food Business)EMERGENCY PROHIBITION NOTICE

Reference Number:

1. To:.....
.....(Food Business Operator)

At:.....
.....
.....(Address of Food Business Operator)

2. *I am satisfied that the health risk condition is fulfilled with respect to:
.....
.....
.....

.....(Name of Food Business)

At:.....
.....
.....(Address of Food Business)

Because:.....
.....
.....

.....
.....

(* See Note 1 overleaf)

YOU MUST NOT USE IT FOR THE PURPOSES OF [THIS] [ANY] [THIS OR ANY SIMILAR]† (Insert name of the FOOD BUSINESS+).

[† Officer to delete as appropriate]

Signed:

.....
.....(Authorised Officer)

Name in capitals:

.....
.....

Date:

.....
.....

Address:

.....
.....
.....
.....
.....

Tel:

Fax:

E-mail:

Please read the notes overleaf carefully. If you are not sure of your rights or the implications of this notice, you may want to seek legal advice.

(Name the Food Business) Emergency Prohibition Notice (Reverse)

NOTES

1. When you receive this notice you must IMMEDIATELY stop using the premises, process, treatment or equipment described by the officer in paragraph 2 of the notice and located at the address stated.
2. If you believe that you have acted to remove the health risk condition, you should apply in writing to the authority for a certificate, which would allow you to use the premises, process, treatment or equipment again. You can do this even if the court hearing has not taken place.
3. You are not allowed to use the premises, process, treatment or equipment for the purpose specified in paragraph 2 of the notice (name & section of the regulation) Regulations as applied by regulation (no.) until (a) a court decides you may do so; (b) the authority issues you with a certificate as in paragraph 2 above;
4. A copy of this notice must, by law, be fixed on the premises or equipment which is not to be used.

WARNING

ANYONE WHO KNOWINGLY CONTRAVENES THIS NOTICE IS GUILTY OF AN OFFENCE

Offenders are liable to be fined and/or imprisoned as per gravity of an offence.

Date.....

DRAFT (Subject to modifications)

Certification that Health Risk Condition No Longer Exists

Or

Certification for Lifting of the Prohibition Order

Insert Regulation Name & No.

CERTIFICATE THAT THE HEALTH RISK CONDITION NO LONGER EXISTS

Or

CERTIFICATE FOR LIFTING OF THE PROHIBITION ORDER

1. To:(Food Business Operator)

At:.....
.....
.....(Address of Food Business Operator)

Name of food business
.....
.....

Address of food business
.....
.....
.....

2. The enforcement authority certifies that it is satisfied that you have taken sufficient measures to secure the removal of the imminent* risk of injury to health described in the:

(Name of the Food Business) Prohibition Order*

(Name of the Food Business) Emergency Prohibition Notice*

(Name of the Food Business) Emergency Prohibition Order*

[* Officer to delete as appropriate]

served on you on(date).

Signed:(Authorised Officer)

Name in capitals:

.....

Date:

.....

Address:

.....

.....

.....

Tel: Fax:

.....

E-mail:

THIS CERTIFICATE MEANS THAT YOU MAY NOW USE THE PREMISES, PROCESS, TREATMENT OR EQUIPMENT AGAIN.

Certification that Health Risk Condition No Longer Exists (Reverse)

Or

Certification For Lifting the Prohibition Order

NOTES

1. The authority is now satisfied that the health risk condition no longer exists in respect of the circumstances that caused the authority to issue you with an Emergency Prohibition Notice or the court to impose a Prohibition Order or Hygiene Emergency Prohibition Order*.
2. The relevant notice or order is now lifted and you may use the premises, process, treatment or equipment again.

[* Officer to delete as appropriate]

PREREQUISITE PROGRAMMES -GOOD HYGIENIC PRACTICES (GHP)

The foundation for Food Safety is infrastructure and hygiene. Quality and food safety improvement and maintenance is a continuous process. It can be achieved if primary production measures, production operations, storage and packaging are monitored properly with care. Food Regulations have substantial influence on the manufacturer.

Adoption of Good Hygienic Practice (GHP), Good Manufacturing Practice (GMP), food safety management systems based on HACCP/ISO 22000 and quality management systems based on ISO 9001 help food processing industries to maintain food quality and safety. In India, quality of export consignments is certified by several Government Agencies. The Quality and food safety inspection is carried out by conducting physical, chemical and microbiological examinations and monitoring of levels of various toxic contaminants like aflatoxins, heavy metals and pesticide and drug residues in various foods. Since most of food poisoning cases arise out of microbiological contamination, therefore, stringent measures are taken to control these contaminants during the manufacture of food products.

International basis for GHP

The Codex Alimentarius Commission brought out the Recommended International Code of Practice-General Principles of Food Hygiene in 1969 which has undergone four revisions and current version is (CAC/RCP1(1969) rev.4(20030. This has enunciated 8 principles of food hygiene (See Fig. 01)

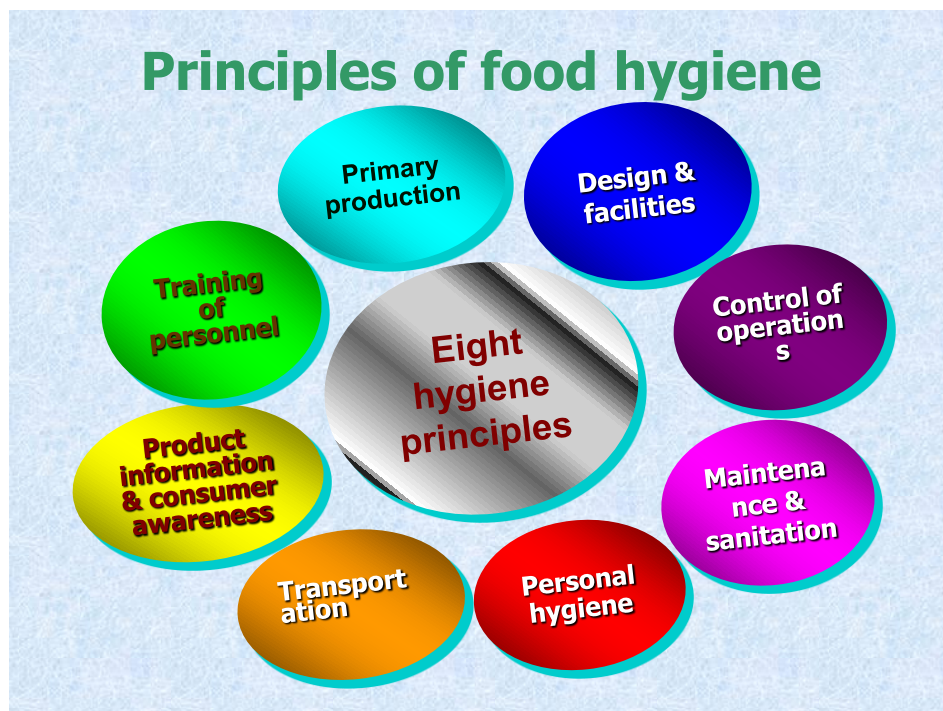


Fig 01 Eight Principles of Food Hygien

International food trade, and foreign travel, are increasing, bringing important social and economic changes. But this also makes the spread of illness around the world easier. Effective hygiene control, therefore, is vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. The

General Principles are commended to Governments, industry (including individual primary producers, manufacturers, processors, food service operators and retailers) and consumers alike.

Objectives of GHP

- identify the essential principles of food hygiene applicable throughout the food chain (including primary production through to the final consumer), to achieve the goal of ensuring that food is safe and suitable for human consumption;
- recommend a HACCP-based approach as a means to enhance food safety;
- indicate how to implement those principles.

Scope and Use

Governments can consider the contents of this document and decide how best they should encourage the implementation of these general principles to:

- protect consumers adequately from illness or injury caused by food; policies need to consider the vulnerability of different groups within the population
- provide assurance that food is suitable for human consumption
- maintain confidence in internationally traded food
- provide health education programs which effectively communicate the principles of food hygiene to industry and consumers.

1.PRIMARY PRODUCTION

Objective: Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

- avoiding use of areas where the environment poses a threat to food safety
- controlling contaminants/diseases of animals/plants to safeguard food safety;
- adopting practices to ensure food is produced under hygienic conditions.

Rationale: To reduce likelihood of introducing a hazard which may adversely affect food safety, or its suitability for consumption, at later stages of food chain.

1.1 Environmental Hygiene

Consider potential sources of contamination from the environment. Primary food production should not be carried on in areas where presence of potentially harmful substances may lead to unacceptable level of such substances in food.

1.2 Hygienic production of food sources

The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular, this includes identifying points where a high probability of contamination may exist and taking specific measures to minimize that probability producers should implement measures to:

- a) Control contamination from air, soil, water, feedstuffs, fertilizers , pesticides, veterinary drugs or any other agent used in primary production;
- b) Control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect product suitability.
- c) Protect food sources from faecal and other contamination.

1.3 Handling, storage and transport

Procedures should be in place to:

- sort food and food ingredients to segregate material which is evidently unfit for human consumption;
- dispose of any rejected material in a hygienic manner; and
- Protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

Care should be taken to prevent deterioration and spoilage through measures which may include controlling temperature, humidity, and/or other controls.

Cleaning, maintenance and personnel hygiene

Appropriate facilities and procedures should be in place to ensure that:

- any necessary cleaning and maintenance is carried out effectively; and
- an appropriate degree of personal hygiene is maintained.

