

**TRAINING MANUAL FOR FOOD SAFETY REGULATORS**

**Vol V – KEY ASPECTS TO ENSURE FOOD SAFETY**

**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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## **Introduction**

Safety of food and water is a requirement of public health. Safety refers to all those hazards which make food injurious to health. These hazards arise from improper agricultural practices, poor hygiene at all stages of the food chain, lack of preventive controls in food processing operations, misuse of chemicals, contaminated inputs, or inappropriate storage and handling. Specific concerns about food hazards are chemical and microbiological contaminants, biological toxins, pesticide residues, veterinary drug residues, and allergens.

**Food and nutrition surveillance** is the collection, integration, analysis, interpretation and dissemination of data related to food and nutrient intakes; food safety and environmental exposures; nutritional status; nutrition-related health outcomes; knowledge, attitudes and practices about healthy eating and other related lifestyle factors; demographics; personal and environmental health determinants; and factors affecting access to safe, affordable, nutritious foods.

Public health surveillance of food borne disease is critical to the performance of food safety systems (Hedberg and Hirschhorn, 1996). Surveillance of human illness and epidemiological investigation of outbreaks can identify previously unknown hazards and provide feedback on the effectiveness of existing control measures. For example, the investigation of a multistate outbreak of *Salmonella* Stanley infection in 1995 led to the first identification of alfalfa sprouts as a vehicle for *Salmonella*. An outbreak of *Salmonella* enteritidis infections associated with commercially processed ice cream revealed a failure of the company's Hazard Analysis Critical Control Point plan to control for hazards in the transportation of ingredients. *The development of national and international surveillance networks is one of the effective ways to identify and control these widely dispersed outbreaks.*

An efficient food surveillance system must -

- ensure that only safe and wholesome foods are marketed
- take decisions based on science
- empower authorities to detect sources of contamination and take necessary action to prevent contaminated foods from reaching the consumer
- enforce compliance by farmers, manufacturers, distributors, importers, and other stakeholders
- be transparent and promote public confidence

## **International Practices: Some Examples**

Regulatory agencies around the world adopt a multi-stakeholders involvement to deal with food safety matters. These stakeholders include Ministries – Agriculture, Food Processing, Health, Consumer Affairs; R & D institutions; Consumer Organizations; Analytical Laboratories – both Government and Private Sector; NGOs; Farming Community and Food Industry. The food safety committees / authority examine all aspects of chemical / microbiological contamination, conduct total diet surveys, carry out risk analysis, formulate standards and suggest appropriate action including policies.

## **United Kingdom**

### ***UK Food Surveillance system***

The **Food Standards Agency** has commissioned the introduction, development and rollout of a UK Food Surveillance System (UKFSS).

The project was conceived in 2001. The UKFSS is a national database that centrally holds a record of all food samples submitted for food analysis by official control laboratories on

behalf of local authorities and port health authorities. The system is currently being rolled out across England and Wales, and is fully operational in Northern Ireland and Scotland.

This project was initially developed by Food Standards Agency Scotland (FSAS) in conjunction with Health Protection Scotland (HPS) to provide a standardised data capture, storage, querying and reporting functionality for the microbiological and chemical analysis of food samples in Scotland.

Following this successful development, the Food Standards Agency (FSA) commissioned a consulting firm to assess the Food Surveillance System (FSS). This assessment concluded the system as stable, robust, secure and efficient and therefore 'fit for purpose'. A pilot to assess rolling-out the system outside Scotland started in April 2003 and concentrated on chemical contaminant analysis sampling involving six public analyst laboratories and their partner councils in England.

Additional work was commissioned by the FSA and developed by HPS to develop the FSS across the whole of the UK to standardise data capture, storage, querying and reporting functionality for the microbiological and chemical analysis of animal feeds samples. UKFSS is therefore now able to collect validated sample data across Great Britain and Northern Ireland for food and animal feeds for all enforcement authorities.

The system has now been used routinely by 29 out of the 32 local authorities in Scotland since 2005 and has been fully operational in Northern Ireland since January 2007. The current phase, Phase 2 completes the rollout of the UKFSS to all local authorities in England and Wales. The project will also continue to promote use of the database throughout Scotland and Northern Ireland as a risk-based sampling tool for local authorities and to monitor national trends in food safety and standards.

Reports have now been produced on microbiological and chemical food sampling conducted in Scotland and Northern Ireland using UKFSS data from 2007.

The next stage of this 5-year project develops the involvement wider to include The Health Protection Agency in England (Phase 3), the UK Port Health Authority (Phase 4) and the National Health Protection Service in Wales (Phase 5).

## **Project components**

- **Surveillance**

Data gathering by sampling officers will be conducted in the field. The officer will enter relevant information on food related premises into a database on a laptop or mobile computer along with sample identifiers at the time samples are taken. Samples will be identified and submitted to an associated public analyst or NHS Scotland laboratory. All laboratories participating in this system will require to be UKAS accredited and on the EU Official List for food law enforcement.

- **Sample Analysis**

The laboratories will perform the appropriate analysis/examination and enter the results into their local database system. The public analyst laboratories are using a dedicated laboratory information management system while NHS laboratories are using a range of heterogeneous systems.

- **Data Processing**

Data will be extracted from the bespoke software system designed for capturing food /animal feeds sampling data into the corresponding laboratory database. The data will be uploaded into the centralised food analysis database at HPS.

- **Data Abstraction and Reporting**

The uploaded surveillance and analysis data will be available for querying via a secure system on a web server at HPS. This will provide controlled access to the centralised database by local councils, public analysts, NHS laboratories and the FSAS. The database may be queried and reports obtained using an authorised internet connection to the web server.

- **Linking to External Agencies and other Sources**

It is the intention through the development of this system to have links into any comparable surveillance systems being developed in the longer term in Europe. Investigations are also taking place on the validity of linking the food data to human health data, veterinary data and, where appropriate, commercially held quality-control data. Linking these data with the proposed system will require alignment on interface processes, but, given a full description of the external data sources, the extension to provide comparative analysis reports based upon gathered and external data should prove relatively straightforward.

- **Access Levels**

Access to the database will be provided to individual councils, laboratories and the Food Standards Agency. In general, however, it is anticipated that local councils will have full access to all data provided by them initially through the individual samples and summarised data at liaison group and national level. Similarly the FSAS will have access to summary information from all councils based on the data required for official returns (thus removing the need for double entry at council level). Reports will be generated on routine areas of surveillance on quarterly, six-monthly and an annual basis, however individual querying can be undertaken at local or national level and individual councils will have the facility to obtain pre-determined reports automatically generated.

### **Procedure to carry out Food Surveillance in jurisdiction to identify potentially hazardous foods**

Food is inspected in accordance with relevant legislation, the Food Law Code of Practice (Scotland) and relevant guidance to ensure that it meets the legally prescribed standards.

#### **1. Chemical sampling**

##### **a) Approved premises**

The importance of sampling more intensively from manufacturers and processors is being recognized. Accordingly, food from approved food premises, which manufacture or process foods, will be sampled at least twice or three times annually. The following table shows the differing types of approved premises and the appropriate sampling visit frequency;

<b>Approval category</b>	<b>Visit frequency per year</b>
Meat products	3
Minced meat or meat preparations	3
Fishery products	2
Egg products	2
Shellfish purification or despatch centre	2
Dairy products	2

The sample visit frequency is at the discretion of the Business Regulation Service Manager, Food Hygiene Regulation Manager or Food Standards Regulation Manager and may be increased for premises where;

- the area of distribution of products and the range of outlets is substantial,
- the consequences of quality failures are significant,
- the risk associated with the process is high and efficiency of controls important,
- the number of product lines is extensive,
- a large number of ingredients make up the final product,
- there is a history of failure to meet the required standards,
- local knowledge indicates increased risk, or
- new legislation is introduced.

Samples will, wherever possible, be taken from approved premises two months prior to planned food standards inspections to allow the inspecting officers to have the results at

their disposal. Additional samples may also be taken by inspecting officers during, or following, any inspection or other visit.

Where the sampling cycle is more frequent than the inspection frequency, adverse results will be actioned and investigated as necessary.

#### **b) Routine sampling**

Non-manufacturing premises or approved premises which are predominantly retailers or caterers will be sampled at a frequency based on their food standards risk score. The sampling frequency indicated by the revised Food Law Code of Practice (Scotland) is as follows:

<b>Risk category</b>	<b>Minimum sample frequency</b>
A	Once per year
B	Once every two years
C	Once every three years

Wherever possible samples will be taken from non-manufacturing or approved premises approximately two months prior to planned food standards inspections so that analysis results are available prior to and at the inspection. Additional samples may also be taken by inspecting officers during, or following, any inspection or other visit.

At the discretion of the Business Regulation Manager or Food Hygiene Regulation Manager or Food Standards Regulation Manager, the frequency and number of samples may be increased, as necessary, where;

- there is a history of failure to meet the required standards,
- local knowledge of traders or practices indicates risk, or
- new legislation is introduced.

#### **c) Selecting food to be sampled**

Once premises have been selected for chemical sampling, appropriate food(s) or food ingredient(s) shall be sampled with regard given to the type of premises and processes undertaken. The food(s) or ingredient(s) chosen will have a statutory compositional standard or recommended compositional standard, which it can be tested against. The food should also be one which is manufactured or processed or prepared on the premises.

#### **d) Formal samples**

In accordance with the enforcement policy which promotes action which is consistent, fair and proportionate, formal enforcement samples will in general be taken after routine samples have been found to fail statutory requirements, and where appropriate, no satisfactory remedial action has been instigated by the producer / manufacturer or retailer.

Formal enforcement samples will be taken immediately when:

- the potential breach of statutory requirements is significant,
- complaints of a serious nature have been received, or
- deemed necessary by the Business Regulation Manager or Food Hygiene Regulation Manager or Food Standards Regulation Manager

Formal enforcement samples will be taken over and above routine samples.

#### **e) Special investigations**

Where there is an incident which requires a special investigation, then appropriate samples will be taken, after consultation with appointed public analyst if required, to assist in the investigation.

#### **f) Enhanced remote transit sheds**

Appropriate samples will be taken from any food received at an enhanced remote transit shed in accordance with the imported food procedure.

## 2. Bacteriological sampling

### a) Approved premises

The importance of frequent bacteriological sampling from premises which manufacture or process food is being recognized. Accordingly, food from premises which have received approval under product specific legislation will be sampled at least twice or thrice annually. The following table shows the differing types of approved premises and the appropriate sampling visit frequency.

<b>Approval category</b>	<b>Visit frequency per year</b>
Meat products	3
Minced meat or meat preparations	3
Fishery products	2
Egg products	2
Shellfish purification or despatch centre	2
Dairy products	2

The sample visit frequency is at the discretion of the Business Regulation Manager, Food Hygiene Regulation Manager or Food Standards Regulation Manager and may be increased for premises where;

- the area of distribution of products and the range of outlets is substantial,
- the consequences of quality failures are significant,
- the risk associated with the process is high and the efficiency of controls important,
- the number of product lines is extensive,
- a large number of ingredients make up the final product,
- there is a history of failure to meet the required standards,
- local knowledge indicates increased risk, or
- new legislation is introduced.

Samples will, wherever possible, be taken from approved premises prior to planned food standards inspections to allow the inspecting officer to have the results at their disposal. Additional samples may also be taken by inspecting officers during, or following, any inspection or other visit.

Where the sampling cycle is more frequent than the inspection frequency, adverse results will be actioned and investigated as necessary.

### b) Routine sampling

Non-manufacturing premises or approved premises, which are predominantly retailers or caterers, will be sampled at a frequency based on their food standards risk score. The sampling frequency indicated by the revised Code of Practice Scotland is as follows:

<b>Risk category</b>	<b>Minimum sampling frequency</b>
A	Once per year
B	Once every two years
C	Once every three years

Wherever possible samples will be taken from non-manufacturing or approved premises prior to planned food hygiene or standards inspections so that analysis results are available to be viewed and discussed at the inspection. Additional samples may also be taken by inspecting officers during, or following, any inspection or other visit..

At the discretion of the Business Regulation Manager, Food Hygiene Regulation Manager or Food Standards Regulation Manager, the frequency and number of samples may be increased as necessary where;

- there is a history of failure to meet the required standards,
- local knowledge of traders or practices indicates risk, or
- new legislation is introduced.

### **c) Selecting foods to be sampled**

Once premises have been selected for bacteriological sampling, appropriate food(s) or food ingredient(s) shall be sampled with regard given to the type premises and processes undertaken. The food to be sampled should have been handled, prepared or processed on the premises.

If the food(s) or ingredient(s) chosen has statutory standard to meet, it shall be examined accordingly. Otherwise, foods shall be examined to ensure they have been produced in a hygienic manner and are safe to eat.

### **d) Formal samples**

In accordance with the enforcement policy which promotes action which is consistent, fair and proportionate, formal enforcement samples will in general be taken after routine samples have been found to fail statutory requirements, and where appropriate, no satisfactory remedial action has been instigated by the producer / manufacturer or retailer.

Formal enforcement samples will be taken immediately when;

- the potential breach of statutory requirements is significant,
- complaints of a serious nature have been received, or
- deemed necessary by the Business Regulation Manager or Food Hygiene Regulation Manager or Food Standards Regulation Manager

Formal enforcement samples will be taken over and above routine samples.

### **e) Special investigations**

Where there is an incident which requires special investigation, the appropriate samples including swabs will be taken, after consultation with appointed food examiner if required, to assist in the investigation.

### **f) Enhanced remote transit sheds**

Appropriate samples will be taken of any food received at an enhanced remote transit shed in accordance with our imported food procedure.

## **Sampling procedure**

All food sampling undertaken by the enforcement officers will be carried out in accordance with;

- the Food Safety Act 1990,
- the Food Law Code of Practice (Scotland) (Chapter 6),
- the Food Law Practice Guidance (Scotland) (Chapter 6),
- the Food Safety (Sampling and Qualifications) Regulations 1990, and
- the Food Hygiene (Scotland) Regulations 2006.

The enforcement policy on food safety legislation and the quality assurance documentation both advise that enforcement action and sampling should comply with the above documentation.