2. ESTABLISHMENT, DESIGN AND FACILITIES

Objectives: Depending on nature of operations, and associated risks, premises, equipment and facilities should be located, designed and constructed to ensure:

- contamination is minimized.
- design and layout permit appropriate maintenance, cleaning and disinfections and minimize air-borne contamination.
- surfaces and materials, in particular those in contact with food, are non-toxic in intended use, suitably durable, and easy to maintain and clean.
- where appropriate, suitable facilities are available for temperature, humidity and other controls.
- there is effective protection against pest access and harborage

Rationale: Attention to good hygienic design and construction, appropriate location, and provision of adequate facilities, is necessary to control hazards.

2.1 Location and Establishment

Potential sources of contamination need to be considered when deciding where to locate food establishments and effectiveness of any reasonable measures that might be taken to protect food.

Establishments should be located away from:

- environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;
- areas subject to flooding unless sufficient safeguards are provided;
- areas prone to infestations of pests;
- areas where wastes, either solid or liquid, cannot be removed effectively.

Equipment should be located so that it:

- permits adequate maintenance and cleaning;
- functions in accordance with its intended use; and
- facilitates good hygiene practices, including monitoring.

2.2 Premises and Rooms

2.2.1 Design and layout

The internal design and layout of food establishments should permit good food hygiene practices appropriately, including protection against cross-contamination between and during operations by foodstuffs.

2.2.2 Internal structures and fittings

Structures within food establishments should be soundly built of durable materials and be easy to maintain, clean and where appropriate, able to be disinfected.

- the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use
- walls and partitions should have a smooth surface up to a height appropriate to operation
- floors should be constructed to allow adequate drainage and cleaning
- ceilings and overhead fixtures should minimize build up of dirt and condensation, and the shedding of particles
- windows should be easy to clean, be constructed to minimize the build up of dirt.
- doors should have smooth, non-absorbent surfaces, and be easy to clean and, where necessary, disinfect
- working surfaces that come into direct contact with food should be in sound condition, durable and easy to clean, maintain and disinfect.

2.2.3 Temporary/mobile premises and vending machines

Premises and structures include market stalls, mobile sales and street vending vehicles, temporary premises in which food is handled such as tents. Such premises and structures should be sited, designed and constructed to avoid, contaminating food and harboring pests.

2.3 Equipment

2.3.1 Equipment and containers coming into contact with food, should be designed and constructed to ensure that, they can be adequately cleaned, disinfected and maintained to avoid the contamination of food.

2.3.2 Food control and monitoring equipment

Equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively. These requirements are intended to ensure that:

- harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled;
- where appropriate, critical limits established in HACCP-based plans can be monitored; and
- temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.

2.3.3 Containers for waste and inedible substances

Containers for waste, by-products and inedible or dangerous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material.

2.4 Facilities

2.4.1 Water supply

An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food. Non-potable water shall have a separate system.

2.4.2 Drainage and waste disposal

Adequate drainage and waste disposal systems and facilities should be provided. They should be designed and constructed so that the risk of contaminating food or the potable water supply is avoided.

2.4.3 Cleaning

Provide adequate facilities for cleaning food, utensils and equipment. Facilities should have an adequate supply of hot and cold potable water where appropriate.

2.4.4 Personnel hygiene facilities and toilets

Personnel hygiene facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Where appropriate, suitably located and designated facilities should include:

- adequate means of hygienically washing and drying hands
- lavatories of appropriate hygienic design
- adequate changing facilities for personnel

2.4.5 Temperature control

Depending on nature of food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food temperatures, and when necessary, controlling ambient temperatures to ensure food safety and suitability.

2.4.6 Air quality and ventilation

Provide adequate means of natural or mechanical ventilation to:

- minimize contamination of food e.g. from aerosols/condensation droplets
- control ambient temperatures
- control odours which might affect the suitability of food
- control humidity, to ensure the safety and suitability of food.

Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas.

2.4.7 Lighting

Provide adequate lighting to carry out operation in a hygienic manner. Lighting should not result in misleading colour. Intensity should be adequate. Protect lighting fixtures to ensure that food is not contaminated by breakages.

2.4.8 Storage

Provide adequate facilities for storage of food, ingredients and non-food chemicals. Design and construct facilities to :

- permit adequate maintenance and cleaning
- avoid pest access and harborage
- enable food to be effectively protected from contamination during storage
- provide environment (temperature and humidity) to avoid food deterioration
- Provide secure storage facilities for cleaning materials/hazardous substances

3. CONTROL OF OPERATION

Objective: To produce food which is safe and suitable for human consumption by:

- formulating design requirements with respect to raw materials,
- composition, processing, distribution, and consumer use to be met in the manufacture and
- handling of specific food items; and
- designing, implementing, monitoring and reviewing effective control systems.

Rationale: To reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards.

3.1 Control of food hazards

Control food hazards through the use of systems such as HACCP. They should:

- identify any steps in their operations which are critical to the safety of food
- implement effective control procedures at those steps
- monitor control procedures to ensure their continuing effectiveness
- review control procedures periodically, and whenever the operations change.

These systems should be applied throughout the food chain to control food hygiene throughout the shelf-life of the product through proper product and process design.

3.2 Key aspects of hygiene control systems

3.2.1 Time and temperature control

Inadequate food temperature control is one of the most common causes of food borne illness or food spoilage. Such controls include time and temperature of cooking, cooling, processing and storage. Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety and suitability of food. Temperature control systems should take into account:

- the nature of the food, e.g. its water activity (R_w factor), pH, and likely initial level and types of microorganisms,
- the intended shelf-life of the product,
- the method of packaging and processing,
- how the product is intended to be used.

Such systems should also specify tolerable limits for time and temperature variations. Temperature recording devices should be checked at regular intervals and tested for accuracy.

3.2.3 Specific process steps

Other steps which contribute to food hygiene may include e.g. chilling, thermal processing, irradiation, drying, chemical preservation, vacuum or modified atmospheric packaging

3.2.4 Microbiological and other specifications

Where microbiological, chemical or physical specifications are used in any food control system, such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and action limits.

3.2.5 Microbiological cross-contamination

Pathogens can be transferred from one food to another, either by direct contact or by food handlers, contact surfaces or the air. Raw, unprocessed food should be effectively separated, either physically or by time, from ready-to-eat foods, with effective intermediate

cleaning and where appropriate disinfection. Access to processing areas may need to be restricted or controlled.

3.2.6 Physical and chemical contamination

Systems should be in place to prevent contamination of foods by foreign bodies such as glass or metal sheards from machinery, dust, harmful fumes and unwanted chemicals. In manufacturing and processing, suitable detection or screening devices should be used where necessary.

3.2.7 Incoming material requirements

No raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing.

3.2.8 Packaging

Packaging design and materials should provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labeling.

3.2.9 Water

3.2.9.1 In contact with food

Only potable water, should be used in food handling and processing, with the following exceptions:

- for steam production, fire control and other similar purposes not connected with food; and
- in certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water).

Water re-circulated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use.

3.2.9.2 As an ingredient

Potable water should be used wherever necessary to avoid food contamination.

3.2.9.3 Ice and steam

Ice should be made from potable. Ice and steam should be produced, handled and stored to protect them from contamination. Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

3.3 Management and supervision

The type of control and supervision needed will depend on size of business, nature of its activities and types of food involved. Managers and supervisors should have enough knowledge of food hygiene principles and practices.

3.4 Documentation and records

Appropriate records of processing, production and distribution should be retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and effectiveness of the food safety control system.

3.5 Recall procedures

Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable complete recall of any implicated lot of finished food from

market. Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

4. ESTABLISHMENT, MAINTENANCE & SANITATION

Objective: To establish effective systems to:

- ensure adequate and appropriate maintenance and cleaning
- control pests
- manage waste
- monitor effectiveness of maintenance and sanitation procedures

Rationale: To facilitate the continuing effective control of food hazards, pests, and other agents likely to contaminate food.

4.1 Maintenance and cleaning

4.1.1 Establishments and equipment should be kept in an appropriate state of repair and condition to:

- facilitate all sanitation procedures
- function as intended, particularly at critical steps
- prevent contamination of food, e.g. from metal shread, flaking plaster, debris and chemicals.

Cleaning should remove food residues and dirt which may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the food business.

4.1.2 Cleaning procedures and methods

Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing etc. Cleaning procedures will involve, where appropriate:

- removing gross debris from surfaces
- applying a detergent solution to loosen soil and bacterial film and hold them in solution or suspension
- rinsing with water to remove loosened soil and residues of detergent
- dry cleaning or other methods for removing/collecting residues and debris
- disinfection with subsequent rinsing unless the manufacturers' instructions indicate on scientific basis that rinsing is not required.

4.2 Cleaning programmes

Cleaning/disinfection programmes should ensure that all parts of establishment are appropriately clean, and should include the cleaning of cleaning equipment. Where written cleaning programmes are used, they should specify:

- areas, items of equipment and utensils to be cleaned
- responsibility for particular tasks
- method and frequency of cleaning
- monitoring arrangements.

4.3 Pest control systems

4.3.1 Pests are threat to safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Avoid creating an environment conducive to pests.

4.3.2 Preventing access

Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed.

4.3.2 Harborage and infestation

The availability of food and water encourages pest harborage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls.

4.3.3 Monitoring and detection

Establishments and surrounding areas should be regularly examined for evidence of infestation.

4.3.4 Eradication

Pest infestations should be dealt with immediately and without adversely affecting food safety or suitability.

4.4 Waste management

Make suitable provision for removal and storage of waste. Waste must not accumulate in working areas. Waste stores must be kept clean.

4.5 Monitoring effectiveness

Sanitation systems should be monitored for effectiveness, periodically verified by means such as audit pre-operational inspections or microbiological sampling.

5. ESTABLISHMENT: PERSONAL HYGIENE

Objectives: To ensure that those who come directly or indirectly into contact with food are not likely to contaminate food by:

- maintaining an appropriate degree of personal cleanliness;
- behaving and operating in an appropriate manner.

Rationale: People who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers.

5.1 Health status

People known, or suspected, to be suffering from, or to be a carrier of a disease or illness likely to be transmitted through food, should not be allowed to enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management. Medical examination of a food handler should be carried out if clinically or epidemiologically indicated.

5.2 Illness and injuries

Conditions to be reported to management for medical examination and/or possible exclusion from food handling can be considered, are jaundice, diarrhoea, vomiting, fever, sore throat with fever, visibly infected skin lesions and discharges from ear, eye or nose.

5.3 Personal cleanliness

Food handlers should maintain a high degree of personal cleanliness. Personnel should always wash their hands when personal cleanliness may affect food safety, for example:

- at the start of food handling activities;
- immediately after using the toilet; and
- after handling raw food or any contaminated material, where this could result in contamination of other food items; they should avoid handling ready-to-eat food, where appropriate.

5.4 Personal behaviour

People should avoid behaviour which could result in contamination of food.

5.5 Visitors

Visitors to food manufacturing, processing or handling areas should, wear protective clothing and adhere to personal hygiene provisions in this section.

6. TRANSPORTATION

Objectives: Measures should be taken where necessary to:

- protect food from potential sources of contamination;
- protect food from damage likely to render the food unsuitable for consumption; and
- provide an environment which effectively controls the growth of pathogenic or spoilage micro-organisms and the production of toxins in food.

Rationale: Food may become contaminated, or may not reach its destination in a suitable condition for consumption, unless effective control measures are taken during transport. Food must be adequately protected during transport.

6.1 Requirements

Conveyances/bulk containers should be designed and constructed so that they:

- do not contaminate foods or packaging;
- can be effectively cleaned and, where necessary, disinfected
- permit effective separation of different foods or foods from non-food items where necessary during transport
- provide effective protection from contamination, including dust and fumes;
- can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from microbial growth
- allow any necessary temperature, humidity and other conditions to be checked.

6.2 Use and maintenance

Conveyances and containers for transporting food should be kept in a state of cleanliness, repair and condition.

7. PRODUCT INFORMATION AND CONSUMER AWARENESS

Objectives: Products should bear appropriate information to ensure that:

- adequate and accessible information is available to the next person in the food chain to enable them to handle the product safely and correctly;
- the lot or batch can be easily identified and recalled if necessary.

Rationale: Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain.

7.2 Product information

All food products should be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store and prepare and use the product safely and correctly.

7.3 Labelling

Prepackaged foods should be labeled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely.

7.4 Consumer education

Health education programs should cover general food hygiene. Such programs should enable consumers to understand the importance of any product information and to follow any instructions accompanying products, and make informed choices.

8. TRAINING

Objective: Personnel who come into contact with food should be trained in food hygiene to a level appropriate to operations they are to perform.

Rationale: Inadequate hygiene training and supervision of people pose a potential threat to food safety and its suitability for consumption.

8.1 Awareness and responsibilities

All personnel should be aware of their role in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle strong cleaning or hazardous chemicals should be instructed in safe handling techniques.

8.2 Training programmes

Level of training depends on the following factors:

- nature of food and its ability to sustain growth of harmful micro-organisms
- manner in which food is handled/packed
- extent/nature of processing or further preparation before final consumption
- conditions under which the food will be stored
- expected length of time before consumption.

PREREQUISITE PROGRAMME- GOOD MANUFACTURING PRACTICES

Good Manufacturing Practices (GMP) refers to the Practices which manufacturers, processors, and packagers should take as proactive steps to ensure that their products are safe, pure, and effective.

GMP requires a quality approach to manufacturing, enabling companies to minimize or eliminate instances of contamination, mixups, and errors. This in turn, protects the consumer from purchasing unsafe and poor quality products. Failure of firms to comply with GMP can result in very serious consequences including recall, seizure, fines, and imprisonment. It addresses issues including recordkeeping, personnel qualifications, sanitation, cleanliness, equipment verification, process validation, and complaint handling. Most GMP requirements are very general and open-ended, allowing each manufacturer to decide individually how to best implement the necessary controls. This provides much flexibility, but also requires that the manufacturer interpret the requirements in a manner which makes sense for each individual business.

Good Manufacturing Practice in food industry

Personnel

a) **Disease control:** Any person who, appears to have, an illness, open lesion, including boils, sores, or infected wounds shall be excluded from any operations which may be expected to result in food contamination.

b) **Cleanliness:** All persons working in direct contact with food shall conform to following hygienic practices while on duty:

- 1) Wearing garments suitable to the operation to avoid contamination of food,
- 2) Maintaining adequate personal cleanliness,
- 3) Washing hands thoroughly in an adequate hand-washing facility,
- 4) Removing all unsecured jewellery and other objects that might fall into food, equipment, or containers,
- 5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable material,
- 6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints,
- 7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed,
- 8) Confining the following to areas other than where food may be exposed : eating food, chewing gum, drinking beverages, or using tobacco,
- 9) Taking any other necessary precautions to protect against contamination of food by perspiration, cosmetics, tobacco, chemicals, medicines applied to skin.

c) **Education and training:** Personnel responsible for identifying sanitation failures should have a background of education or experience to provide a level of competency necessary for production of clean and safe food.

d) **Supervision:** Responsibility for assuring compliance by all personnel with all requirements of this part shall be clearly assigned to competent supervisory personnel.

Plant and grounds

a) **Grounds:** shall be kept in a condition that will protect against the contamination of food. The methods for maintenance of grounds are as follows :

- 1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests,

- 2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed,
- 3) Adequately draining areas that may contribute to contamination to food by seepage, foot-borne filth, or providing a breeding place for pests,
- 4) Operating systems for waste treatment and disposal so that they do not constitute a source of contamination in areas where food is exposed.

b) **Plant construction and design:** The plant and facilities shall:

- 1) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations.
- 2) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials.
- 3) Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels.
- 4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair.
- 5) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored.
- 6) Provide adequate ventilation or control equipment to minimize odors and vapors in areas where they may contaminate food.
- 7) Provide, where necessary, adequate screening or other protection against pests.

Sanitary operations

a) **General maintenance:** Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition.

b) **Substances used in cleaning and sanitizing; storage of toxic materials :**

- 1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms.
- 2) Toxic cleaning compounds, sanitizing agents shall be identified, held, and stored in a manner that protects against contamination of food.

c) **Pest control:** No pests shall be allowed in any area of a food plant. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food-contact surfaces, and food-packaging materials.

d) **Sanitation of food-contact surfaces:** All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned frequently to protect against contamination of food.

- 1) Food-contact surfaces used for manufacturing or holding low-moisture food shall be in a dry, sanitary condition at the time of use.
- 2) In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food-contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food-contact surfaces may have become contaminated.
- 3) Non-food-contact surfaces of equipment used in the operation of food plants should be cleaned frequently to protect against contamination of food.
- 4) Single-service articles should be stored in appropriate containers.
- 5) Sanitizing agents shall be adequate and safe under conditions of use.

e) **Storage and handling of cleaned portable equipment and utensils:** Cleaned and sanitized portable equipment with food-contact surfaces and utensils should be stored so as to protect food-contact surfaces from contamination.

Sanitary facilities and controls

Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:

a) **Water supply.** The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. Any water that contacts food or food-contact surfaces shall be safe and of adequate sanitary quality.

b) **Plumbing.** Plumbing shall be of adequate size and design and adequately installed and maintained to:

- 1) Carry sufficient quantities of water to required locations throughout the plant.
- 2) Properly convey sewage and liquid disposable waste from the plant.
- 3) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.
- 4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- 5) Provide that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

c) **Sewage disposal.** Sewage disposal shall be made into an adequate sewerage system or disposed off through other adequate means.

d) **Toilet facilities.** Each plant shall provide its employees with adequate, readily accessible toilet facilities.

e) **Hand-washing facilities.** Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Compliance with this requirement may be accomplished by providing:

- 1) Hand-washing facilities and, where appropriate hand-sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands.
- 2) Effective hand-cleaning and sanitizing preparations.
- 3) Suitable drying devices.
- 4) Devices or fixtures, such as water taps, so designed and constructed to protect against recontamination of clean, sanitized hands.
- 5) Readily understandable signs directing employees to wash and, where appropriate, sanitize their hands.
- 6) Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.

f) **Rubbish and offal disposal.** Rubbish and solid waste shall be so conveyed, stored, and disposed of as to minimize the development of odour, minimize the potential for the waste becoming so an attractant and harborage place for pests.

Equipment and utensils

a) All plant equipment and utensils shall be so designed and of such material (food grade) and workmanship as to be adequately cleanable.

b) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter.

c) Equipment that is in manufacturing area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

d) Holding, conveying, and manufacturing systems shall be of design and construction that enables them to be maintained in sanitary condition.

e) Each freezer used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating temperature recording device.

f) Instruments and controls shall be accurate and adequately maintained, and adequate in number for their designated uses.

g) Compressed air or other gases introduced into food shall be treated in such a way that food is not contaminated.