The undernoted ISO 9001: 2000 quality assurance procedures are relevant to food sampling and should be read in conjunction with this document;

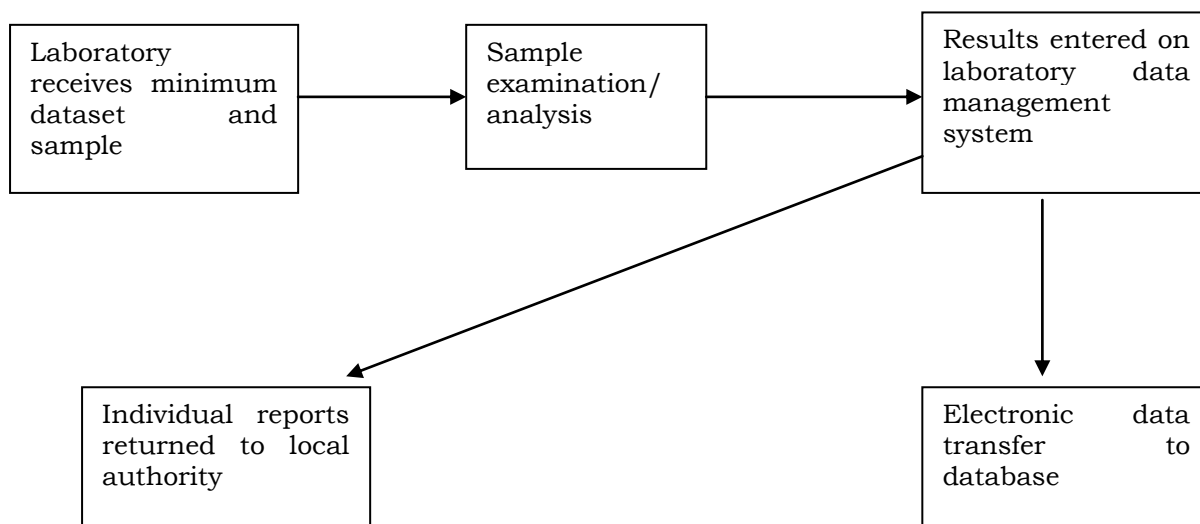
- food and water monitoring, surveillance & control (QAP5.3), and



- sampling (QAP4) which deals with the identification, traceability, handling, packaging and delivery of products and samples.

All documented procedures relating to food sampling are reviewed periodically and amended where necessary.

Minimum quantities of food to be submitted for analysis or examination are in accordance with the guidance issued by the appointed food examiner or public analyst.



## Steps to be taken for reporting and dealing with food incidents

### 1. Reporting

#### Incident report form for food and feed recalls and withdrawals (Food Standards Agency)

The Agency has produced an **online form (Annexure 1)** so food and feed businesses can notify the Agency if they need to withdraw products from the market. The form can also be used by food authorities to report incidents. They should also notify the local authority where the food business operator is based, or, in the case of imports, the relevant Port Health Authority. When it is completed and submitted, it will notify the Agency's Food Incidents Branch of the withdrawal/recall.

The reporting system, which has a secure login feature, allows users to save and print the data they are submitting about new food incidents and products known to be affected. For each report sent to the Agency, the user will be provided with an automatic electronic receipt and an individual reference number.

The Agency's Incidents Branch will verify all information received, to ensure its authenticity. After verification, the information will be automatically included in the Agency's Incidents Database. This will greatly improve the handling and bringing together of food incident information, particularly where long lists of products need to be sent to the Agency.

### 2. Dealing

#### a) Food Standards Agency Incident Response Protocol

Guidance for businesses and others on how to respond to a food or feed incident is available. A protocol has also been developed for Food Standards Agency (FSA) staff so they have a clear understanding of their respective roles and responsibilities during an incident, and how they fit into the overall process.

- **Definition of an incident**

An incident is any event where, based on the information available, there are concerns about actual or suspected threats to the safety or quality of food that could require intervention to protect consumers interests.

- **Classification of incidents**

Incidents are classified as either High, Medium or Low. To determine which incidents are High, Medium or Low, a classification matrix has been developed.

The classification level should be regularly reviewed during the course of the incident and updated as appropriate.

It is the responsibility of the Investigating Officer to ensure that each incident is classified, using the classification matrix as a guide.

- **Notification**

Any part of the Food Standards Agency may receive an incident report. Any Agency official receiving information meeting the criteria must pass the information immediately to the Incidents Branch.

The Agency also receives incident reports via the European Commission Rapid Alert System for Food and Feed (RASFF). The Incidents Branch will log all incidents on the Agency's UK-wide Incidents Database.

The Incident Response Protocol should be activated as soon as the Agency is notified of any incident. All parts of the Food Standards Agency adhere to the principles laid out in the Protocol.

- **Roles & Responsibilities**

The majority of incidents that the Agency deals with are classified as either Low or Medium. During High incidents, where senior management may need to be more actively involved in the process, different roles and responsibilities apply.

Unless determined otherwise by the Strategic Director appointed for a high level incident, communications with Ministers, government departments, local authorities, media and food business operators in devolved countries will be managed by the devolved offices.

- **Incidents branch**

The Incidents Branch will act as the first point of contact with external stakeholders for incidents and will maintain the official audit trail for the investigation by co-ordinating the logging, collation and distribution of information required during the investigation.

## **b) North Lanarkshire Council response**

All food alerts and incidents will be dealt with in accordance with the provisions of the "Food Law Code of Practice (Scotland)".

Responsibility for dealing with food hazards and incidents rests with the Business Regulation Manager or in his absence the Food Hygiene Regulation/Food Standards Regulation Managers. The Head of Protective Services is to be kept informed and requested to provide assistance, if necessary.

If a food hazard has resulted in an outbreak of foodborne illness then the matter will be discussed with the relevant health board and consideration will be given to the activation of the outbreak control plan.

Serious local outbreaks will be immediately notified to Health Protection Service and the Food Standards Agency.

Food Incidents which are contraventions of food law but not food hazards will be resolved locally with the food business concerned.

On identification of a food hazard an assessment will be made to determine the likely scale, extent and severity of the risk to public health or safety of the hazard.

Action will be taken at the earliest opportunity to protect public health which may include the recall or seizure of foodstuffs and/or closure of premises.

Serious localised food hazards and non-localised food hazards will be notified to the Food Standards Agency using a copy of the incident report form.

In regard to Food Alert for Action (FAFA) the action to be taken will be to a level of at least that which is specified within the FAFA. Appropriate arrangements will be made by the Business Regulation Manager, or in his absence, the Food Hygiene Regulation/Food Standards Regulation Manager to ensure that adequate resources are made available to quickly and effectively respond to the FAFA.

So far as Food Alert for Information (FAFI) are concerned, details will be provided to all staff for background purposes and also in order that they have the opportunity of making further checks, as appropriate.

Contact details of other relevant bodies and local authorities are contained within the council's emergency contact handbook and also the Food Standards Agency's Directory of Environmental Health Departments.

An out of office hours stand by service is provided to deal with emergency enquiries.

In regard to food alerts received outside normal working hours, the standby officer has discretion to take appropriate action regarding food alerts but must immediately notify the Business Regulation Manager using the telephone number listed in the stand by folder in the event of an emergency. Arrangements have been made to access council offices, out of hours.

Where the Business Regulation Manager is unavailable then the standby officer should alert Food Hygiene Regulation/Food Standards Regulation Managers.

## **Food Alerts**

Food Alerts are the FSA's way of letting local authorities and consumers know about problems associated with food and, in some cases, provide details of specific action to be taken.

They are issued 'For Information' where a solution to the problem has been put in place or 'For Action' where intervention by enforcement authorities is required. They are often issued in conjunction with a product withdrawal or recall by a manufacturer, retailer or distributor.

## **Recent Food Alert**

Tangerine Confectionery recalls certain batches of Butterkist Sweet Microwave Popcorn due to the potential presence of rice weevil (*Sitophilus oryzae*) within the product.

Friday 12 March 2010

Food Alert: for Information

Ref: 09/2010

Tangerine Confectionery has recalled four batch codes of Butterkist Sweet Microwave Popcorn due to the potential presence of rice weevil (*Sitophilus oryzae*) within the product.

Tangerine Confectionery has undertaken a product recall of 4 batch codes and point-of-sale notices will be displayed in relevant stores to notify the public of the recall. The notice advises consumers of the reason for the recall and the actions they should take if they have already purchased the affected product.

### **The Rapid Alert System for Food and Feed (RASFF)**

The **Health and Consumers Directorate-General of the European Commission** manages the Rapid Alert System for food and Feed (RASFF).

The RASFF was put in place to provide food and feed control authorities with an effective tool to exchange information about measures taken responding to serious risks detected in relation to foods. This exchange of information helps Member States to act more rapidly and in a coordinated manner in response to a health threat caused by food or feed. Its effectiveness is ensured by keeping its structure simple: it consists essentially of clearly identified contact points in the Commission, European Food Safety Authority (EFSA), European Free Trade Association (EFTA) and at national level in member countries, exchanging information in a clear and structured way by means of templates.

### **How are RASFF notifications made?**

RASFF members each have a designated contact point that is responsible for sending RASFF notifications to the Commission.

Food inspectors have inspected a product on the market or at the border. They may have taken samples and have received the results from the laboratory. It is found that the product is non-complaint and needs to be reported inside the national system. The authority decides if the issue falls under the scope of the RASFF and reports it to the national RASFF contact point. The national contact point verifies and completes the RASFF notification where necessary and forwards it to the European Commission. It uses a RASFF notification form to provide details of the findings and measures taken and adds relevant documents such as bills, lists of companies having received the products, analytical reports, etc. Templates are used to collect all information on the RASFF notification form.

### **What is the responsibility of the European Commission in the RASFF?**

The Commission, responsible for managing the system, is providing knowledge and a technological platform to facilitate transmission and handling of the RASFF notifications. It receives all notifications from members of the network and performs the following checks on them, prior to making them available to all members of the network:

- a completeness check
- legislative requirements
- verification if the subject of the notification falls within the scope of the RASFF
- translation into English of the information on the notification form
- classification of the notification
- members of the network flagged for action
- recurrences of similar problems relating to the same professional operator and/or hazard/country of origin.

The Commission must inform a non-member of RASFF (third countries) if a product subject to a notification has been exported to that country or when a product originating from that country has been the subject of a notification. In this way, the country can take corrective measures where needed and appropriate.

**Sample Food Incident Report Form for Food Authorities**

**(Draft –subject to modification)**

**FOOD INCIDENT REPORT FORM**

TO BE COMPLETED BY THE INVESTIGATING OFFICER/REPRESENTATIVE AND FAXED TO THE AGENCY ON: Tel. No. ....

1. Reporting Food Authority’s name and address:
2. Name of reporting Officer including telephone, fax and e-mail details:
3. Date and time initial information received by Food Authority:
4. Initial information received by:
5. Received from (include Local Authority, Designated officer etc, address, telephone number and contact name where possible):
6. Method (telephone/fax/letter/other):
7. Brief description of incident:
8. Type of contamination:
9. Description of product  
Type of Product:  
Product Name:  
Brand Name:  
Batch Code/s:  
Description of Packaging:  
Pack Size:  
Durability Date/s or Code/s:  
Country of Origin:  
Importer/Distributor (including contact details):  
Manufacturer (including contact details):
10. Has clinical illness occurred?  
Details (type of illness, symptoms, numbers of consumers affected etc):
11. Full details of distribution (including Importing Countries) e.g. quantities/areas, and when the particular product/batch in question was first placed on the market:
12. Is the manufacturer/retailer/supplier aware of the incident, if so what are their proposals for dealing with it?

13. Assessment of hazard (please circle):

Local	Retail
Regional	Catering
Manufacture	National
International	Import/Export

14. Other relevant contact details (e.g. home and/or originating authority/ other)

Name:

Address, telephone and fax numbers, e-mail address:

15. Has any enforcement action already been taken? For example, have samples been taken for examination or analysis, or detention notices served, or food seized? Please fax any laboratory reports or detention notices etc to the FSSAI with this form, or as soon as possible thereafter.

16. Has there been media interest? Yes/No

If there has been a press release please fax to the FSSA with this form.

17. Any additional information: Please attach additional pages if necessary.

Signed:

Date:

Job Title:

# TRACEABILITY

**ISO 22005 has defined traceability as** “ability to follow the movement of a feed or food through specified stage(s) of production, processing and distribution”. Traceability systems should be able to document the history of the product and/or locate a product in the food chain. Traceability systems contribute to the search for the cause of nonconformity and the ability to withdraw and/or recall products if necessary. Traceability systems can improve appropriate use and reliability of information, effectiveness and productivity of the organization. Movement can relate to the origin of the materials, processing history or distribution of the food, and should address at least one step forward and one step backward for each organization in the chain.

## Principles of traceability

Traceability systems should be

- verifiable,
- applied consistently and equitably,
- results oriented,
- cost effective,
- practical to apply,
- compliant with any applicable regulations or policy, and
- compliant with defined accuracy requirements.

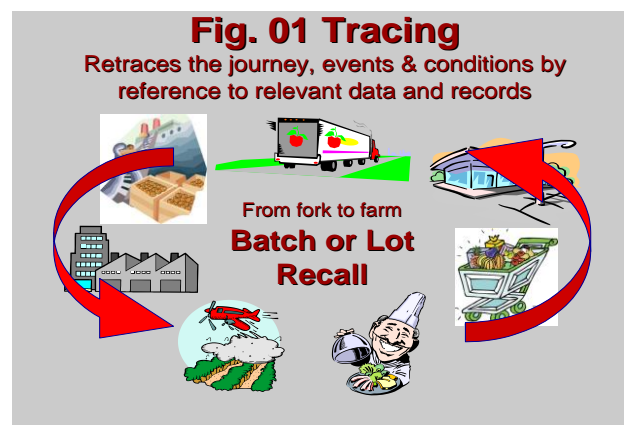
## Objectives of traceability

In developing a food chain traceability system, it is necessary to identify the specific objectives to be achieved. These objectives should take into consideration the traceability principles. Examples of objectives are the following:

- to support food safety and/or quality objectives;
- to meet customer specification(s);
- to determine the history or origin of the product;
- to facilitate the withdrawal and/or recall of products;
- to identify the responsible organizations in the feed and food chain;
- to facilitate the verification of specific information about the product;
- to communicate information to relevant stakeholders and consumers;
- to fulfil any local, regional, national or international regulations or policies;
- to improve the effectiveness, productivity and profitability of the organization.

Traceability system comprises two primary capabilities, the ability to track movements and to trace custody of a food product in the food chain. In defining traceability, it is important to distinguish between the terms “tracking” and “tracing”. The tracing is the ability to recreate the history of a product in the food chain and to identify the origin, movements and relevant associated information of a particular unit and/or batch of product located within the supply chain by reference to records held upstream (See Fig01).

Tracking is the ability to trace the destination of a product in a food chain and to follow a



path of a specified unit and/or batch of product through the supply chain as it moves from organizations towards the final point-of-process, point-of-sale, point-of-service or point of consumption (See Fig.02). In other words, it is the movement of the product forward through the food chain to understand where it has gone, what it has gone into and what it has come into contact with.

#### **Four main factors to allow traceability:**

- Identification of what has to be traced,
- Recording of the related data,
- The links between all data recorded, and
- The communication of data.

But to ensure traceability along the whole supply chain, there is inter-dependency of all stakeholders involved, so there is a need for a common language, hence, the role of standardisation.

The issues which have a bearing on the subject of traceability are:

- a) The place of traceability in risk management ;
- b) The use of traceability for product integrity, authenticity and identification ;
- c) The use of equivalent measures ;
- d) The practicability of traceability, and the feasibility of its application in developing countries ;
- e) Consumer confidence and information concerning the nature and origin of products ;
- f) The possibility of using traceability for liability and redress.

#### **Components of the Traceability/ Product Tracing Tool**

- a) The food supply chain is very complex and involves several companies, wherein various ingredients, components and packaging as well as the process of inspection play an important role. In selecting the items sought to be traced, there are a number of other factors that would also need to be ascertained, such as, the origin of food ingredients, processing history, definition of the batch, links between manufacturing batches, methods of production, methods of analysis, storage, personnel involved, the entire supply & distribution chain system, etc. It may also be necessary to establish product integrity, authenticity and identification at all the stages for consumer confidence in the context of food inspection and certification system. It might also need to address liability issues and redress mechanism.
- b) The context of traceability incorporates different features of the process of implementation of HACCP/ISO 22000 etc. in food businesses requiring record keeping at relevant stages of the value chain, where practicable. It also provides for preserving product identity. It is acknowledged that traceability/product tracing is not an end in itself but an instrument seeking to achieve the particular objective(s), such as production of safe food and protection from unfair trade practices.

#### **Importance**

Traceability is a tool to control quality, to find the cause of a quality problem, help in logistics and in rationalizing the process linked to logistics flow. It plays an important role in consumer safety, in allowing speedy and targeted recalls and withdrawal. It answers the requirement of regulations, and is a part of marketing in contributing to the protection of brand image.



## **Limitations of Implementing the Traceability/ Product Tracing tool**

- In countries where the product raw material, ingredients and components are produced by SMEs or in a co-operative structure or are procured through the market systems in smaller volumes, the backward identification of the product becomes quite difficult.
- Where the raw material, ingredients or components are of such nature (e.g. liquids or sometimes even solids) that these are inseparable, tracing to its source is impractical.
- In some developing countries, due to small farm holdings, farm production is in very small volumes. Marketable volumes are built up at the collection centers before being taken to a packing house or processing center. In such situations, traceability/product tracing is possible only up to the stage of a packing house or processing center and not up to the primary level, unless an extra effort is put in place to bring in the small holdings into the fold through a grower group or through the system of recording data of the chain-of-custody.

## **Alternatives to Traceability/ Product Tracing Tool**

- a) At the primary level, group farming with an internal control system and record keeping can be a feasible alternative. In such alternative systems, random checks for food safety needs will work out to be cost effective to the farmer or producer.
- b) Food safety controls through HACCP/ISO 22000 applicable according to the size of the operation including checks of contaminants and appropriate labeling of batch/lot numbers with expiry dates, where applicable take into account the concerns of traceability needs.
- c) Management of non-conformities pointed out by food safety experts from within or outside the production system with respect to the required rules and procedures as well as regular training of manpower involved in the production process.
- d) Regular documentation of inputs and practices followed in the production system that facilitates identification of the possible reasons of contamination in food.

Application of the alternatives would depend upon the nature and extent of risk involved that should be determined on the basis of necessary risk management needs and the stage at which the alternative(s) should be applied should also be identified.

## **Recommended Steps for the Application of Traceability/ Product Tracing Tool**

The following steps can be followed by countries for the application of traceability/product tracing tool in the context of food import and export inspection & certification system:

- a) Identification and communication of the objectives and scope of traceability/product tracing by the importing country to the exporting country as required in respect of the specified product along with Performance Objectives.
- b) Identification and communication of what is to be traced and, if appropriate, stage of the food chain as a risk management option. The recommendation may also state the suggested method of analysis, need for relevant data (e.g., origin, processing history, storage, and personnel), establishment of links between the recorded data, establishment of the integrity/authenticity of the links and liability/redress mechanism, if applicable.
- c) Provide information to the exporting country about the possible causes of the risk, nature and extent of the risk and the assessment of risk by not applying the traceability/product tracing tool. This assessment would apply to concerns relating to food safety and deceptive marketing practices.
- d) The importing country should suggest possible cost effective alternative yet equivalent measures (e.g., HACCP, internal control system, record keeping, random checks or other means to facilitate identification of the possible means of contamination, lot/batch numbers, labeling, management of non-compliances) to address the risk concerns without the use of traceability/product tracing tool to ensure protection from the assessed food safety risks and deceptive marketing

practices on a case-by-case basis depending upon the nature of the product and production/marketing practices.

- e) The importing country should also take into account that when and as appropriate a traceability/product tracing tool is to be implemented, it should be transparent, practical, technically feasible and economically viable and that it should not be more trade restrictive than necessary.
- f) The extent of application of traceability in the food chain should also be established taking into account evaluation of the various alternatives referred to above to achieve the same objective.
- g) Application of the traceability/product tracing tool should adequately address the needs of the developing countries and their traditional practices and may be applied as a food safety objective (SPS measure) and as a legitimate objective (TBT measure).
- h) The exporting country should be able to establish that the alternative measures selected for application would appropriately address the risk concerns of the importing country without the need for application of a traceability/product tracing tool.

It must not be forgotten that traceability is only a tool for the establishment of product authenticity, reliability, identification of the problem areas for the purposes of tracking and product recall. Food safety will come with the implementation of appropriate practices like Good Agricultural Practices, Good Manufacturing Practices, Good Handling Practices, HACCP, ISO-22000 coupled with Quality Management systems.

ISO has brought out ISO 22005 which enunciates better approach to traceability of food products.

# FOOD PRODUCT RECALL

A **product recall** is a request to return to the manufacturer a batch or an entire production run of a product, usually due to the discovery of safety issues. The recall is an effort to limit liability for corporate negligence and to improve or avoid damage to publicity. Recalls are costly to a company because they often entail replacing the recalled product or paying for damage caused by use, although possibly less costly than consequential costs caused by damage to brand name and reduced trust in the manufacturer.

A food recall includes any corrective action by a company needed to protect consumers from potentially adverse effects of a contaminated, adulterated, or misbranded product. A recall is a voluntary action, and the recall decision is made by the company management. If the company does not initiate a recall, the government agency responsible for the particular product category may request that the company do so.

Manufacturers strive to prevent a recall, employ Food Safety Management Systems( ISO 22000, Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Points (HACCP) plans. It is important to be ready for a recall well before a problem occurs. Management must be part of an effective recall plan and team.

Despite the undesirable nature of a recall event, it is in the best interest of the manufacturing company to complete the recall quickly. Because the manufacturer is responsible for all of the costs involved in this process, it is critical to have a plan to cover recall expenses, to expedite the process without creating negative public opinion, and to prevent down time. When crisis hits, it is too late to work on the recall plan. Preplanning is vital to mitigate a crisis. Generally, recall events should be included in the Crisis Management and Emergency Contingency Program for a company.

Factors prompting a food recall include but are not limited to unsafe, contaminated, or mislabeled product, nonconformities to manufacturer's specifications, and missing allergen or other hazard warnings.

## **Purpose of a Recall**

The basis of the recall concept depends on a company's food safety policies, ethical understanding, regulatory requirements, and financial constraints. A recall protects not only the consumer, but also the company. A smooth recall process can save a company's name and prevent further damage due to negative publicity. Destroying, replacing, or altering the product are the three main corrective actions.

A recall plan should strive to achieve the following **goals**:

- Protect consumer health
- Comply with existing rules and regulations
- Minimize the cost of the recall
- Regain and improve the company's reputation

## **Role of Government Agencies**

Even though a recall is a company management decision, a government agency can force the company to recall potentially misleading and/or hazardous product from distribution and marketing.

## Recall Classification

<b>Classification</b>	<b>Definition</b>	<b>Examples</b>
Class I	This type of recall involves a health hazard where a reasonable probability exists that eating the food would cause serious, adverse health consequences or death.	Meat contaminated with <i>L. monocytogenes</i> in a ready-to-eat food product; <i>E. coli</i> O157:H7 in raw beef; allergens such as peanuts or eggs (not listed on the label).
Class II	This type of recall indicates a potential health hazard where a remote probability of adverse health consequences from eating the food exists, or if the resulting condition is temporary or medically reversible.	Presence of FD&C Yellow #5 dye in candy; presence of dry milk, a Class II allergen, as an ingredient in sausage without mention of the dry milk on the label.
Class III	This type of recall involves situations in which eating the food will not or is not likely to cause adverse health consequences.	A package containing fewer or lower weight products than shown on the package label or improperly labeled processed meat in which added water is not listed on the label as required by federal regulations.

### Food recall procedures (Section 28)

If the food business operator has reason to believe that food manufactured by him is not in compliance with the act or rules, he shall initiate withdrawal from market and inform competent authorities of the risk and also the action taken.

A proposed draft regulation on this is under discussion wherein “Recall” means action taken to remove a marketed food product from distribution, sale and consumption that may pose a safety hazard to consumers and is divided into two stages as follows:

- i) Firm initiated Recall and
- ii) Authority initiated recall

#### i) Firm initiated Recall

A firm, either of its own through any other sources viz. Wholesaler, distributor, retailer, exporter, importer, consumer, media etc., coming to know that any of its products is unsafe or deficient violating provisions of the act and rules, & regulations made there under, may initiate a recall. In such situations, the firm is required to submit a recall alert notification to LCA immediately but not later than 24 hours. To ensure speedy communication, such alert can be sent by Fax, e-mail, On-line and / or by post. The LCA will inform of such recall alerts to Food Authority within 24 hours of receipt.

#### ii) Authority initiated recall

The LCA/ Food Authority may direct a firm to initiate a recall if a food product manufactured and distributed by him poses a health hazard or violation and the firm has not initiated a recall on its own.

Seizure or other court action may be taken when a firm refuses to undertake a recall directed by the LCA, or where the LCA/ Food Authority has sufficient reasons to believe that recall would not be effective, determines that a recall is ineffective, or discovers that violation is continuing. The cost incurred by the LCA/ Food Authority for carrying out such actions will be recovered from the firm responsible for such violation.

## **A Successful Recall Process**

- **Planning ahead:** A successful recall process depends on planning of the recall management well before a problem occurs.
- **Acting quickly:** Time is a vital factor in the recall process. The sooner harmful or misleading events are prevented, the faster the negative publicity and financial burden are eliminated.
- **Effective communication during a recall:** The firm should immediately provide recall instructions to everyone in the product distribution channels. Public notification about the recall through press releases and specialized media is also an integral part of the recall process.
- **Recall assessment:** Post-recall assessment is extremely important in determining the effectiveness of the recall plan in order to improve the efficacy of potential future recalls. The current recall plan also should be evaluated through simulated recalls.

### **Product recall- management responsibility**

To enable and facilitate the complete and timely recall of lots of end products which have been identified as unsafe, the top management of the company should appoint personnel having the authority to initiate a recall and personnel responsible for executing the recall, and the company should establish and maintain a documented procedure for:

- notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
- handling of recalled products as well as affected lots of the products still in stock, and
- the sequence of actions to be taken.

Recalled products should be kept secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe.

The cause, extent and result of a recall should be recorded and reported to top management as input to the management decisions to prevent recurrence. The company should verify and record the effectiveness of the recall programme through the use of appropriate techniques such as mock recall

### **Conclusions**

Planning ahead, rapid and well-coordinated action in the distribution channels, and truthful communication with the public are the most important elements for completion of a successful recall process and for regaining consumer confidence. The ultimate responsibility for removing the product from circulation before damage or injury are caused belongs to the manufacturer. A recall requires manpower and financial resources. When a traceability system and a well-conceived recall plan are in place, the recall is likely to be successful and less expensive.

## RISK ANALYSIS

Risk analysis is a powerful tool for carrying out science-based analysis and for reaching sound, consistent solutions to food safety problems. It provides information on hazards in food to be linked directly to data on the risk to human health, to improve food safety decision-making processes. It is a structured, systematic, disciplined, decision-making process for food safety. Risk analysis is defined by the Codex Alimentarius Commission as *"a process consisting of three components: risk assessment, risk management and risk communication (See Fig.01).*

### Risk Analysis Framework



The three components are essential, complementary parts of the overall discipline. In the course of a typical food safety risk analysis, almost constant interactions occur between risk managers and risk assessors within an environment characterized by risk communication. This approach has now gained wide acceptance as the preferred choice for assessing possible links between hazards in the food chain and actual risks to human health, and takes into account a wide range of inputs to decision-making on appropriate control measures.