Processes and Controls

a) Raw materials/ ingredients

- 1) Raw materials shall be inspected and segregated to ascertain that they are clean and suitable for processing into food;
- 2) Raw materials shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans;
- 3) Raw materials susceptible to contamination with aflatoxin, undesirable microorganisms, or extraneous material shall comply with regulations;
- 4) Raw materials shall be held so as to protect against contamination and shall be held at such temperature and humidity as to prevent food adulteration;
- 5) Frozen raw materials shall be kept frozen. If thawing is required it shall be done in a manner that prevents the raw materials from becoming contaminated; and
- 6) Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.

b) Manufacturing operations

- 1) Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing.
- 2) Manufacturing shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms,
- 3) Food that can support the rapid growth of undesirable microorganisms, shall be held in a manner that prevents the food from becoming adulterated.
 - (i) Maintaining refrigerated foods at 5°C or below, frozen foods in a frozen state and hot foods at 60°C or above
 - (ii) Heat treating acid or acidified foods to destroy mesophilic microorganisms
- 4) Work-in-process shall be handled so as to protect against contamination.
- 5) Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse.
- 6) Equipment, containers, and utensils shall be maintained during manufacturing or storage in a manner that protects against contamination.
- 7) Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food.
- 8) Mechanical manufacturing steps shall be performed so as to protect food against contamination.
- 9) Filling, assembling, packaging, and other operations shall be performed in such a way that food is protected against contamination.
- 10) Ice shall be made from water that is safe and of adequate sanitary quality.
- 11) Manufacturing areas/equipment used for manufacturing human food should not be used to manufacture nonhuman use food.

Warehousing and distribution.

Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.

Maximum Defect Action Levels

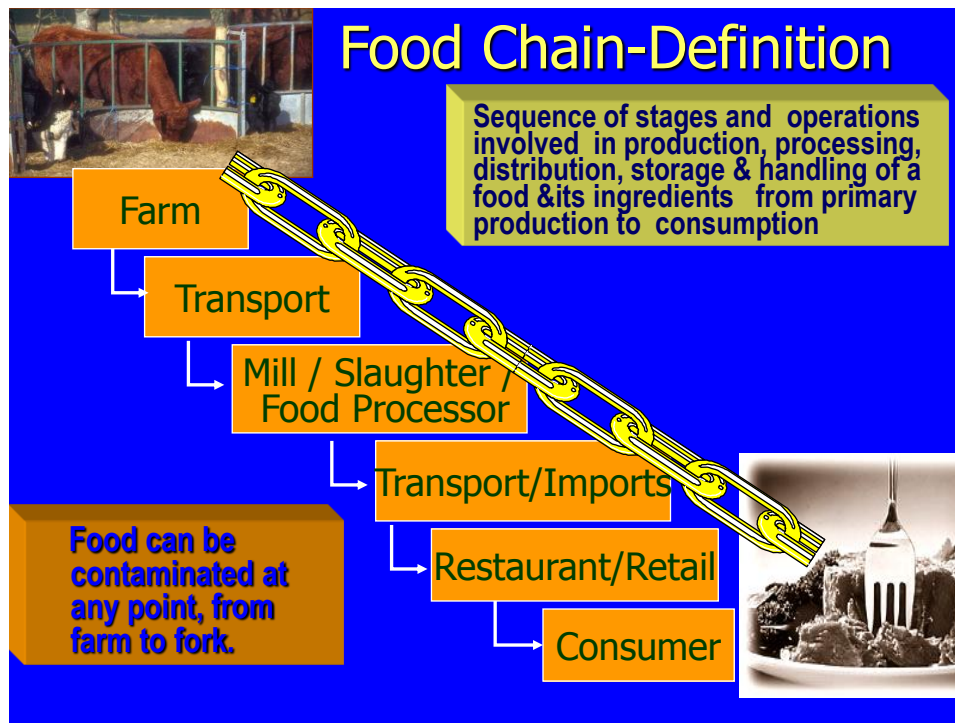
Defect action levels are established for foods whenever it is necessary and feasible to do so.

FOOD SAFETY MANAGEMENT SYSTEMS-HACCP

Codex has defined *HACCP* as a system which identifies, evaluates, and controls hazards which are significant for food safety. More broadly it is a scientific and rational approach to food safety which analyzes potential hazards, determines the critical control points in a food process and develops monitoring procedures to determine if the hazards identified are being effectively controlled. It enhances food safety besides better use of resources and timely response to problems. HACCP has signaled a shift in emphasis from resource intensive end-product inspection and testing to preventive control of hazards at all stages of food production. This is the reason why HACCP system is now widely embraced by the food industries and by the government regulatory agencies around the world as a most cost-effective means of minimizing the occurrence of identifiable food borne biological, chemical and physical hazards and maximizing product safety. It is a system which targets critical areas of processing and in doing so reduces the risk of manufacturing and selling unsafe products

The primary objective of a HACCP programme is to produce reliably a safe food. This means a product which is free of microbiological, chemical or physical hazards. Industry is fairly familiar with various microbiological, chemical and physical hazards and trying to avoid various common hazards. Despite familiarity and knowledge of food poisoning from microbiological and chemical causes, or injury from glass, wire and other dangerous physical objects, their control is difficult and occasionally they result in serious consumer safety exposures and expensive product recalls and retrievals. It is therefore necessary to have technical orientation on common microbiological, chemical and physical hazards that may cause serious problems in foods.

HACCP can be applied throughout the food chain (See Fig 02) from the primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health to enhance food safety and provide other significant benefits. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.



The HACCP system is based on seven principles (See Fig.03)

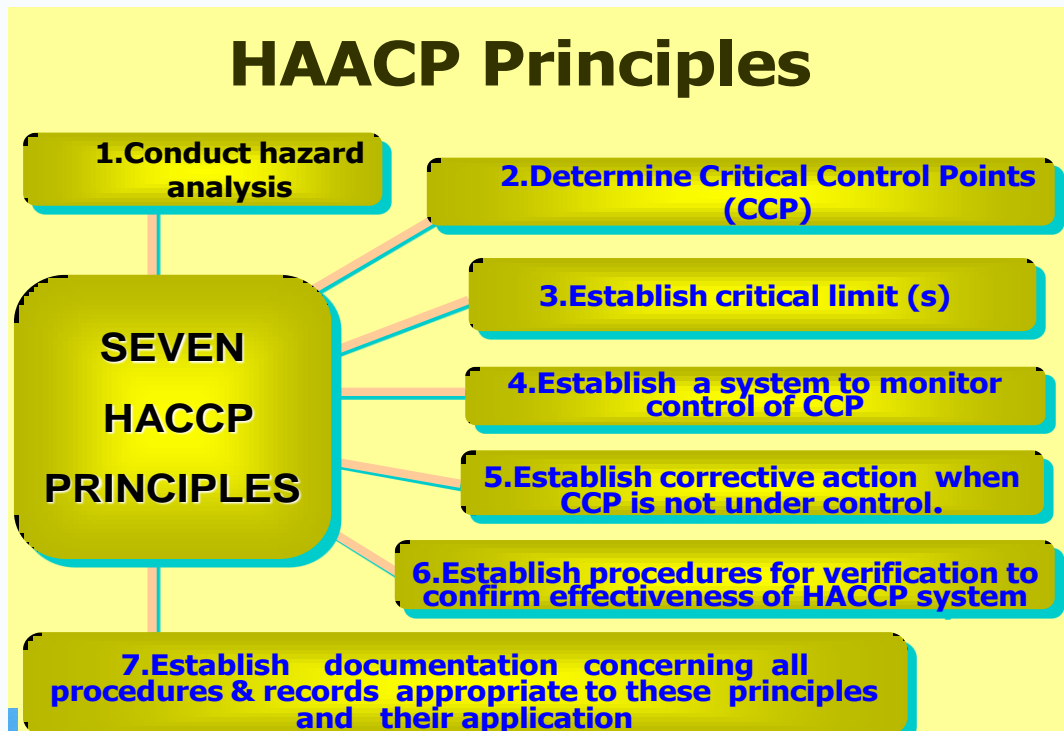


Fig 03 Seven principles of HACCP

GUIDELINES FOR THE APPLICATION OF HACCP SYSTEM

The HACCP system, which is based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. The HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

The successful application of HACCP requires the full commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering, according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as ISO 9001, and is the system of choice in the management of food safety within such systems.

Prior to the application of HACCP to any sector of the food chain, that sector should have in place prerequisite programmes [described in previous sections](#) and appropriate food safety requirements. These prerequisite programs to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system. For all type of food business, management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills.

During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence related to food safety. The intent of the HACCP system is to focus control at Critical Control Points (CCP_s). Redesign of the operation should be considered if a

hazard which must be controlled is identified but no preventive measures exist(See decision Tree).

The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate.

DEVELOPMENT OF HACCP PLAN

The application of HACCP principles consists of the 12 step development as identified in the Logic Sequence for application of HACCP(See Fig 04). It has two portions- first five steps are called preliminary steps and next seven steps are based on seven principles of HACCP.

PRELIMINARY STEPS

1) Establishment of a multi- disciplinary team

When a food industry embarks upon implementing HACCP system, it becomes necessary to gather together as much expertise and experience on the discussion table as possible including involvement of top management. As development of HACCP based food safety management programme requires a multi-disciplinary team effort, it should include, when appropriate expertise in veterinary health, production, microbiology, toxicology, public health, food technology, environmental health, chemistry and engineering according to the particular study. This cross-functional expertise is necessary to adequately analyze all physical, chemical and biological hazards through the food chain.

2) Describe the product

The organization should describe its product(s). The description should include the major raw material, food ingredients, preservation and packing materials used and their impact on food safety . This can also include a brief description of how the process occurs and/ products are produced and stored. It would be useful if hazards that may exist either in ingredients or in packing material are identified. A description of the method of distribution includes type of transport and any special consideration to maintain product safety. Separate HACCP plan should be made for each product. But if two or more products have the identical raw material , ingredients, process operations, packaging, storage and distribution, they can be clubbed together in one HACCP plan.

3) Identify intended use

The intended use should be based on the expected uses of the product by the end user or consumer. It should be indicated how the product is to be used including if it is to be fully cooked before consumption, what preparations will be needed , what will be serving requirements, shelf life etc. If consumer has special consideration such as infant or geriatrics it should be made clear so that necessary emphasis may be given to safeguard their special interest. For instance ice cream is consumed without further processing by general population including high risk groups but infant milk food is meant for infants and is given special consideration.

4) Construct a process flow diagram

The HACCP team constructs a detailed process flow diagram for each product indicating critical steps of control. Each step within the specified area of operation is analyzed for the particular part of the operation under consideration to produce the flow diagram. When applying HACCP system to a given operation, consideration is given to steps preceding and following the specified operation. The process flow diagram is used as the basis of the

hazard analysis and should therefore contain sufficient technical detail for the study to progress

5) **On-site verification of process flow diagram**

When the process flow diagram is complete, it is verified by the HACCP team at site to confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

STEPS BASED ON HACCP RINCIPLES

6. Principle 1: Conduct a hazard analysis. When the process flow diagram is completed and verified, the HACCP team conducts a hazard analysis and lists all the biological, chemical and physical hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture and distribution until the point of consumption. When conducting the hazard analysis, consideration must be given to the impact of raw materials, ingredients, manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, consumer populations at risk and epidemiological evidence relative to food safety. Plans determine the food safety hazards and identify the preventive measures the plan can apply to control these hazards. A food safety hazard is any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

7. Principle 2: Identify critical control points. A Critical Control Point (CCP) is a point, step, or procedure in a food manufacturing process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to an acceptable level. The identification of a CCP in the HACCP system is facilitated by the application of a decision tree (See Fig 05). All hazards that may be reasonably expected to occur, at each step, should be considered.

8. Principle 3: Establish critical limits for each critical control point. A critical limit is the maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level. Since the critical control points define the boundaries between safe and unsafe products, it is vital that they are specified at the correct levels and validated at each criteria. The HACCP team should therefore fully understand the criteria governing safety at each CCP in order to set the appropriate critical limits. Critical limits must be specified for each preventative measure.

9. Principle 4: Establish monitoring system for each critical control point. Monitoring activities are necessary to ensure that the process is under control at each critical control point. Monitoring is one of the most important aspects of the HACCP system. It is the scheduled measurement a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP and provide information in time for corrective action to regain control of the process.

10. Principle 5: Establish corrective actions. These are actions to be taken when monitoring indicates a deviation from an established critical limit. The final rule requires a plant's HACCP plan to identify the corrective actions to be taken if a critical limit is not met. Corrective actions are intended to ensure that no product injurious to health or otherwise adulterated as a result of the deviation enters commerce.

11. Principle 6: Establish verification procedures. Verification ensures the HACCP plan is adequate, that is, working as intended. Verification procedures may include such activities as review of HACCP plans, CCP records, critical limits and microbial sampling and analysis. Verification also includes 'validation' - the process of finding evidence for the accuracy of the HACCP system (e.g. scientific evidence for critical limitations). Validation

ensures that the plants do what they were designed to do; that is, they are successful in ensuring the production of safe product.

12. Principle 7: Establish record keeping procedures. Efficient and accurate record keeping is essential to the application of a HACCP system. Records need to be kept of all areas which are critical to product safety to demonstrate that the HACCP system is in compliance with the documented system. The HACCP regulation requires that all plants maintain certain documents, including its hazard analysis and written HACCP plan, and records documenting the monitoring of critical control points, critical limits, verification activities, and the handling of processing deviations.

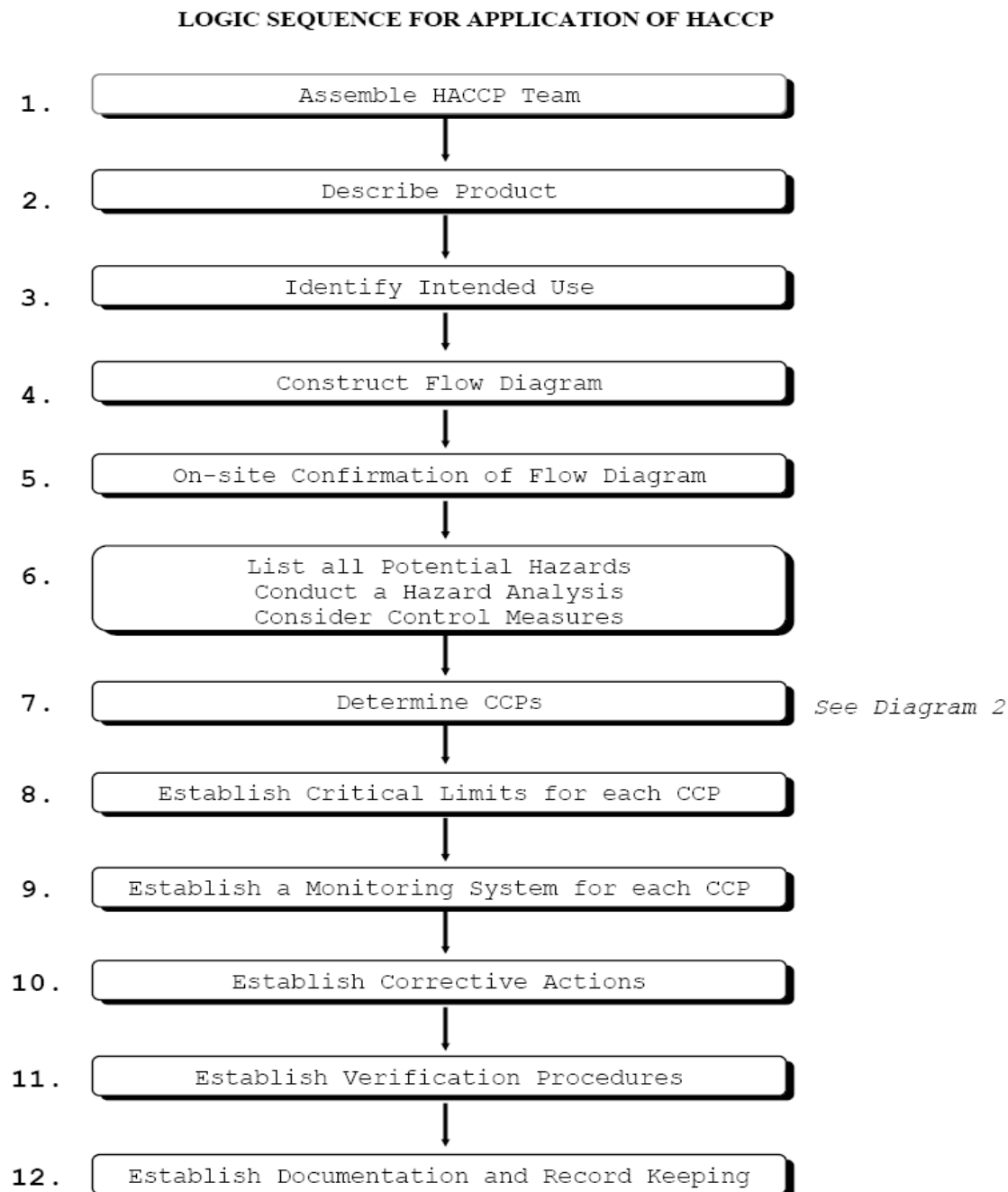


Fig.04 Logic sequence for application of HACCP

EXAMPLE OF DECISION TREE TO IDENTIFY CCPs

(answer questions in sequence)