### Principles for risk analysis

Risk analysis should:

- follow a structured approach comprising the three distinct components: risk assessment, management and communication,
- be based on all available scientific data,
- be applied consistently,
- be open, transparent and documented,
- be evaluated and reviewed as appropriate on the basis of new scientific data,

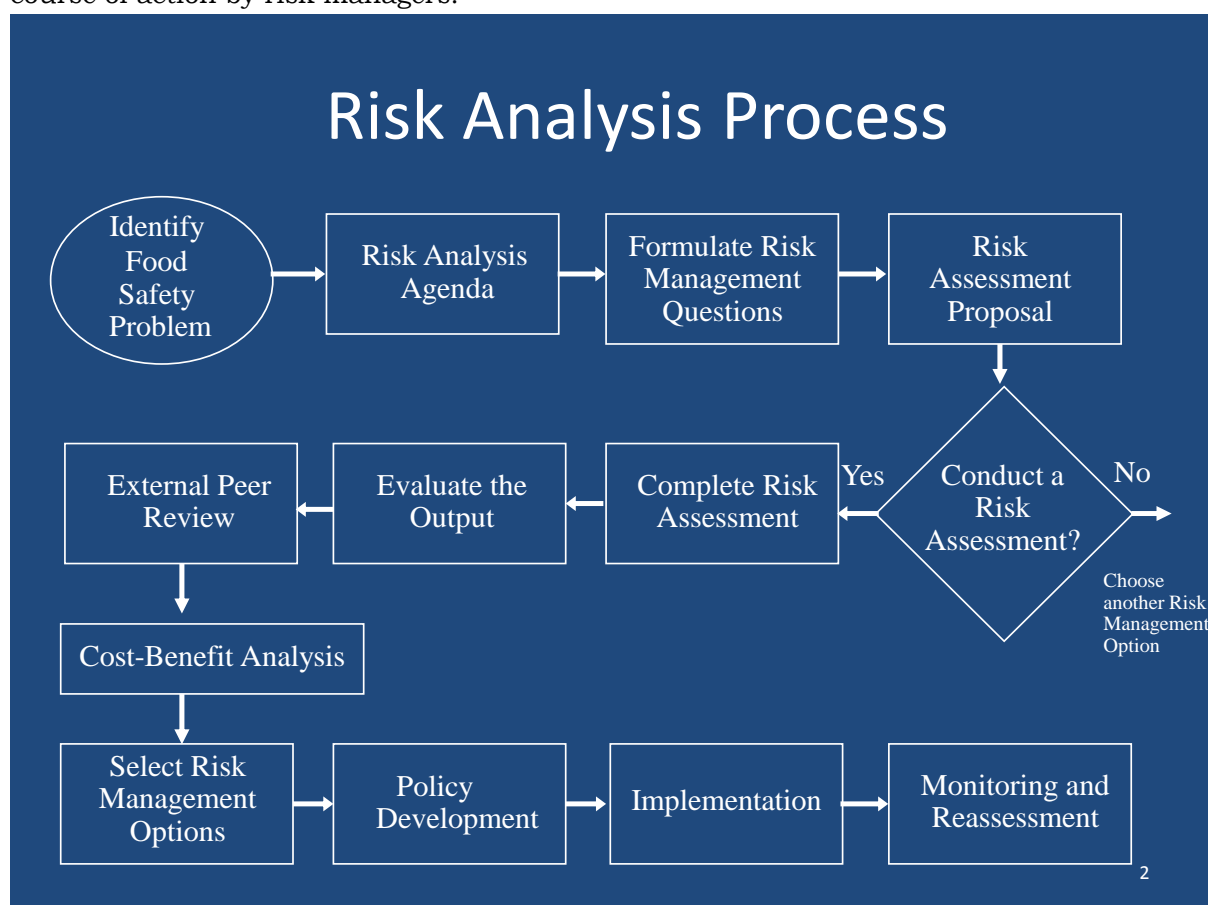
- be based on a clear consideration of uncertainty and variability.

### Factors involved in Risk Analysis

- Risk analysis is an iterative, ongoing and highly interactive process that should be evaluated and reviewed as necessary on the basis of new data, information or changes in the context.
- There is need to have a well functioning food safety system, the support and participation of key stakeholders (government, industry, academia, consumers), and basic knowledge of risk analysis discipline to perform successful risk analysis.
- Risk analysis should be based on all available scientific evidence, information on perceptions, costs, environmental, cultural factors, etc., which is gathered and analyzed according to scientific principles to the extent possible.

### Risk Analysis Process

Risk Assessment is the central scientific component of risk analysis but risk management, defines the problem, articulates the goals of the risk analysis and identifies the questions to be answered by the risk assessment. The science-based tasks of ‘measuring’ and ‘describing’ the nature of the risk being analysed (i.e. risk characterization) are performed during the risk assessment. Risk management and risk assessment are performed within an open and transparent environment based on communication and dialogue. Risk communication encompasses an interactive exchange of information and opinions among risk managers, risk assessors, the risk analysis team, consumers and other stakeholders. The process often culminates with the implementation and continuous monitoring of a course of action by risk managers.



## **GENERAL ASPECTS OF RISK ANALYSIS**

1. The overall objective of risk analysis applied to food safety is to ensure human health protection.
2. Risk analysis principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non discriminatory manner.
3. To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system.
4. Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program.
5. Risk analysis should be:
  - Applied consistently;
  - Open, transparent and documented; and
  - Evaluated and reviewed in the light of newly available scientific data.
6. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality of data and information should be accessible to all interested parties.
7. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.
8. It is recognized that national governments will use different approaches and time frames in the application of these principles taking into account national capacities and resources. For the purpose of the present document, the term “interested parties” refers to “risk assessors, risk managers, consumers, industry, the academic community and, other relevant parties and their representative organizations”. However, it is recognized that interaction between risk managers and risk assessors is essential for practical application.
9. National governments should take into account relevant guidance and information obtained from risk analysis activities pertaining to human health protection conducted by Codex, FAO, WHO and other relevant international intergovernmental organizations, including OIE and IPPC.
10. With the support of international organizations where appropriate, national governments should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective application of risk analysis principles and techniques in their food control systems.
11. National governments should share information and experiences on risk analysis with relevant international organisations, other national governments (e.g. at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate a broader and, where appropriate, more consistent, application of risk analysis.



## **Benefits of Food Safety Risk Analysis**

- Better identification and targeting of public health problems ultimately facilitate improvements in managing food safety
- Better utilization of resources by focusing the highest food safety risks.
- Trade opportunities- risk analysis provide a solid basis for negotiating access to markets in other countries by objectively demonstrating the absence of hazards or the effective control of hazards to produce a safe food.
- Risk analysis identifies gaps and uncertainties in scientific knowledge on risks, which can help set research priorities
- A community better informed about food safety issues, leading to improving production, manufacturing and trading practices.

## **RISK ASSESSMENT**

Risk Assessment is the central scientific component of risk analysis and has evolved primarily because of the need to make decisions to protect health in the face of scientific uncertainty. Risk assessment generally described as characterizing the potential adverse effects to life and health resulting from exposure to hazards over a specified time period. Risk management and risk assessment are separate but closely linked activities, and ongoing, effective communication between those carrying out the separate functions is essential.

### **Principles of risk assessment**

- a) Risk assessment should be based upon sound scientific principles, data and evidence.
- b) Risk assessment should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment, and risk characterization.
- c) A risk assessment should clearly state the purpose of the exercise, including the report of risk estimate that will be the output.
- d) A risk assessment should be transparent. This requires systematic documentation, statement of assumptions and value judgments and rationale, and a formal record.
- e) The risk estimate should contain a detailed description of uncertainty and where the uncertainty arose during the risk assessment process.
- f) The data generated should be of quality and precision that minimizes uncertainty in the risk estimate to the extent possible.
- g) A risk assessment, depending upon its purpose should explicitly consider the dynamics of microbiological growth, survival, and death in foods, severity and occurrence of chemical risk and the complexity of the interaction between human and agent following consumption
- h) Risk estimates should be re-assessed over time by comparison with independent human health data where possible.
- i) A risk assessment may need re-evaluation as new data and information becomes available.
- j) There should be a functional separation between risk assessment and risk management

### **Basic components of risk assessment**

The risk assessment process is generally represented as consisting of four steps, described by Codex. Following identification of the hazard(s), the order in which these tasks can be carried out is not fixed; the process is normally highly iterative, with steps repeated as data and assumptions are refined.

## **1. Hazard identification**

Specific identification of the hazard(s) of concern is a key step in risk assessment and begins a process of estimation of risks specifically due to that hazard(s). Hazard identification may have already been carried out to a sufficient level during risk profiling; this generally is the case for risks due to chemical hazards. For microbial hazards, the risk profile may have identified specific risk factors associated with different strains of pathogens, and subsequent risk assessment may focus on particular subtypes. Risk managers are the primary arbiters of such decisions.

## **2. Hazard characterization**

During hazard characterization, risk assessors describe the nature and extent of the adverse health effects known to be associated with the specific hazard. If possible, a dose-response relationship is established between different levels of exposure to the hazard in food at the point of consumption and the likelihood of different adverse health effects. Types of data that can be used to establish dose-response relationships include animal toxicity studies, clinical human exposure studies and epidemiological data from investigations of illness.

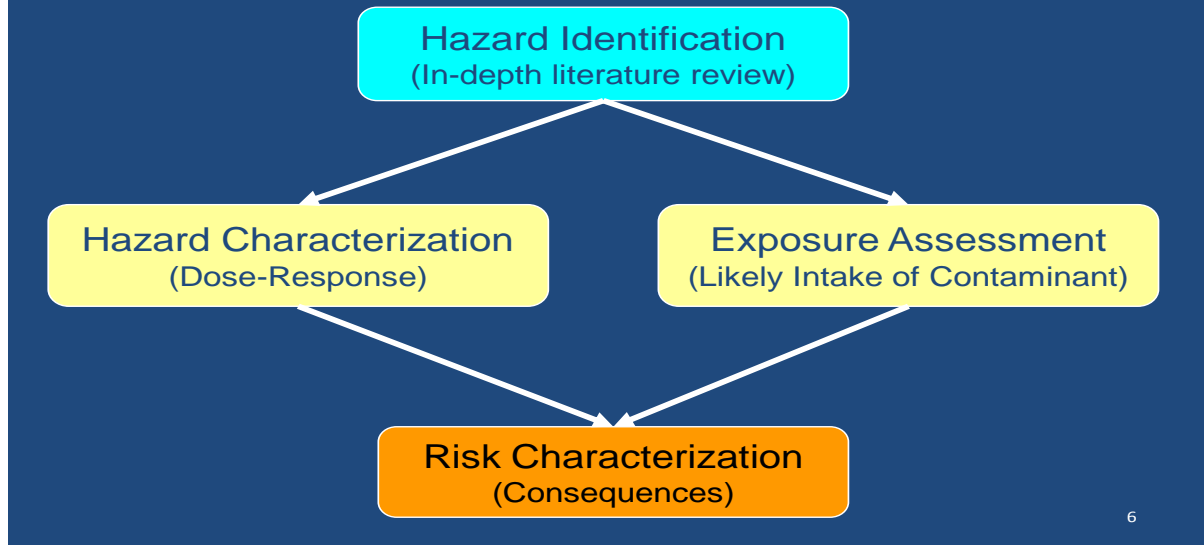
## **3. Exposure assessment**

Exposure assessment characterizes the amount of hazard that is consumed by various members of the exposed population(s). The analysis makes use of the levels of hazard in raw materials, in food ingredients added to the primary food and in the general food environment to track changes in levels throughout the food production chain. These data are combined with the food consumption patterns of the target consumer population to assess exposure to the hazard over a particular period of time in foods as actually consumed.

## **4. Risk characterization**

During risk characterization, outputs from the previous three steps are integrated to generate an estimate of risk. Estimates can take a number of forms and uncertainty and variability must also be described if possible. A risk characterization often includes narrative on other aspects of the risk assessment, such as comparative rankings with risks from other foods, impacts on risk of various “what if” scenarios, and further scientific work needed to reduce gaps. Risk characterization for chronic exposure to chemical hazards does not typically include estimates of the likelihood and severity of adverse health effects associated with different levels of exposure. A “notional zero risk” approach is generally taken and where possible the goal is to limit exposure to levels judged unlikely to have any adverse effects at all.

# Risk Assessment Paradigm



## General characteristics of food safety risk assessment:

- a) A risk assessment should be objective, transparent, fully documented and available for independent scrutiny.
- b) The functions of risk assessment and risk management should be carried out separately to the extent practicable.
- c) Risk assessors and risk managers should engage in an iterative and on-going dialogue throughout risk assessment.
- d) Risk assessment should follow a structured and systematic process.
- e) Risk assessment should be based on scientific data and should take into account the whole “production-to-consumption” food pathway.
- f) Uncertainties in risk estimates and their origins and impacts should be clearly documented, and explained to risk managers.
- g) A risk assessment should be subject to peer review if considered appropriate.
- h) A risk assessment should be reviewed and updated as new information permits or requires.

## Approaches for risk Assessment

There are many situations at the national level where no risk assessment of any form is available or feasible. In other situations, an active decision may be taken to use a scientific approach that does not include risk assessment. Obviously the advantages that flow from using risk assessment to set food safety control measures cannot be realized in such scenarios; nevertheless, choices to apply other scientific approaches are likely to be reasonable and appropriate in their own right.

1. **Risk Assessment:** The way four analytical steps are applied differs somewhat for microbiological and chemical hazards. For microbiological hazards, the occurrence and transmission of the hazard at various stages from food production to consumption is evaluated, thus moving "forward" through the various stages of the food chain to arrive at an estimate of risk. In contrast, for chemical hazards, "safety evaluation" is a standard risk assessment methodology. In that approach, maximum exposure levels are identified to fit a "notional zero risk" outcome.

2. **Use of Ranking Tools:** Risk ranking, using tools that rely on knowledge of risk factors to rank risks and prioritize regulatory controls, is often commissioned by risk managers. Such rankings may or may not be based on risk assessments. Some tools categorize a food business against specified risk factors, e.g. by type of food, type of food preparation, type of business, compliance record, food user subpopulation. Other tools are used to rank hazard-food combinations in a national context by deriving a "comparative risk" scoring system. Risk ranking methods not based on risk assessments are not a good substitute for ranking methodologies that do incorporate risk assessment.
3. **Epidemiology:** is increasingly being used in food safety to study the links between the frequency and distribution of adverse health effects in specific populations and specific food-borne hazards. This includes observational studies of human illness such as case-control, analysis of surveillance data, and focused research. The usefulness of epidemiology depends on the availability of data.
4. **Combination of Approaches:** As a practical matter these various approaches are often used in combination or feed into each other (e.g. epidemiological data feed into hazard identification and hazard characterization steps of any risk assessment). Ways in which they can be integrated vary widely on a case-by-case basis

## **RISK MANAGEMENT**

Risk Management is the process of weighing up the various possible policies, taking account of the evaluation of risks and other factors involved in the health protection of consumers and the promotion of fair trade practices, and taking decisions accordingly, i.e. choosing and implementing the appropriate prevention and monitoring measures. The management of food-related risk therefore involves balancing the recommendations formulated by the experts commissioned to scientifically evaluate the risks, and the resources of all types that social and commercial groups and manufacturers can set aside for dealing with these risks.