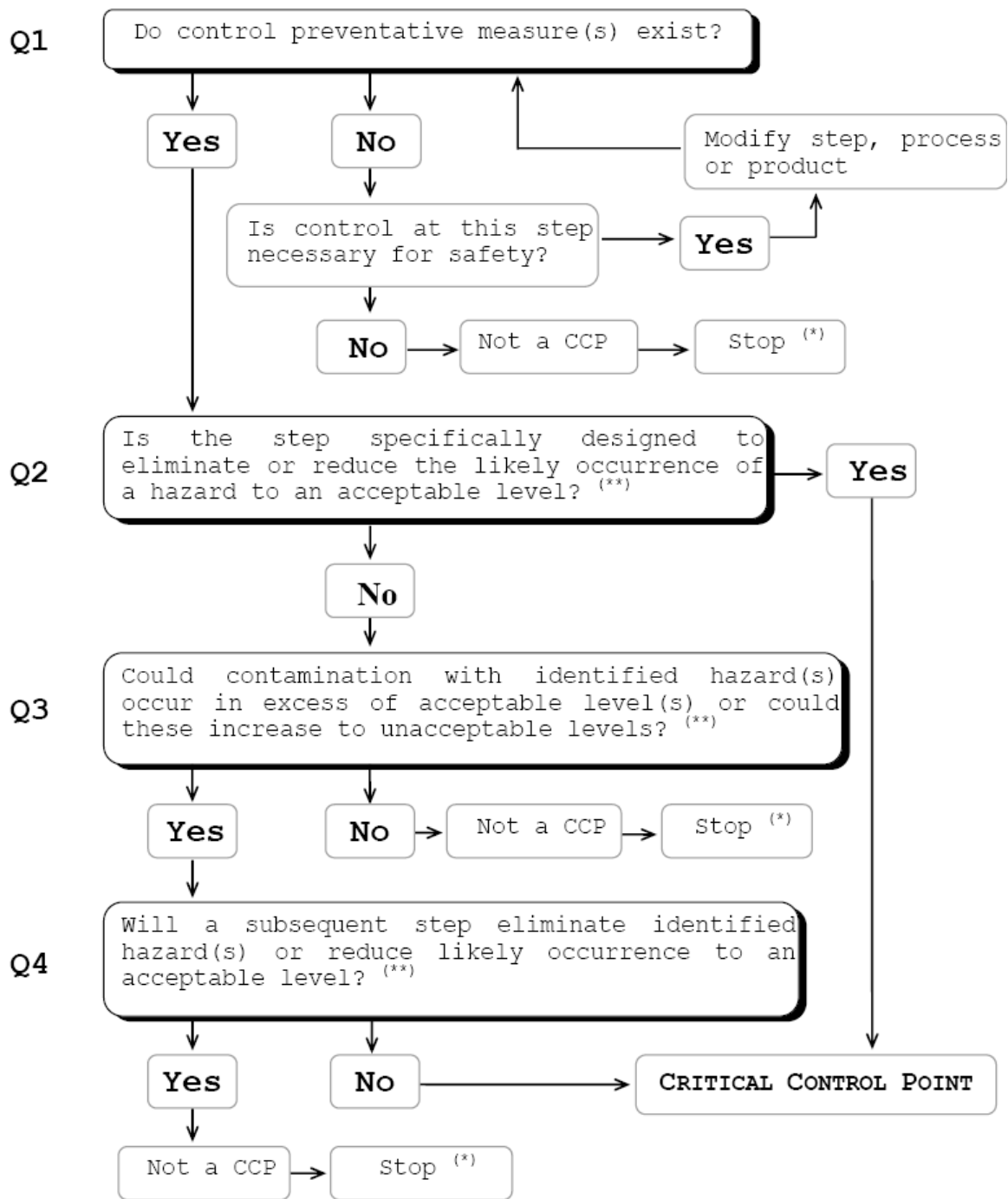


Fig 05 Decision tree

The Codex Alimentarius Commission brought out an International Standards on Food Safety Management System (HACCP) in 1997. The food industries keenly awaiting for such an international standards implemented it in their operations and got certification through implementation in their operations. Since this was not a requirement standard, a number of countries and regions developed their own standards based on HACCP for the supply of safe food. Thus one model developed by Codex became 20 models in its application with differing scope and uneven levels of food safety.

The international Organization for standardization stepped in and brought out ISO 22000:2005 Food safety management systems - Requirements for any organization in the food chain. This standard has been developed by the experts from the food industry, along with representatives of specialized international organizations and in close cooperation with the Codex Alimentarius Commission for providing a framework of internationally harmonized requirements.

The aim of this International Standard is to harmonize on a global level the requirements for food safety management for businesses within the food chain. It is particularly intended for application by organizations that seek a more focused, coherent and integrated food safety management system than is normally required by law. It requires an organization to meet any applicable food safety related statutory and regulatory requirement through its food safety management system.

Who Should Use ISO 22000: 2005?

Since ISO 22000 is a generic food safety management standard, it can be used by any organization directly or indirectly involved in the food chain. It applies to all organizations in the food chain. It doesn't matter how complex the organization is or what size it is, ISO 22000 can help ensure the safety of its food products.

The food chain consists of the entire sequence of stages and operations involved in the creation and consumption of food products. This includes every step from initial production to final consumption. More precisely, it includes the production, processing, distribution, storage, and handling of all food and food ingredients.

The food chain also includes organizations that do not directly handle food. These include organizations that produce feed for animals. It also includes organizations that produce materials that will eventually come into contact with food or food ingredients.

Why to use ISO 22000: 2005

ISO 22000 will help you to achieve the following objectives:

- a) To establish a food safety management system (FSMS).
- b) To ensure that products do not cause adverse health effects.
- c) To demonstrate compliance with external safety requirements.
- d) To evaluate customers' food safety requirements.
- e) To provide safe products and enhance customer satisfaction.
- f) To export food products and penetrate international markets.
- g) To communicate safety issues throughout the food chain.
- h) To ensure compliance with company's food safety policy

Key Elements of ISO 22000

ISO 22000 combines generally recognized key elements to ensure food safety along the food chain (See Fig 06):

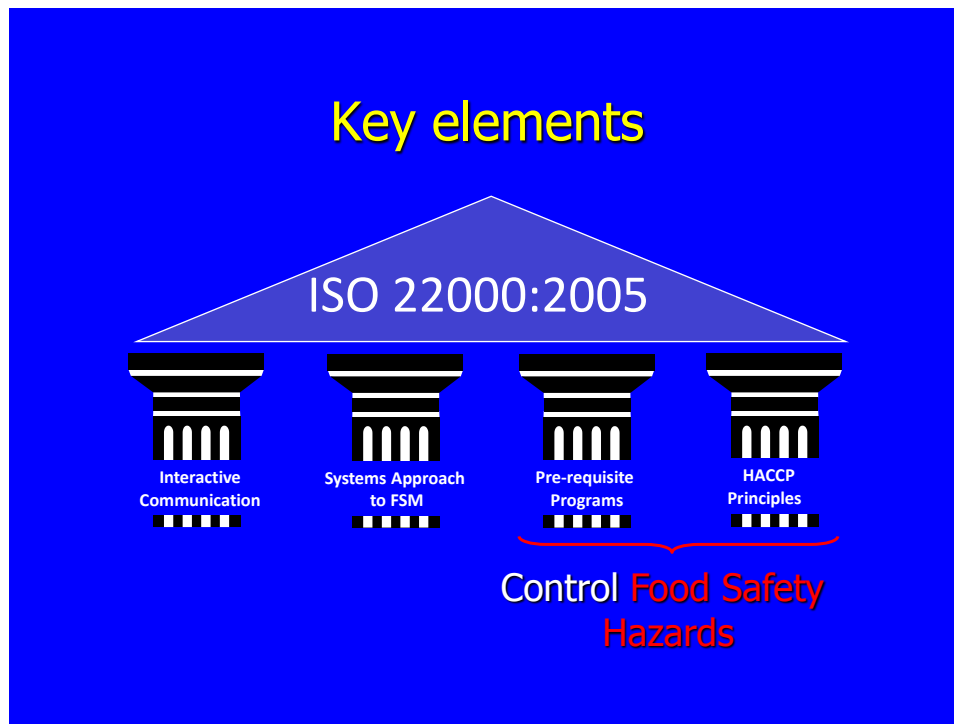


Fig 06 Key elements of ISO 2200

Interactive Communication

ISO 22000 requires that interactive communication (i.e. proactive, open, continuous dialogue with the stake holders to ensure that:

- a) all relevant food safety hazards are identified and adequately controlled at each step within the food chain through communication to all parties in the food chain.
- b) Communication with customers and suppliers, based on the information generated through systematic hazard analysis is maintained to establish customer and supplier requirements in terms of feasibility, need and impact on the end product.

Systems approach to Food Safety Management

The most effective food safety systems are designed, operated and updated within the framework of a structured management system and incorporated into the overall management activities of the organization. This provides maximum benefit for the organization and interested parties. The standard has taken due consideration of the provisions of ISO 9001:2008 in order to enhance compatibility of the two standards.

Prerequisite Programme

Prerequisite programs (PRPs) are the conditions that must be established throughout the food chain and the activities and practices that must be performed in order to establish and maintain a hygienic environment. PRPs must be suitable and be capable of providing food that is safe for human consumption. PRPs are also referred to as good hygienic practices, good agricultural practices, good production practices, good manufacturing practices, good distribution practices, and good trading practices.

Operational prerequisite programs (OPRPs) are prerequisite programs (PRPs) that are essential. They are essential because a hazard analysis has shown that they are necessary in order to control specific food safety hazards. OPRPs are used to reduce the likelihood that products will be exposed to hazards, that they will be contaminated, and that hazards will proliferate. OPRPs are also used to reduce the likelihood that the processing environment will be exposed to hazards.

HACCP Principles

ISO 22000 integrates the HACCP 7 principles (See Box) developed by the Codex Alimentarius Commission and dynamically combine it with PRPs necessary to control and reduce any food safety hazards identified for the end products delivered to the next step in the food chain to acceptable levels.

<p>HACCP PRINCIPLES</p> <ol style="list-style-type: none">1. Conduct a hazard analysis;2. Determine the Critical Control Points (CCP's);3. Establish critical limit(s);4. Establish a system to monitor control of the CCP;5. Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control;6. Establish procedures for verification to confirm that the HACCP system is working effectively; and7. Establish documentation concerning all procedures and records appropriate to these principles and their applications

ISO 22000 Food Safety Management System

FSMS is a set of interrelated or interacting elements (system) to establish policy and objectives and to achieve those objectives used to direct and control an organization with regard to food safety.

An ideal food safety management system in an enterprise should be one that:

- meets the **food safety policy** (overall intentions and direction of an enterprise related to food safety as formally expressed by top management), and achieve the measurable **objectives** related to the policy
- meets performance of “**effectiveness**” (extent to which planned activities are realized and planned results achieved) and “**efficiency**” (relationship between the results achieved and the resources needed).
- applies proven **management principles** (comprehensive and fundamental rule or belief) for leading and operating an enterprise, aimed at continually improving performance over the long term by focusing on customers while addressing the needs of all other stakeholders.

An effective FSMS should be one that:

- is well-established, documented, implemented, maintained and continually improved / updated
- has its products / services that actually meet its intended usage and are safe
- is proactive and innovative, scientific, risk-avoiding and prevention-oriented

Model of the ISO 22000

The ISO 22000 model is a continuous improvement process-based FSMS with systematic approach to developing, planning, validating, establishing, implementing, monitoring, verifying and improving the FSMS.