### **General Principles of Food Safety Risk Management**

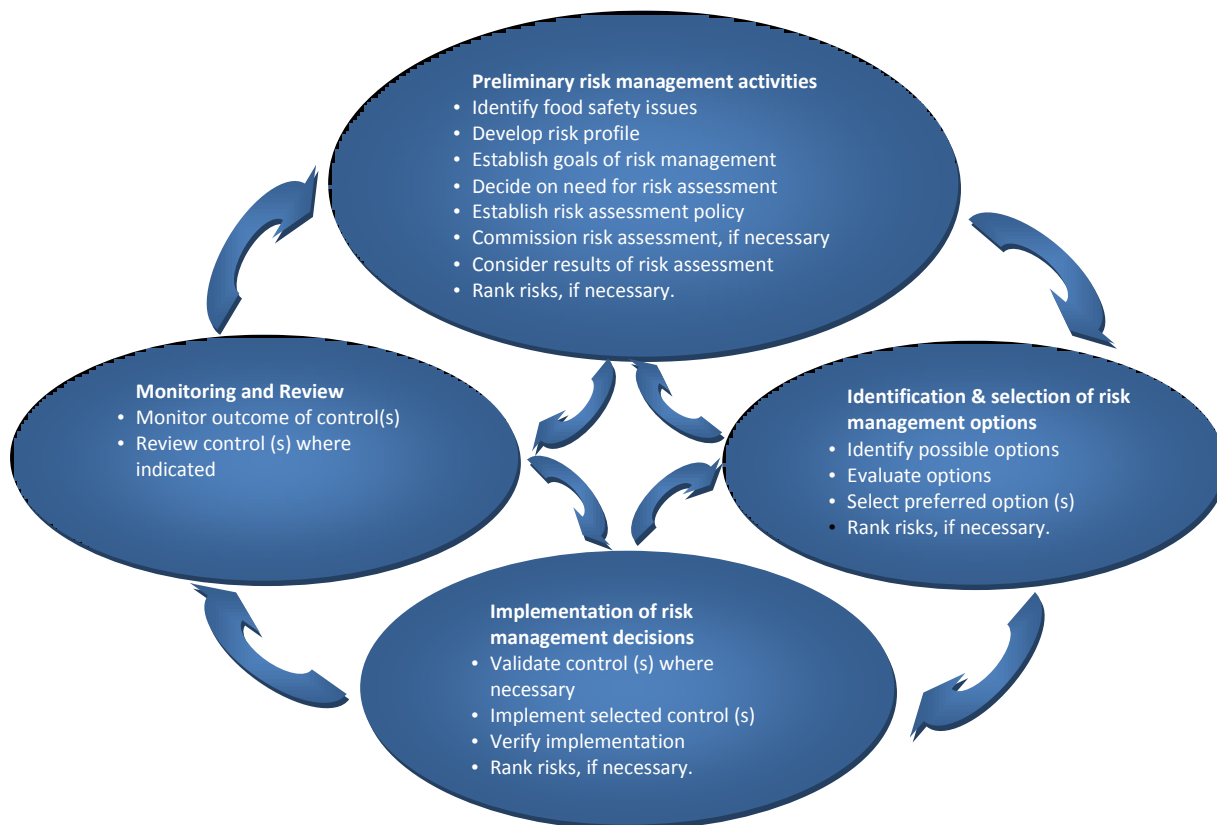
1. Protection of human health should be the primary objective in risk management decisions.
2. Risk management should follow a structured approach.
3. Risk management decisions and practices should be transparent, consistent and fully documented.
4. Risk management should take into account the whole food chain.
5. Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment.
6. Risk managers should take account of risks resulting from regional differences in hazards in the food chain and regional differences in available risk management options.
7. Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process.
8. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions.

## **Risk Management Framework**

A generic Risk Management Framework for food safety risk management must be functional in both strategic, long term situations (e.g. development of international and national standards when sufficient time is available) and in the short term work of national food safety authorities (e.g. responding rapidly to a disease outbreak). In all cases, it is necessary to strive to obtain the best scientific information available.

There are four components of risk management frameworks:

- a) **Preliminary risk management activities** comprise the initial process. It includes the establishment of a risk profile to facilitate consideration of the issue within a particular context, and provides as much information as possible to guide further action. As a result of this process, the risk manager may commission a risk assessment as an independent scientific process to inform decision-making.
- b) **Evaluation of risk management options** is the weighing of available options for managing a food safety issue in light of scientific information on risks and other factors, and may include reaching a decision on an appropriate level of consumer protection. Optimization of food control measures in terms of their efficiency, effectiveness, technological feasibility and practicality at selected points throughout the food-chain is an important goal. A cost-benefit analysis could be performed at this stage.
- c) **Implementation of the risk management decision** will usually involve regulatory food safety measures, which may include the use of HACCP. Flexibility in the choice of individual measures applied by industry is a desirable element, as long as the overall programme can be objectively shown to achieve the stated goals. Ongoing verification of the application of food safety measures is essential.
- d) **Monitoring and review** is the gathering and analyzing of data so as to give an overview of food safety and consumer health. Monitoring of contaminants in food and foodborne disease surveillance should identify new food safety problems as they emerge. Where there is evidence that required public health goals are not being achieved, redesign of food safety measures will be needed.



**Generic framework of risk management**

## **RISK COMMUNICATION**

Risk communication is an interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions

Risk communication is an integral part of risk analysis together with risk management and risk assessment. Risk communication provides timely, relevant and accurate information to members of the risk analysis team, as well as external stakeholders, in order to improve knowledge about the nature and effects of a specific food safety risk. Successful risk communication is a prerequisite for effective risk management and risk assessment. The key considerations in risk communication are:

- Risk communication should facilitate an open and interactive exchange of information, facts and opinions about food safety risks.
- Internal risk communication takes place among members of the risk analysis team.
- External risk communication occurs between the risk analysis team and external stakeholders.
- Science and emotion define risks, and risk communication must address both aspects. Although food safety experts focus on science, the general public is usually more concerned about the emotional aspects of the risk.
- Risk communication should always have a clear goal.
- Responsibility for risk communication should be clearly defined and assigned to one or more members of the risk analysis team.

- Risk communication provides a platform to actively involve external stakeholders as soon, and as meaningfully, as possible in the risk analysis process.

Risk communication encompasses a continuous and interactive exchange of information and opinions between risk assessors, risk managers, consumers, industry, academic institutions and other interested stakeholders throughout the risk analysis process. Risk communication should involve a two-way dialogue. Risk communicators must provide external stakeholders with clear and timely information about the food safety risk and measures to manage it; this information should be communicated in a way that stakeholders can easily understand and using a media that they can easily access. In addition, it is essential for risk communicators to solicit feedback from external stakeholders and listen to their opinions in order to refine the key message communicated and to fully and adequately address stakeholder concerns.

The fundamental goal of risk communication is to provide meaningful, relevant and accurate information in clear and understandable terms, targeted to a specific audience. Risk communication may not resolve all the differences between parties, but it should lead to a better understanding of those differences. Risk communication should also lead to more widely understood and accepted risk management decisions. Effective risk communication should have goals that build and maintain trust and confidence. It should facilitate a higher degree of consensus and support by all interested parties for the risk management option(s) being proposed.

### **Goals of risk communication**

- a) To promote awareness and understanding among all participants of the specific issues under consideration during the risk analysis process.
- b) To promote consistency and transparency in arriving at and implementing risk management decisions.
- c) To provide a sound basis for understanding the proposed and/or implemented risk management decisions.
- d) To improve the overall effectiveness and efficiency of the risk analysis process.
- e) To contribute to the development and delivery of effective information and education programmes, when they are selected as risk management options.
- f) To foster public trust and confidence in the safety of the food supply.
- g) To strengthen working relationships and mutual respect among all participants.
- h) To promote the appropriate involvement of all interested parties in the risk communication process.
- i) To exchange information on the knowledge, attitudes, values, practices and perceptions of interested parties concerning risks associated with food

Many different kinds of individuals and groups involved in all aspects of the food chain from farm to fork (including production, processing, distribution, sale and consumption) are affected by food safety risks (see Box 01). Risk communication is an integral and ongoing part of the risk analysis exercise, and all stakeholders should be involved from the start. Risk communication makes stakeholders aware of the process at each stage of the Risk Assessment. This helps to ensure that the logic, outcomes, significance, and limitations of the Risk Assessment are clearly understood by all the stakeholders.

**Box 01: Food Safety stakeholders**

- Farmers and feed producers
- Processors, manufacturers, distributors and their vendors
- Product wholesalers and retailers
- Consumers
- Advocacy groups (consumer, environmental, religious, other lobbying groups, etc.)
- Community groups
- Public health community and health care providers
- Universities and research institutions
- Government agencies of concern in industry
- Representatives of different cultural, economic or ethnic groups
- Different concerned associations/confederations
- Labour unions
- Trade associations and
- Media



## **Food Safety Plan at Gram Panchayat and Municipality**

- “Means the adoption of Good Manufacturing Practices, Good hygiene practices, HACCP and such other practices as may be specified by regulation, for the food Business”
- FSP consists of programs, plans, policies, procedures, practices, processes, goals, objectives, methods, controls, roles, responsibilities, relationships, documents, records, and resources.
- A FSP is often one part of a larger management system.

## **General Parameters for Food Safety Plan for Panchayat and Municipalities**

- 1) To identify and categorise the food business of the Food Business Operators in the area (Panchayat/Municipalities).
- 2) To inspect the premises of Food Business Operator at periodical intervals and based on the inspection. Wherever necessary, improvement notices to be issued.
- 3) Food Safety Officer to take samples of food of Food Business Operator at such time as may be reasonably necessary and to send such samples for analysis.
- 4) To evaluate and ascertain the quality drinking water used (through scientific tests) used as ingredient in food and to take appropriate steps to eliminate contaminants in the water, if on analysis it is found that water in any area has contaminants which are not safe for drinking purposes.
- 5) To review arrangements for disposal of waste by the public in general and the food business operators in particular for the purpose of ensuring that contaminated waste does not spread to food items.
- 6) To investigate food poisoning incidents in any area and to send appropriate reports to the competent authorities and simultaneously take remedial measures to eliminate recurrence of such incidents in future.
- 7) To interact with industries and consumers and to create awareness among them for food safety.
- 8) To prepare and distribute to the general public pamphlets containing food safety measures to be taken by them. Such information may also be disseminated through media.

## **How to prepare Food Safety Plan for Village/ Panchayat/ District**

1. Firstly, Food Safety Plan should highlight the Aims & Objectives of the Plan of respective Village/ Panchayat/ District.

Some of the aims & objectives are illustrated below as an example.

### **AIMS & OBJECTIVES:**

- To ensure that all food intended for human consumption that is manufactured, prepared or sold in the \_\_\_\_\_(name of the district) complies with FSS Act.
- To carry out interventions in food premises which may include inspections, audits, verification & surveillance of food businesses in accordance with the FSS Act, 2006.

- To advise & educate consumers, businesses & other services & users on food safety matters
  - To investigate & take appropriate action on all complaints relating to food safety matters
  - To prevent the spread of food poisoning
  - To ensure all measures pertaining to food safety are followed at all stages of food chain
  - To ensure that private water supplies such as wells & bore wells used as a source of water for food production purposes are safe & comply with legal requirements.
  - To carry out a planned food sampling procedures.
2. The Plan should indicate the name & size of district/Taluka/Village & should also indicate number & various types of food industries in that particular district/Taluka/Village as shown below:

<b>Type of Food Industry</b>	<b>Number</b>
<b>Large Scale</b>	
<b>Medium Scale</b>	
<b>Small scale</b>	
<b>Cottage industry</b>	
<b>Catering unit/Home scale</b>	
<b>Hotels</b>	
<b>Restaurant/ Dhabas</b>	
<b>Co-operatives (Food Business)</b>	
<b>Wholesale premises</b>	
<b>Any other (specify)</b>	

### 3. Food Premises Inspection

Frequency of inspection carried out to be specified based on nature of food industry. Inspection should be carried out at all stages of food chain & should highlight all below mentioned parameters:

- a) **Raw materials:** It should specify :
  - Source of RM procurement
  - Quality
  - Storage conditions
  - Rotation of raw materials on FIFO, FEFO & FMFO basis.
  
- b) **Water & Ice:** Following parameters to be indicated:
  - Source of water
    - i. Municipal/ Panchayat Authority-Supply
    - ii. In-house treated water
    - iii. Tube well
    - iv. Packaged water
    - v. Any other (specify)
  - Is water used for various purposes safe & free from contamination
    - i. Water for drinking
    - ii. Water for cooking as an ingredient
    - iii. Water for processing of food (Steam purpose/Cooling purpose etc)
    - iv. Water for washing of equipments, utensils, containers, kiosks etc.
    - v. Water for hand washing
  - Is ice used for various preparations made from potable water

- Handling of ice
- Storage conditions of ice
- Frequency of testing of water & ice
- c) **Preparation & Processing:** It should specify:
  - Cooking/ processing/cooling/freezing/drying temperature
  - Storage conditions of cooked food
  - Segregation & labeling of Veg. & Non Veg. products
  - Handling of food before serving
  - Transportation & handling of prepared food
- d) **Display of food**
  - Temperature & condition of counter display
  - Labeling of products displayed
  - Segregation & labeling of Veg. & Non Veg. products
  - Principle of FIFO,FMFO & FEFO
- e) **Utensils & Equipments**
  - Conditions of utensils /equipments
  - Is food grade material used
  - Storage
- f) **Cleaning & Hygienic conditions of establishment & surrounding/ environment**
- g) **Lighting facility**
- h) **Garbage disposal facility:** It should specify :
  - Number of waste bins
  - Segregation of wastes & colour coding of waste bins
  - Conditions of waste bin i.e. whether clean, leak proof, foot operated etc.
  - Location of the waste bins
- i) **Pest Control**
  - Is Pest Management followed?
  - Installation of Insect electrocuting device (IED)
- j) **Personal Hygiene:** It should include:
  - Appropriate work clothing of staff members handling food
  - Hand washing facility
  - Worker's Health
- k) Training (s) Organized

4. **Number of Trainings** carried out:

Area	Number
<b>Food Safety</b>	
<b>Hygiene of the area</b>	
<b>Working Practices</b>	
<b>Personal Hygiene</b>	

5. **Number of Improvement Notices** issued

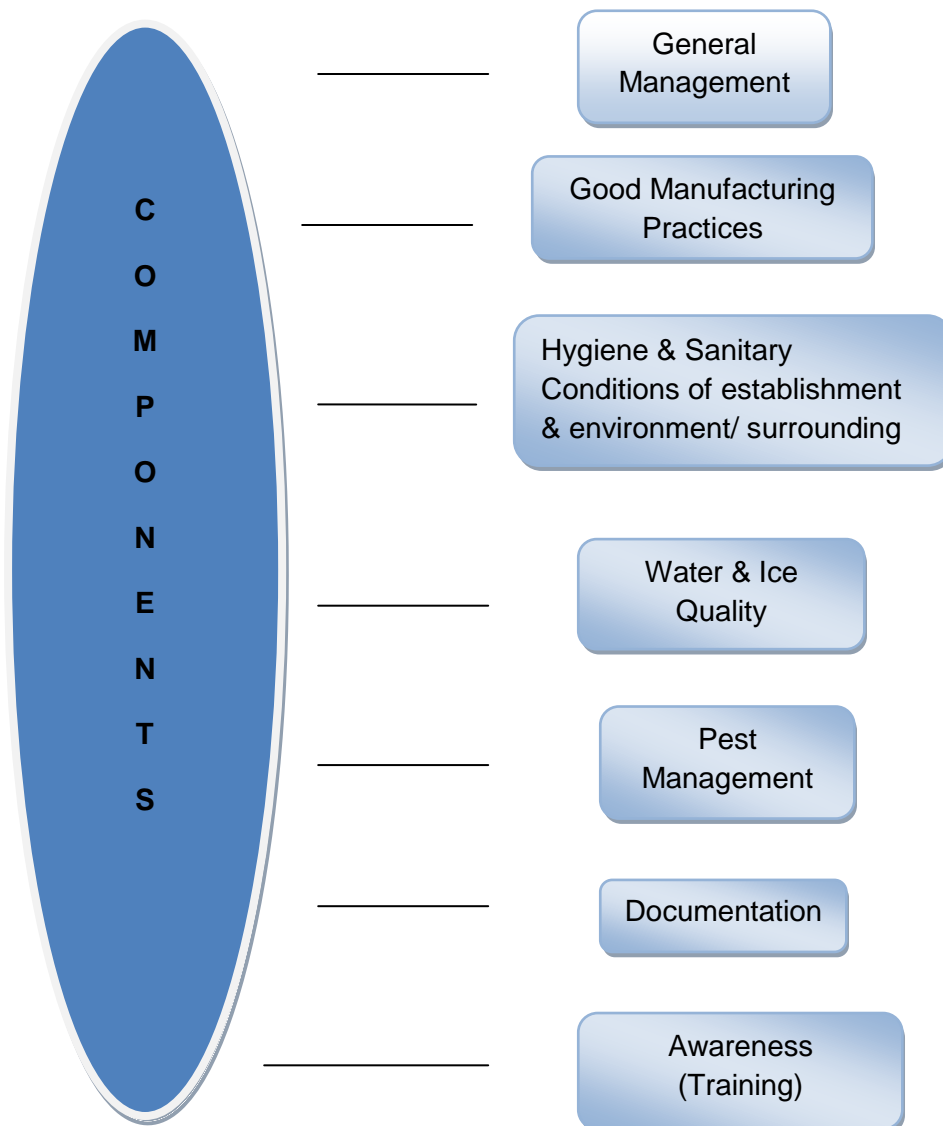
6. Has **corrective actions** followed as mentioned in Improvement Notices?

7. **Food Poisoning Incidents:** It should indicate:

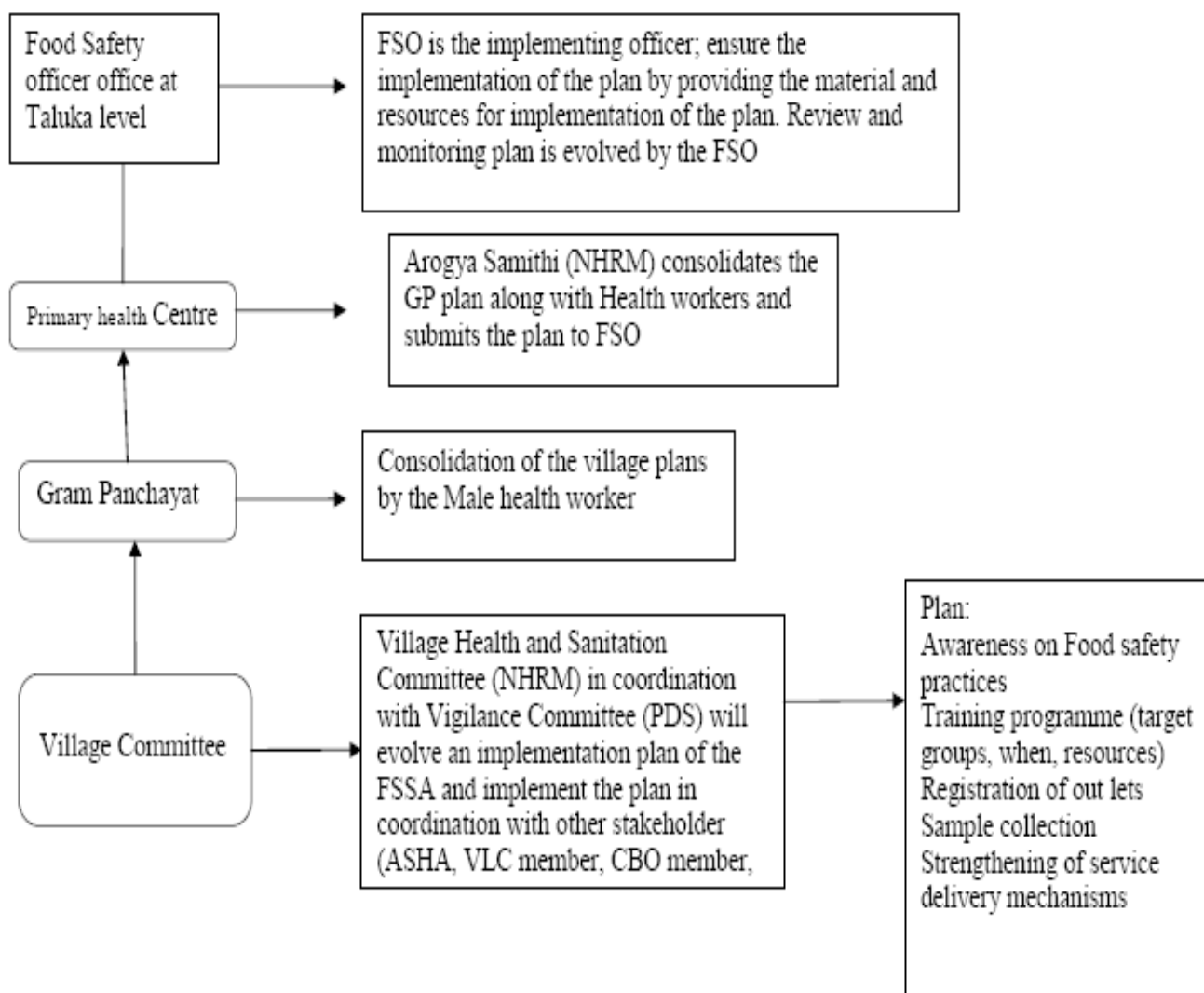
- Number of incidents occurred
- Investigations & reports
- Remedial measures taken

8. **Number of Health & Safety complaints** in a particular district/ village/ panchayat & what **remedial measures** taken? It may include about water sources and waste disposal system in the area.
9. **Number & type of promotional activities** done for creating awareness among consumers for food safety

**Key-Components of Safety Plan for Inspection of Food Premises**



**Structure and Process at Panchayati Raj Institutions (PRI)**



## **Allocation of responsibilities & implementation**

Each state will have a food safety commissioner who will be the implementing agency. The FSS Act, 2006, provides for appointment of Designated Officer in each districts by the Food Safety Commissioners of the states. The power to grant or cancel licence of the Food Business Operator is vested with the Designated Officer of the district. The food inspector will be designated as the Food Safety Officer.

### **Responsibilities of State food safety Authorities**

- Local Food safety Officer of respective district/ panchayat/ village shall send the sample to the Food Analyst for analysis.
- Food safety official shall monitor & inspect Sanitary & Hygiene condition of the establishment & environment / surrounding & Preparation /Processing conditions.
- Designated officer of each district shall educate & organize training to food handlers, vendors & others stake holders to create awareness using audio-visual aid etc. in the Municipal/Panchayats areas under his/her Jurisdiction.
- Designated Officer shall carry investigation of Food Poisoning incidents & shall take remedial measures to eliminate recurrence of such incidents in future.
- Designated officer shall monitor number of Health & Safety complaints in a particular district/ village/ panchayat & appropriate remedial measures taken
- Designated officer shall supervise whether corrective actions are taken as per 'Improvement Notices' issued.

### **Responsibility of Municipal Council /Corporation**

- Municipal Corporation of respective districts/ village/ panchayat shall evaluate & ascertain the quality of drinking water & water used as an ingredient in food & to take appropriate steps to eliminate contaminants in the water.
- Shall ascertain whether appropriate pest control measures are followed.
- Shall ascertain whether proper waste disposal system/sewage/ drainage system is in place.

### **Responsibility of Pollution Control Board**

- To review arrangements for disposal of waste & waste water treatment facility being maintained in various food processing Industries.

### **Role of Food Safety Officers:**

- Will be responsible for implementation in the taluka.
- Will plan out strategies to ensure food safety.
- Notice hazards for food safety and take suitable action to overcome this.
- Network with other departments.
- Ensures that reports documented and updated information available at all the times.
- Work in sync with the food labs at district level.
- Regular review of work done in the villages and Taluka levels.
- Set up and ensure smooth working of the Grievance Cell.
- Create a Resource Center with all information under FSA related to the district.
- Help the enforcement cell to ensure compliance with the rules of FSA.
- Responsible for registration and renewals.
- Responsible for building of safety standards in the Panchayat
- Building awareness about food safety standards among Panchayat members, teachers, school children and other citizen, (Start a Food Safety Club)

- Maintaining Food safety standards during village fairs.
- Physical verification of place of business.
- Address grievances at village/Panchayat level if possible.
- Networking with other dept. for help at Panchayat level.
- Conduct workshops on food safety standards for elected members, women's groups, vendors and people connected with food business.
- Collect samples for testing
- Ensure that food safety standards are followed in schools and *anganwadis*.

### **RESPONSIBILITIES**

<b>Department</b>	<b>Convergence Issues</b>
Women and Child Department	<ul style="list-style-type: none"> <li>➤ Train Anganwadi worker to spread awareness on food safety counsel pregnant women for safe and nutritional food</li> <li>➤ Orient SHGs on food safety issues and ask them to monitor midday meals or areas in the village where food is prepared for community</li> <li>➤ Anganwadi workers to involve in the planning process at the village level.</li> </ul>
Rural Development and Panchayat Raj	<ul style="list-style-type: none"> <li>➤ Advocacy</li> <li>➤ Issue instructions to Panchayats to register the food business.</li> <li>➤ Issue guidelines to Panchayats to discuss Food Safety related issues relevant to the village in Gram Sabhas and other meetings</li> <li>➤ Request Panchayats with their own budget to allocate resources to supplement Sample collection cost.</li> </ul>
Youth Affairs & Sports	<ul style="list-style-type: none"> <li>➤ Conduct special campaigns/ programmes by the NSS on safe food for rural youth</li> </ul>
Education	<ul style="list-style-type: none"> <li>➤ Include Food Safety awareness in Education Programme.</li> <li>➤ Design project work for students on food safety</li> <li>➤ Training of Food Safety to Cooks and Teacher who are involved in Mid Meal Programme</li> </ul>

## **Introduction**

Many countries are greatly dependent upon food products from other countries for an adequate supply to satisfy all their nutritional requirements. In these cases, the quality of imported foods is very important if these needs are to be met. The possibility exists that food products considered to be of inferior quality may be “dumped”, i.e., shipped to another country with a less well developed food control system, either because the receiving country has less stringent laws and regulations, or because it does not have the ability or knowledge to monitor adequately the quality of imported foods. Thus, an effective food control and inspection service is the first line of defence against “dumped” or inferior food imports.

## **EXPORTS**

### **Introduction**

Most developing and developed countries are concerned their trade in food commodities, both raw and processed. One of the important factors influencing such trade is the confidence of the purchaser in the safety and quality of food being imported. This confidence can be maintained only if an efficient food inspection and control service is in existence in the exporting country. In addition, many importing countries are now starting to demand certification that certain products are free from pathogenic microorganisms or other contaminants.

Some food control authorities have made special arrangements for certification and the inspector may be called upon to sign export certification documents attesting to product safety, quality or other requirements, as may be stipulated. Such certification often involves a combination of inspection and analytical findings before such certification can be issued.

In addition to the general and specific guidelines, special attention should be directed to the specialized Codex Codes of Hygienic Practice. One of these codes could be used as the basis for establishing and specifying hygienic processing conditions and practices acceptable to both parties. In all countries the food laws and regulations are intended to protect the consumer and ensure that foods are pure and wholesome, safe to eat, and produced, stored and handled under sanitary conditions.

In recognizing that quality and safety can be assured through application of proper or well designed food control systems (exports and imports), the Codex Alimentarius Commission established the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) to develop principles and guidelines in this area.

Although food control should cover both export and import as is evident from the terms of reference of this Committee and most of the documents it developed, most governments have emphasized on development and strengthening of import control systems with a view to protecting their populations and to prevent dumping of inferior quality products into their country. However, the situation in India and some other exporting countries has been somewhat different, with export inspection and certification being compulsory in certain food items.



## **Export Control Systems in India**

India has been operating export control systems since 1963 which have been well-defined and established under the Export (Quality Control and Inspection) Act, 1963. The Act empowers the Central Government to notify commodities for pre-shipment inspection and certification, specify the minimum standards (generally recognizing international, importing countries' standards and contractual specifications), and prescribe the manner of export inspection and certification, whether compulsory or voluntary.

The export control system is operated by the Export Inspection Council of India (EIC), India's official export certification body, through its field organizations, the Export Inspection Agencies, having head offices in Chennai, Delhi, Kochi, Kolkata and Mumbai with 41 sub-offices including laboratories around the country.

Over the years, under the provision of the Act, nearly 1000 commodities have been notified by the government for pre-shipment inspection and certification covering such sectors as chemicals, pesticides, rubber products, engineering products, food and agricultural products, textiles, footwear etc. However, presently only sensitive items such as marine products, egg products, dairy products, poultry products and honey are under compulsory export certification by the Export Inspection Council of India. In the case of other food products, although many of these are notified under the Act, there is no compulsory certification and in many cases, and in case required by an importing government, EIC certifies the products. An example is the case of black pepper exported to USA, or basmati rice to the EC for duty benefits, etc. However, if required by the buyer or government, these food items may be certified by private inspection agencies. Details of export control systems being operated by the Export Inspection Council of India are given in the Conference Room Document prepared by India.