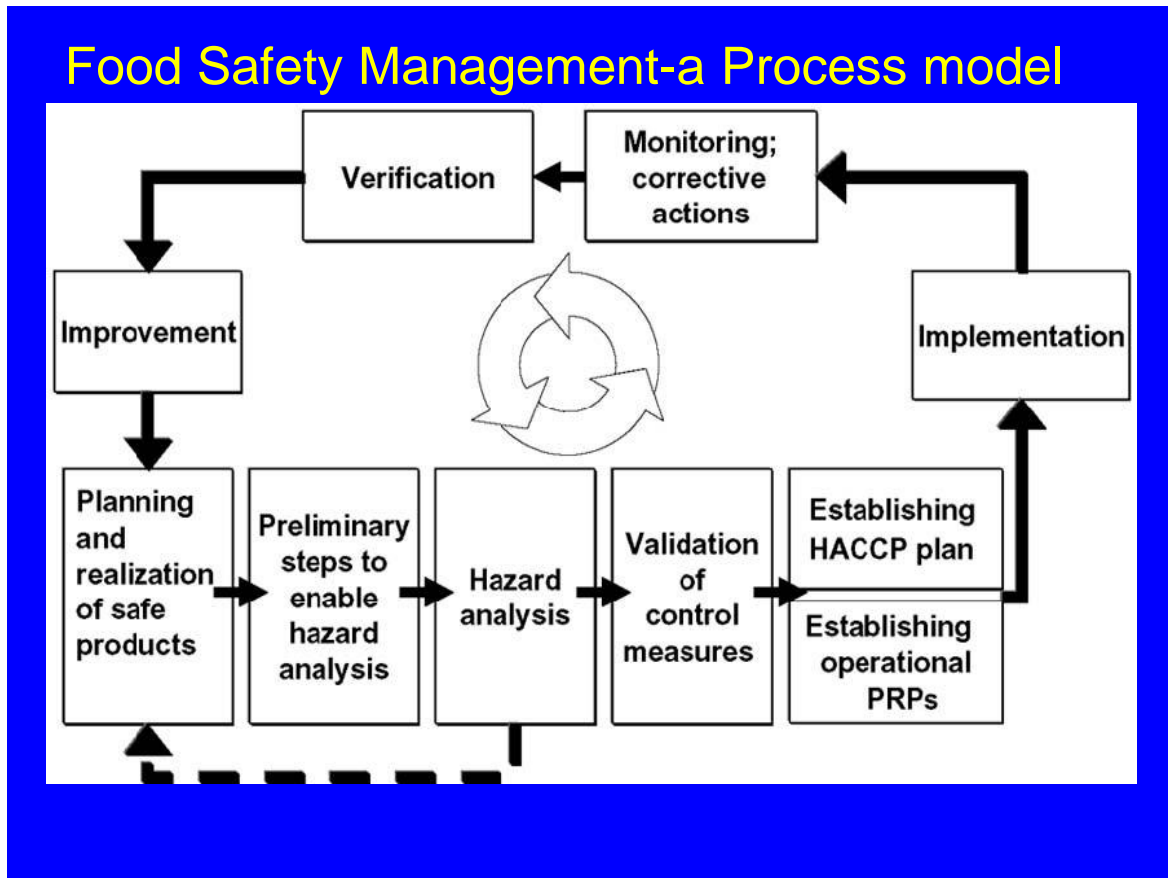


Fig 07 A model of food safety management system

Key Requirements of the ISO 22000: 2005

The ISO 22000 standard is a management system standard that sets requirements for results without setting requirements for resources. This standard sets out specific requirements for the five areas shown in the fig.08).



Fig 08 Main elements of ISO 22000

Detailed clause wise requirements of ISO 22000

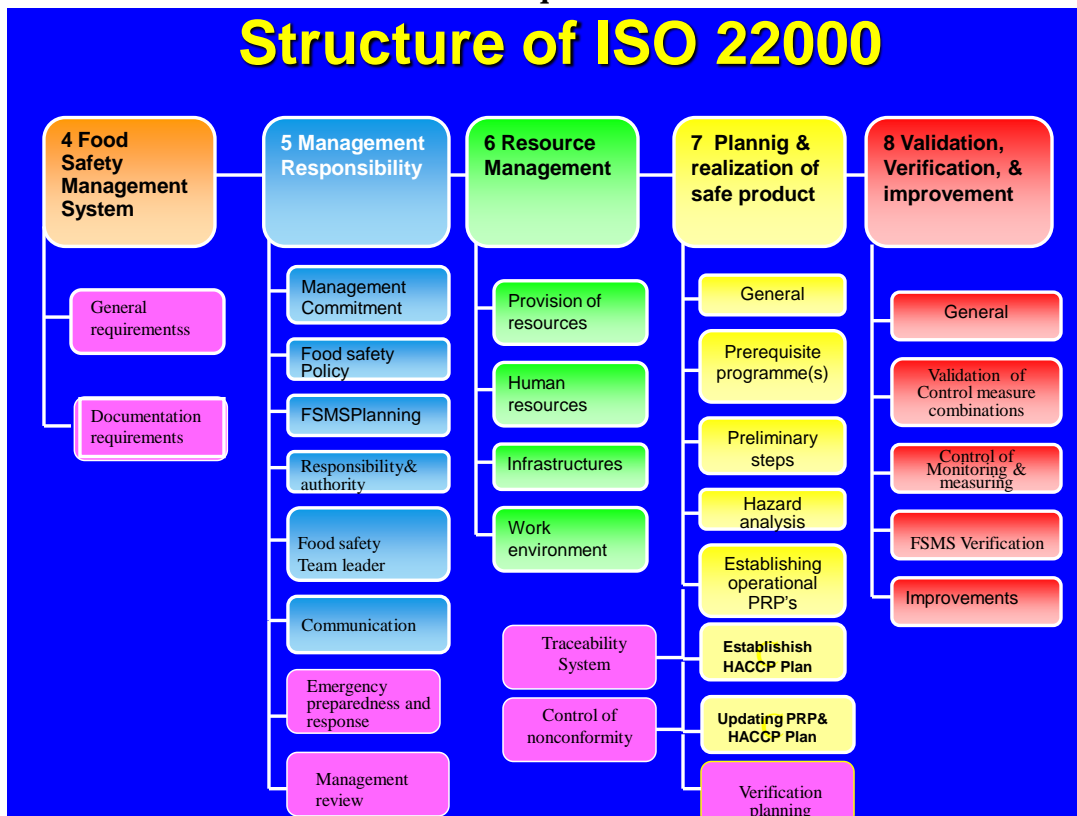


Fig 09 Complete structure of ISO 22000

Implementation model for food safety control measures

ISO 22000 requires that organizations to plan and develop processes needed for realization of safe product, implement, operate and ensure effectiveness of planned activities. This includes PRP's, Operational PRP's and/or HACCP plan. The organization uses a dynamic and systematic process approach to develop the food safety management system. This is achieved through effective development, implementation, monitoring of planned activities, maintenance and verification of control measures, updating the food processes and process environment, and through appropriate actions in the event of the production of nonconformities.

ISO 22000 groups control measures into three groups(See Fig 10):

- i) Prerequisite programmes (PRPs) that manage the basic conditions and activities; the PRPs are not selected for the purpose of controlling specific identified hazards but for the purpose of maintaining a hygienic production, processing and/or handling environment;
- ii) Operational prerequisite programmes (OPRPs) that manage those control measures that the hazard analysis identifies as necessary to control identified hazards to acceptable levels, and which are not otherwise managed by the HACCP plan; and
- iii) HACCP plan to manage those control measures that the hazard analysis identifies as necessary to control identified hazards to acceptable levels, and which are applied at critical control points (CCP's).

FOOD SAFETY MANAGENT SYSTEM PLAN		
CONSTITUTION OF A MULTIDISCIPLINARY FOOD SAFETY TEAM		
Gathering information for prerequisites	Gathering information for hazard analysis	
1. Recommended International Code of Practice General Principles of FoodHygiene(CAC/RCP1(1969)Rev-4 (2003)	1. Product characteristics a) Raw materials, ingredients and product-contact materials b) Characteristics of end products	
2. Industry specific guidelines /codes	2. Intended use	
3. Statutory & regulatory requirements in that specific area	3. Flow diagrams, onsite verification. Process steps and control measures	
	HAZARD ASSESSMENT	
	Categorization of Hazards	
	Significant Hazards	
	OPRP's	CCP's
Prerequisite programmes (PRP's)	OPR Programme	HACCP Plan
INSTITUTION OF FOOD SAFETY CONTROL MEASURES		
PRP's	OPR Programme	HACCP Plan
	VALIDATION	
IMPLEMENTATION OF CONTROL MEASURES		
Prerequisite Programme	Operational Prerequisite Programme (OPRP)	HACCP Plan
	MONITORING	
	OPRP Programme	HACCP Plan
VERIFICATION OF CONTROL MEASURES		
PRP's	OPRP Programme	HACCP Plan
Ongoing verification	Ongoing verification	Ongoing verification
Internal Audit	Internal Audit	Internal Audit
Analysis of results of verification activities	Analysis of results of verification activities	Analysis of results of verification activities
PERIODIC UPDATION OF THE SYSTEM		

Fig 10 A working madel

ISO 22000 Certification

ISO 22000 is designed to be used for certification/registration purposes. In other words, once company has established a FSMS that meets ISO's requirements, it can apply for certification to a certification agency to audit the system. If certification agency find after audit that the implemented system meets the ISO 22000 requirements, it will issue an official certificate that states that company's FSMS meets the food safety requirements.

However, it is not mandatory to go for certification. A company can be in compliance without being formally certified by an accredited certification agency. It can self assess the system implemented and declare ISO 22000 compliant company. But company customers and business partners are not likely to accept that the company has an effective FSMS if it is not certified.

Benefits of ISO 22000 for users

Organizations implementing the standard will benefit from:

- Organized and targeted communication among trade partners ;
- Optimization of resources (internally and along the food chain);
- Improved documentation;
- Better planning, less post process verification;
- More efficient and dynamic control of food safety hazards;
- All control measures subjected to hazard analysis;
- Systematic management of prerequisite programmes;
- Wide application because it is focused on end results;
- Valid basis for taking decisions;
- Increased due diligence;
- Control focused on what is necessary, and
- Saving resources by reducing overlapping system audits

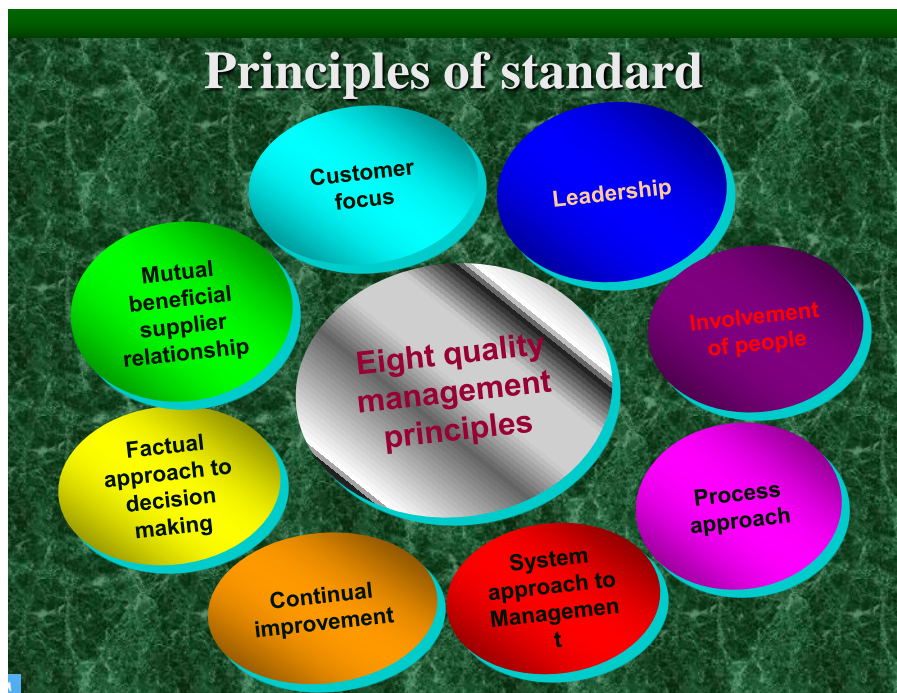
ISO is the most important of international standard setting organisations. It is a world federation of national standards bodies, an international non-governmental organisation with a mandate to prepare and propagate voluntary consensus based international standards.

ISO develops standards through technical committee represented by concern stakeholder. All its standards are voluntary in nature. However, given its credibility as the most internationally accepted organisation, ISO standards have considerable trade affects due to their wide use in international trade.

Introduction to ISO 9001

In pursuit of excellence, quality has taken a tangible form with the advent of ISO 9000 series of standards. It is recognized internationally as a bench mark for measuring quality. It provides measures of an organization's ability to consistently deliver a product or service that meets the requirements of its customers. It also provides a framework for continuous improvement in quality. This is the reason why ISO 9000 series of standards have become the subject of intense focus the world-wide. It is becoming increasingly important both as a potential market place requirement and as a marketable company feature.

ISO 9000 series is generic in nature and are relevant to all types of business whether it be manufacturing industries or service establishments . The first version of ISO 9001 was published in 1987 and since then it has undergone 4 revisions and the latest one is ISO 9001 2008 version. In 1998, ISO published eight QMS principles on which are embedded into the elements of the ISO 9001See Fig ---):.



ISO 9001:2008 Clauses

The standard is divided in eight main clauses as listed below:

- 1) Scope
- 2) Normative references
- 3) Terms and definitions
- 4) Quality Management System

- 5) Management Responsibility
- 6) Resource Management
- 7) Product realization
- 8) Measurement, analysis and improvements

Documentation Structure of ISO 9001: 2008

The documentation structure generally consists of different hierarchical levels. The different hierarchical levels are given in fig ---.



1. Quality policy

The quality policy of the organization should:

- a) Be appropriate to the purpose of the organization;
- b) Include a commitment to comply with requirements and continually improve the effectiveness of quality management system;
- c) provide a framework for establishing and reviewing quality objectives;
- d) be communicated and understood within the organization; and
- e) be reviewed for continuing suitability.

2. Quality Objective

The organization establishes quality objectives including those needed to meet requirements for products at relevant functions and levels within the organization. The Quality objectives should be consistent with the quality policy and be SMART



3. Quality Manual

Quality manual is a document which explains how the requirements of ISO 9001:2000 are planned to be fulfilled by the organisation taking into consideration the type of product/service offered, complexity of processing methods, competence of operating personnel and number of sites where the Quality Management System is implemented.

The manual also contains the general information about the organisation like:

- Establishment and evolution over the years.
- The position in the supply chain.
- The suppliers and customers in the chain.
- The site related details.
- Quality policy and related objectives.
- Organisation chart.
- Applicable statutory and regulatory requirements.
- The structure of QMS documentation.
- The site map from external and internal point of view.
- Roles and responsibilities.
- Details of external resources utilized.

The manual gives reference to or contains all the elements of the QMS documentation. It acts as a reference document for training of new team members of the organisation, communicating the QMS overview to National and International customers and as a supporting document during any statutory and regulatory interaction.

The manual is required to be reviewed periodically by the top management in management review meetings.

4. Procedures

The procedures in ISO 9001 fall in two categories- the documented procedures which are mandatory and procedures needed by the organization depending on its activities (See Fig--).

4.1 The mandatory procedures are:

- Control of documents
- Control of records
- Internal audit
- Control of non-conformity
- Corrective action
- Preventive action

The contents of the documented procedures are as follows:

- **Control of documents:** This procedure contains information related to approval of documents, re-approval of documents, identification of changes, identification of current revision status, availability of relevant versions at points of use, legibility, documents of external origin and management of obsolete documents. A master list of documents is prepared which gives details like document name, document number, issue date, current revision number and date, information about preparation, review and approval of the documents.
- **Control of records:** This procedure defines controls needed for the identification, storage, protection, retrieval, retention time and disposal of records. A master list of records is prepared which gives details like - record name, associated format number and issue date, version of record (soft/hard), record originating process, etc.
- **Internal audits:** This procedure contains the responsibility and requirements for planning and conducting audits, and for reporting results and records. It also contains the details of competence of the internal audit team members.
- **Control of non-conforming product:** This procedure contains the information about the identification and assessment of potentially non-conforming end products to determine their proper handling and review of the corrections carried out. It also specifies the records required to be maintained.
- **Corrective action:** This procedure contains information related to review of non-conformities (including customer complaints), review of trends in monitoring results, determination of causes of non-conformities, evaluating the need for the action, determining and implementing the actions needed, recording the results and reviewing corrective actions taken.
- **Preventive action:** This procedure contains information related to review of potential non-conformities (including customer complaints), review of trends in monitoring results, determination of causes of potential non-conformities, evaluating the need for the action, determining and implementing the actions needed, recording the results and reviewing corrective actions taken.

4.2 Procedures required for planning, operation & control

These procedures vary with the operational complexities of the organization. These normally include:

- Procedure for management review
- Procedure for competence, creating awareness and providing training
- Procedure for maintenance of machinery and equipment
- Procedure for determination, review and communication of customer requirement
- Procedure for purchase of product and services
- Procedure for evaluation, selection and re-evaluation of suppliers
- Procedure for verification of purchased product
- Procedure for identification and traceability
- Procedure for receipt, storage and dispatch of finished goods,
- Procedure for control and calibration of measuring devices
- Procedure for determination of customer satisfaction level
- Procedure for dealing with customer complaints.
- Procedure for measuring and monitoring of final products

5. Work Instructions

The work instructions provide instructional guidance to operational personnel for carrying out micro-activities outlined in different procedures. The details of the contents depend on the competence of the operating personnel, complexity of the process and the nature of product/service. These are normally in imperative form of English. These should be accessible to the operating personnel preferably near their work area. Work instructions should be available in the (local) language, which the operational workforce understands. These documents are to be drafted with the help of the operational personnel and may contain the pictorial presentation of work activities so that non-conformities are avoided.

6. Formats and Records

Records are established to provide evidence of conformity to requirements and of effective operation of the quality management system.

The records are required to be maintained in pre-determined formats as an evidence of activities carried out as per defined quality management system:

- Current competence of all concerned
- Calibration of measuring and monitoring instruments
- Outcome of internal audits
- Output of management review
- Corrective actions
- Training and effectiveness of training given
- Product design input determination
- Product design review
- Product design verification
- Product design validation
- Product design change review
- Corrections of non-conforming product
- Verification of purchased product
- Identification of product where traceability is a requirement
- Release of end product
- Receipt and issue of material/products in stores
- Maintenance (breakdown and preventive)
- Quality objective tracking
- Document change control
- Document distribution

ACCREDITATION OF CERTIFICATION BODIES

Food safety and quality management systems are widely implemented and certified by certification agencies for acceptance of the products and services in the world market. This implies that certification agencies must be credible. How does this credibility come? To exercise control over the operation of certification bodies, accreditation system has been established. There is an International Accreditation Forum (IAF) whose member accreditation bodies in respective countries enjoy acceptance in the world market. In India Quality Council of India, the national accreditation body has been established to oversee the functioning of client certification bodies complying with the ISO/IEC 17021:2006 Conformity Assessment: Requirements for bodies providing audit and certification of management systems. QCI is a member of IAF.

Though accreditation of certification bodies is voluntary, most of the certification bodies operating in India are accredited due commercial compulsions in the market place.