## **Indian Import Policy**

Imports to India are governed by the Foreign Trade (Development and Regulation) Act 1992. Under this Act, imports of all goods are free except for the items regulated by the policy or any other law in force. The present, foreign trade arrangements for different commodities are stated in the. This policy is announced once every five years with annual supplements coming out every year. It is also known as the Foreign Trade Policy or Export Import Policy.

After the liberalization of import policy, almost all the items are allowed to import in India. There is only a very short list of items either banned for import, or those required to be imported through government agencies, or under special license.

## **FDA Import Policy**

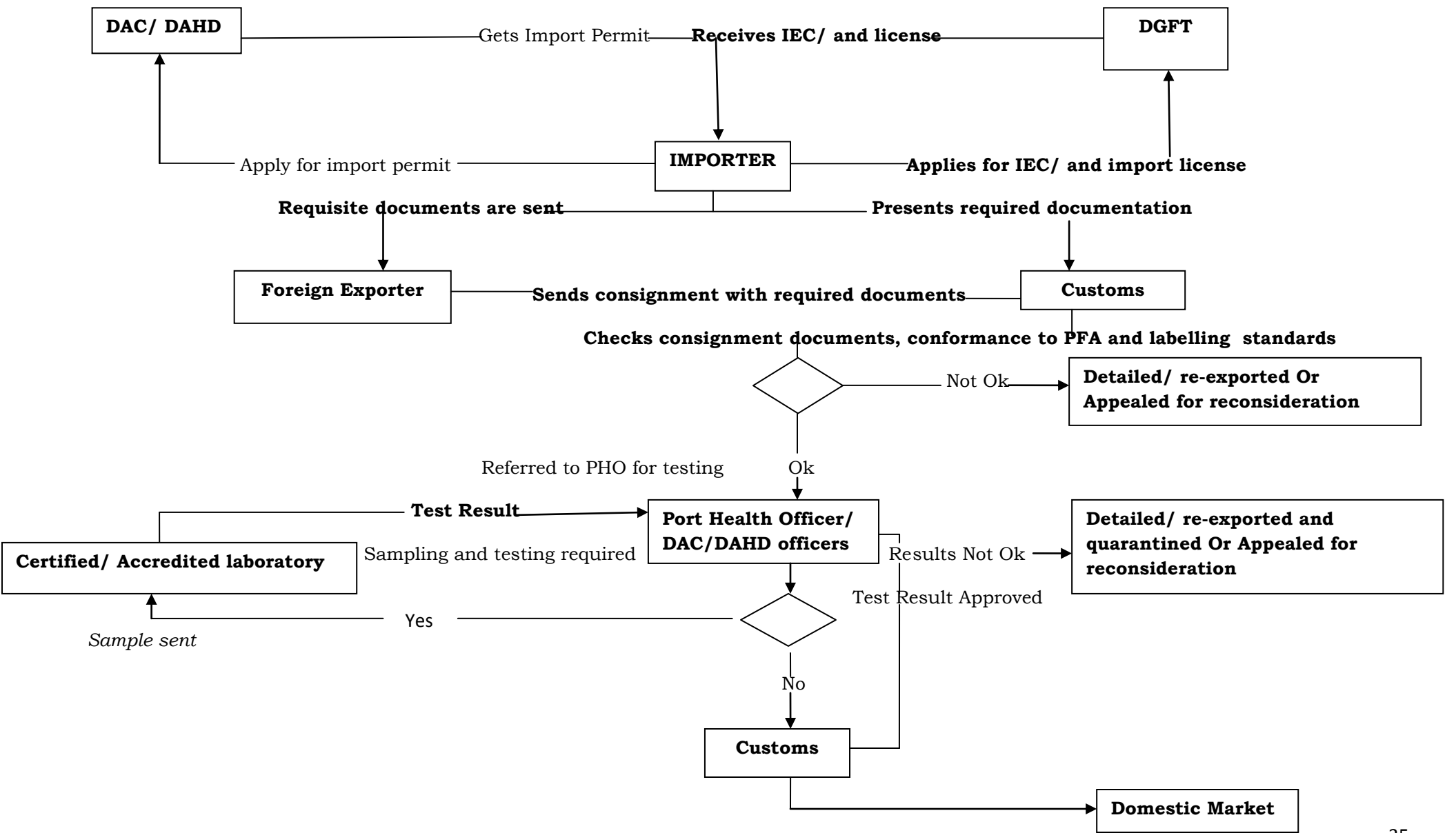
Under provisions of the U.S. law contained in the U.S. Federal Food, Drug and Cosmetic Act, importers of food products intended for introduction into U.S. interstate commerce are responsible for ensuring that the products are safe, sanitary, and labelled according to U.S. requirements. (All imported food is considered to be interstate commerce.) FDA is not authorized under the law to approve, certify, license or otherwise sanction individual food importers, products, labels or shipments. Importers can import foods into the United States without prior sanction by FDA, as long as the facilities that produce, store or otherwise handle the products are registered with FDA, and prior notice of incoming shipments is provided to FDA. Imported food products are subject to FDA inspection when offered for import at U.S. ports of entry. FDA may detain shipments of products offered for import if

the shipments are found not to be in compliance with U.S. requirements. Both imported and domestically-produced foods must meet the same legal requirements in the United States.

All food products imported into the U.S.A. are required to meet the same standards as domestic goods. To enter the U.S.A., imported foods must be pure, wholesome, safe to eat, produced under sanitary conditions, and must meet all U.S. standards including having informative and truthful labelling in English. Due to differences in the attributes of products falling under their respective jurisdictions, the differences in the historical development of the agencies and in their underlying legal authorities, USDA/FSIS and HHS/FDA take different approaches to the regulation of food, including imported food products.

**EXISTING PROCESS MAP - FOR FOOD IMPORT (Subject to modifications)**

**OVERVIEW OF PROCESS MAP**



## **Exim Policy of India**

For the betterment of the Indian import and also export, the government has introduced Exim Policy in India for a five year period. All the items that can be freely imported, items that are prohibited or items that are restricted are mentioned in this list.

The short list of banned items that cannot be imported in India includes beef and tallow, fats and oils, animal rennet and wild animals, including their parts and ivory. List of items that are canalized can only be imported by the government of India or its designated agencies. Canalized list of items include, pulses, cereals and spices. Items on the restricted list (requiring special license) include safety and security related products, plants and animals, insecticides and pesticides, and other items that could have an impact on security, health and environment Registration with a regional licensing authority is a precondition for the import of goods. Customs officials will not permit clearance of goods unless the importer gets an Import Export Code (IEC) number from the regional licensing authority.

## **Protocol in case of rejection or refusal to entry**

In many countries, imported products that do not clear customs control at point of entry because of a violation of a national law or requirement are refused entry. Shipment to a bonded ware house also permits refusal in this manner and is effective in that the product violating national regulations is detained at the customs entry point and cannot be distributed into the domestic market.

In some countries, food control authorities permit release an importers warehouse for purpose of inspection. In that the product is not in bond, it generally acquires domestic or landed status. Without extremely good liaison between the food and customs control authorities, use of this procedure should be considered carefully in that the deposition of the violative shipment becomes much more difficult and complicated.

Normal sampling practices cannot check every article of food. Furthermore, the manpower resources available o a particular country dictate how extensively all shipments can be sampled. The possibility of un- fit or un-satisfactory food products entering a country are a real possibility. With experience, the inspector can develop suitable sampling procedures for each commodity.

When special problems are encountered for a particular product, or with a particular supplier, more inspections or examinations of all shipments of that product, or of all shipments from the same supplier, should be carried out until the problems are corrected.

Care must be exercised when dealing with perishable foods. It may be necessary for them to be delivered to the point of controlled storage, and the examination carried out as they are unloaded into the storage facility.

## **Sampling**

If the inspector's examination of a lot of goods indicates that the product is questionable, a sample should be taken for laboratory examination. Samples may also be taken as a result of specific information as to a bad product, complains received regarding previous shipments of the same food product, or a series of complains regarding various foods from the same supplier.

There should be basic facilities for drawing samples, and some space to select containers and open packages as required. If no facilities are available at the port of entry, the goods may be moved from the importer's premises. If the food is perishable, sampling

and analysis should be conducted as rapidly as possible so that the food can be sold if it proves to be satisfactory.

### **Storage**

Unsatisfactory storage practices can lead to unnecessary waste. In some storage facilities under government control, difficulties may arise over cleanliness and delays. The inspector should check handling practices, and use every opportunity to explain to agents in charge the possible results of delays, bad storage practices and mishandling.

### **Reconditioning**

If a food is found to be un-satisfactory following examination, it may be acceptable after reconditioning. Such reconditioning should be conducted under the supervision of an inspector, with the lot being extensively re-sampled and undergoing laboratory examination.

### **Import intelligence and alert systems**

When a country experience a continuing problem with a particular food product, or a particular shipper, a procedure should be developed to inform all ports of entry to ensure that the product will be developed to inform all ports of entry to ensure that the product will be detained for sampling and analysis. Consideration should also be given to advising other food control authorities within the region or economic grouping with a view to minimize the change of a rejected shipment being transported to a neighbouring country.

### **FDA Import Alerts**

One of the worst places for any foreign manufacturer or shipper to be is on an **FDA import alert**. The effect of such an alert is that FDA automatically detains some or all products from that manufacturer or shipper and requires the U.S. importer to demonstrate the product complies with the Food Drug & Cosmetic Act before FDA will permit the product into the country.

This process can be expensive and adds unnecessary costs to a foreign manufacturer's product making it harder to compete in the U.S. market place. It is very important for manufacturers or shippers appearing on an FDA import alert to get off of the alert as soon as possible.

Through Import Alerts (or the automatic detentions list) FDA publicly identifies products that are likely to be detained without Physical Examination ("DWPE") for a variety of reasons. FDA asserts its authority to automatically detain products under Section 801(a) of the Food Drug & Cosmetic Act. That Section states, "If it appears from the examination of such samples or otherwise that

(1) Such article has been manufactured, processed, or packed under insanitary conditions or

(2) Such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or

(3) Such article is adulterated, misbranded, or in violation of section 505 [relating to new drug approvals] . . . then such article shall be refused admission . . ."

Typically FDA Import Alerts identify a manufacturer, shipper, grower, importer, a geographic area or a combination of these factors as the source of the problem that appears to be in violation of the law. The geographic region could be an entire country (country wide import alerts) or worldwide (effectively creating an automatic barrier to all international trade in that commodity).

Import Alerts instruct FDA import inspectors, investigators, and compliance officers to **automatically detain or detain without physical examination all imports of the affected products** from the **listed manufacturer, shipper, grower, importer, or geographic area**. Once on an Import Alert, FDA will routinely continue to automatically detain the affected products in the future until the manufacturer, shipper, grower, or importer demonstrates to FDA that the apparent violation has been corrected.

### **Packaging and labelling**

Many countries have specific regulations that affect the type and placement of information on the package. Questions regarding labelling controls, formulas, and interpretation of laws or regulations applicable to a particular food product can usually be directed to an appropriate office or bureau in the importing country. General guidance concerning the labelling of pre-packaged foods may be obtained by consulting the Codex General Standard for the Labelling of Pre-packaged Foods. Similar guidance is available from Codex documents dealing with labelling of food additives, guidelines on claims, guidelines on date marking, and draft guidelines on nutritional labelling and on labelling of non-retail containers.

However, some general guidelines can be given. Damage or inferiority in a food should not be concealed by the packaging. The package or label should not be false or misleading in any manner. For example, a closed package should not be filled to or less than its capacity; artificial colouring or flavouring should not be added to make the food appear to be a better grade than it actually is; and the labelling should not make any claims for the food that are not true.

Required label information must be conspicuously displayed, and must be in terms that the ordinary consumer is likely to read and understand under ordinary conditions of purchase. The information should be in the language(s) commonly used in the importing country or countries.

### **Specifications and certifications**

If a product is intended for export only, the foreign purchaser may require that it meet certain specifications. The exporter should ensure that the product will be satisfactory to the regulating authority in the receiving country, and not conflict with any laws or regulations of that country.

It may be possible for products to meet certain specifications to be monitored continuously during the production operation, tested or sampled throughout the production operation, and certified as meeting the specifications, by a competent inspection group. This certification activity would need to have the agreement of receiving country; under the right conditions, acceptance by the receiving could thus be made more probable and speedier. The importing country may want to inspect or certify the food products in the country and plant of origin.

## **Storage**

Foods processed for export must be handled properly after preparation to ensure that they do not then become unsatisfactory because of decomposition, or contamination with bacteria, insects, or other unfit material. Storage facilities must be constructed and maintained so that the proper temperature is maintained and insects and pests cannot gain entry during storage. Storage practices, and the handling of food as it is placed in, or taken out of, storage for shipment should be adapted to the design of the storage area and not damage the shipping container in order to safeguard the food product from being exposed to decomposition or contamination.

## **Transportation**

The same principles hold true for transportation as for storage. All transportation vehicles should be thoroughly inspected before they are loaded to ensure that they are satisfactory for cleanliness and the ability to protect the foods during shipment. The current wide spread use of containers for shipping foods has reduced the potential for damaging foods during handling between storage and the transporting vehicle, and during handling at the export destination. Problems of gaining entry to such containers units constructed of wood, metal, plastics, fibreboards, fibreglass or laminates and they may be refrigerated for shipping frozen goods. Containers can be used for air shipments but they are more commonly associated with shipment by sea and land. The units must be inspected before loading to ensure that they have been constructed properly, are properly maintained and will protect the food product unfit or unsatisfactory. Delays during transportation should be avoided.

## **International standards, codes and recommendations**

In the absence of fully developed national food regulation, importing nations should give their first consideration to the relevant standards developed by the Codex Alimentarius commission.

In addition to the standards for individual food commodities, codex documents listing maximum permissible tolerance for pesticides residues and codex guidelines respecting safe use of food additives are also available as source of reference and guidance in making decisions about the acceptability of imported food products. Another safeguard available to importing nations is the code of Ethics for International Trade in Food adopted by Codex Alimentarius Commission, December 1979.

## Case studies and judicial pronouncement

### *General rules of legal interpretation*

1. **Preamble.**—The preamble of a statute even after repeal has been said to be a good means of finding' out its meaning, and, as it were a key to the understanding of it, and the general object and intention of the Legislature in passing enactment it may legitimately be consulted to solve any ambiguity or to fix the meaning of words which may have more than one or to keep the effect of the Act within its real scope, whenever the enacting part is in any of these respects open to doubt.
2. **Proviso**—It is cardinal rule of interpretation that a proviso to a particular provision of a statute only concerns the field which is covered by the main provision. It carves out an exception to the main provision to which it has been enacted by the proviso and to no other. The scope of the proviso, therefore, is to carve out an exception to the main enactment and it excludes something which otherwise would have been within the rule. It has to operate in the same field and if the language of the main enactment is clear, the proviso cannot be torn apart from the main enactment nor can it be used to nullify by implication what the enactment clearly says nor set at naught the real object of the main enactment, unless the words of the proviso are such that it is its necessary effect.
3. **Part of statutes as aid to construction.**—the parts of statutes are in a popular, though not legal, sense—the title, the preamble, the purview or body of the statute, clauses, provisions, exceptions and illustrations. It is common doctrine, never questioned, that for the purpose of interpretation, all the parts of a statute are to be looked at together, and one part may control another. If possible, they are to be reconciled. Thus, where there are words expressive of a general intention and then of a particular intention incompatible with it, the particular must be taken as an exception to the general and so all the parts will stand. And, as a broad proposition, general words in one clause may be restrained by the particular words in a subsequent clause of the same statute.
4. **Interpretation clause** —it is common practice to provide an interpretation or definition clause in every statute. Where a word or phrase is defined having a particular meaning in an enactment, it is that meaning and that meaning alone which must be given to it in the interpretation of a section of the Act unless there be anything repugnant in the context.
5. It is settled view that in determining the meaning or connotation of words and expressions describing an article in a schedule, one principle which is fairly well settled is that those words and expressions should be construed in the sense in which they are understood in the trade, first by the consumer and then by the dealer. The reason is that it is they who are concerned with it and it is the sense in which they understand which constitutes the legislative intention.

The definition section of a particular statute should be confined as a general rule to explain and define meaning of the word used in that statute and cannot be extended to define those words used in other statutes. A definition given in an Act must be substituted for the word “defined” whenever it occurs in the Act. Where in the same statute the Legislature defines the meanings of the words, it expresses most authoritatively its intent and its definitions and constructions are binding on Courts. Such internal legislative construction is of the highest value and prevails over executive or administrative construction and other intrinsic aids.

6. **Principle of interpretation.**—It is well-known principle of interpretation of statutes that Acts must be construed as a whole. Guidance with regard to the meaning of a particular word or phrase may be found in other words and phrases in the same



section or in other sections, although the utility of an extensive consideration of other parts of the same statute will vary from case to case.

It is an indisputable principle of construction of sections that expression is defined in the statute, unless there is anything repugnant in the subject or context, the expression has to be construed as having the same meaning assigned to it in the dictionary clause of the statute.

7. **Interpretation of statute.**—The Court usually interprets the statute in a manner so as to protect and maintain the object and purpose of the enactment. Any narrow or technical interpretation of the provisions would defeat the legislative policy. The Courts therefore, try to keep the legislative policy in mind in applying the provisions of the Act to the facts of the case.

In interpreting the provision the exercise undertaken by the Court is to make explicit the intention of the Legislature which enacted the legislation. No one has the authority to reframe the legislation for the very good reason that the powers to legislate have not been conferred on anyone, not even the Court.

**Interpretation of section.**—The Courts can merely interpret the section, it cannot re-write, re-cast or re-design the section.

If there is overlapping or any conflict in the statute then on the settled principles of statutory interpretation of law, the statute must be read as a whole and the real intention of the Legislature is to be judged by reading the entire section as a whole.

In order to sustain the presumption of constitutionality of a legislative measure, the Court can take into consideration matters of common knowledge, matters of common report, the history of the times and also assume every state of facts which can be conceived existing at the time of the legislation.

8. **Headings and marginal notes.**—The headings of a statute may be referred for the purpose of finding out doubtful expression in the section. But the headings or subheadings cannot either restrict or extend the scope of the sections when the language used is free from ambiguity. A cross-heading in the Act can properly be used as giving the key to the interpretation of the section unless the wording of the section is inconsistent with such interpretation. Marginal notes stand in the same footing as headings and though they cannot be held to govern the clear text of a section, yet they can be taken as indication of what the Legislature meant. Marginal notes to a section cannot be referred to for the purposes of construing the Act, though they can be referred to in case of obscurity of any expression in the text of the statute, if they can be regarded as inserted by or under the authority of or assented by the Legislature.

It is well-recognised principle of interpretation of statutes that heading and marginal notes can be looked into for the purpose of ascertainment of the intention of the Legislature.

9. **Sections** —Sections constitute the principal or enacting part of statute every section of a statute is a substantive enactment without introductory words. One section may contain more than one enactment.<sup>1</sup> In *Nuth v. Tamplin*, Jessell, MR., observed: “Now any one who contends that a section of an Act of Parliament is not to be read literally must be able to show one of the two things, either that there is some other section which cuts down its meaning or else that the section itself is repugnant to the general purview of the Act”. And yet if the Courts find a latter section in such Act repugnant to a former one the latter must be accepted as repealing the former.’
10. A section may be prospective in some parts and retrospective in other parts. While it is the ordinary rule that substantive rights should not be held to be taken away except by express provision or clear implication, many Acts, though prospective in form, have been given retrospective operation, if the intention of the Legislature is apparent. This is more so, when Acts are passed to protect the public against some evil or abuse.

11. **Sub-sections.**—If two sections or sub-sections of an Act cannot be reconciled as there may be absolute contradiction, it is often held that last must prevail.
12. **Punctuations.**—It is an error to rely on punctuation in construing an Act. Consequently, the Court takes no notice of commas. In the interpretation of statutes, punctuation not being a part of the statute to be construed, is not the determining factor and if the provision as punctuated leads to an absurd result or conflicts with some other provision of the statute which is unambiguous and free from doubt, the punctuation must yield to an interpretation that is reasonable and makes it consistent with the other provisions of the Act.
13. **Rules made by subordinate authority.**—Rules are made by a subordinate authority which is not the Legislature and validity of an Act of a competent Legislature cannot be made to depend upon what some subordinate authority frames and hence in case of any ambiguity between any sections of the Act and some rules, then interpretation of the Act would prevail.
14. **Rules of construction.**—Ordinarily the rule of construction is that the same expression where it appears more than once in the same statute, more so in the same provision, must receive the same meaning unless the context suggests otherwise.’
15. **Special and general provisions—Effect of.**—It is a well-known rule of the interpretation of statutes that a particular enactment is not repealed by a general enactment in the same statute.
16. **Words “also” and “at least”.**—It is well-settled that when in the enactment, the word “also” and “at least” are used they signify unconditional legislative intent.
17. **Issue and serve.**—The fallacy that seems to have crept is to suggest that (barring some very peculiar or compulsive textual compulsion in plain ordinary English,) the word “issue” and the word “serve” are synonyms or identical in terms. But it is not so. Their plain dictionary meaning runs direct by contrary to any such assumption. No dictionary says that the issuance of an order is necessarily the service of such order on a person as well or, in reverses that the service of an order on a person is the mathematical equivalent to its issuance. In Chamber’s Twentieth Century Dictionary, the relevant meanings given to the word “issue” are act of sending out, to put forth, to put into circulation, to publish, to give out for use. On the other hand, the word “serve” in the same dictionary has been given the meaning, as term of law, to deliver or present formally, or give effect to. Similarly, in the New Illustrated Dictionary, the relevant meaning attributed to the word “issue” is come out, be published, send forth, publish, put into circulation whilst the relevant meanings attributed to the word “serve” are to supply a person with; make legal delivery of (writ, etc.), delivery writ, etc. to a person. Thus, it would appear that the words “issue” and “serve” are distinct and separate and indeed the gap between the two may be wide both in point of time and place.
18. **“May”** - the expression “may” in the context of the words does not confer a discretion but conveys almost a mandate.
19. **“May” and “shall”.**—Where the Legislature used two words “may” and “shall” in two different parts of the same provision prima facie it would appear that the Legislature manifested its intention to make one part directory and another mandatory. But that by itself is not decisive. The power of the Court still to ascertain the real intention of the Legislature by carefully examining the scope of the statute to find out whether the provision is directory or mandatory remains unimpaired even where both the words are used in the same provision.

Whether in a given context a statute should be termed mandatory or directory would depend upon the larger aspect of public interest, balanced with the precious right of the common man.

20. **Saving clause.**—Usual saving clause is intended to save anything done or any action taken or any order or direction issued, under a repealed provision of law. But while giving effect to a saving provision, when it provides that something which is done or issued under the repealed provision must be treated as having been done or issued under the newly enacted provision, as earlier order can be saved only if such a direction or order could be effectively and validly made under the new provisions of law, which had repealed the earlier provisions. A saving clause cannot extend the scope of the prohibition contained in the main or enacting clause because it may often be added as a measure of abundant caution.

Whether the saving clause should receive a strict or liberal construction, is a matter upon which there seems to be some conflict of opinion. Perhaps the best rule would make the nature of the construction of the saving clause depend upon the nature of the statute involved, for example, whether it was remedial, penal or procedural.

21. **Where a word has a scientific or technical meaning and also an ordinary meaning according to common parlance in a statute with penal provisions, the latter would prevail.**—It is a well settled principle of construction, as mentioned before, that where the word has a scientific or technical meaning and also an ordinary meaning according to common parlance, it is in the latter sense that in a statute the word must be heard to have been used, unless contrary intention is clearly expressed by the Legislature.

### **The Enforcement Structure and Appeal at various stages**

Enforcement of the Act will happen at various levels as follows:

- **FSO Level:** Inspects, collects sample of food and sends the same to Food Analyst (if so required) for analysis within the succeeding working day. Here the food Business Operator (FBO) can request the FSO in writing to send another set of sample to an accredited lab of his choice within the same time limit as specified above. After receiving the report from the Food Analyst, FSO sends the same to the Designated Officer of that area.
- **Designated Officer Level:** An appeal to the DO at this level (within 30 days time from the date of receiving the analysis report) would be heard and if the DO deems fit he may send the fourth sample to a Referral lab for analysis and reinvestigation. If the analysis report fails which proves that the food is unsafe, DO shall send the case either to Adjudication officer or to the Commissioner depending on the gravity of the contravention or non compliance. He can also take other necessary administrative action including show cause, suspension or cancellation of license in public interest.
- **Adjudication Officer Level** (responsible for handling penalty in the form of fine): He has the power to hold inquiry for the offences punishable under Adjudication and is the final authority to finalize the quantum of penalty in the form of fine according to the offence committed by the FBO. However, upon consideration of the evidences if he is satisfied that the contravention has not taken place; he can dismiss the case against such person.
- **Appellate Tribunal:**  
If the person (FBO) is not satisfied with the decision of the adjudicating officer, he may chose to appeal before an Appellate Tribunal within 30 days time meant for such appeals and if the person is not satisfied with the decision of the tribunal, can file an appeal to the High court within 60 days from the date of communication of the decision or order of the Tribunal. However, High court has the power to extend the period by another two months, if it is satisfied that the appellant is being prevented from filing such appeal. However, there is no further appeal or trial after the High court, hence the decision of High court would be final and binding for

which the appeal is being made. A Presiding Officer of at least District Judge level not below 65 years age to be selected by the State Government to head the Tribunal. At this level, if the petitioner or the applicant is not satisfied with the decision of the Tribunal, he may appeal to High court within 60 days time. The time can be extended further on the decision of the court for another 60 days.

- **Commissioner Level** (empowered to sentence imprisonment): for quantum of punishment, the commissioner may send the case to a First class judicial magistrate or to a Metropolitan Magistrate with limited power of sentencing imprisonment max for three years.
- **Court Level:** If while in the process, after one year, it is felt that the term of imprisonment has to be increased, in such case, the case would be referred to a Special Court which is empowered to handle offences related to grievous injuries or death of the consumer.
- **Special Court:** Central or State government can form such courts if necessary in public interest, only to deal with offences relating to grievous injury or death and for which punishment of imprisonment has been prescribed in the act. Special Court has the power to increase the sentence by up to a maximum of 6 years. Where the Special Court has the opinion that the offence is not triable by it, shall transfer the case for such offences to any court having jurisdiction under Code of Criminal Procedure, 1973.
- All offences not triable by a special court, shall be tried in summary way by a 1<sup>st</sup> class judicial magistrate or by a metropolitan Magistrate and provisions of sections 262 to 265 (both inclusive) of the said code shall apply to such trials.
- Court having jurisdiction under the Code of Criminal Procedure shall proceed with the trial and give away quantum of the penalty with or without fine and the decision of the court will be final.

**Note: However, no civil court shall have the jurisdiction to entertain any suit or proceedings in respect of any matter which an Adjudicating Officer or the Tribunal is empowered under this Act.**

#### **Offences and Penalties (Section 48 & 49)**

Various offences are stated in the Act related to mainly on compromising the quality and safety of the food at various stages. It is important to note that penalty in general would be awarded by the Adjudicating Officer for different offences under section 48 and impose quantum of penalty in the form of fine. This can be considered as the most important change from the current PFA wherein penalty in general used to be imprisonment. Here, imprisonment would be imparted only in case of death or grievous injuries caused.

#### **Recovery of Penalty (Section 96)**

If the imposed penalty is not paid within time that can be recovered as an arrear of land revenue and the defaulters license shall be suspended till the penalty amount is paid.

#### **Adjudication (Section 68)**

- (1) Adjudicating officer- not below Additional District Magistrate with powers of a civil court shall be notified by the State Government as the Adjudicating officer.
- (2) The Adjudicating officer shall, after giving the person reasonable opportunity for making representation in the matter, and if, on such inquiry, he is satisfied that the person has committed the contravention of provisions of this Act or the rules and regulations made there under, impose such penalty s he thinks fit in accordance with the provisions relating to the offence.

- (3) All proceedings before him shall be deemed to be judicial proceedings within the meaning of sections 193 and 228 of the Indian Penal code; and shall be deemed to be a court for the purposes of sections 345 and 346 of the Code of criminal Procedure, 1973.
- (4) While adjudicating the quantum of penalty will be charged having due regard to the guidelines specified in section 49 of the Act.

#### **Appellate Tribunal (Section 70-71)**

##### Food Safety Appellate Tribunal

Central Government or State Government may establish one or more Food Safety Appellate Tribunal under one presiding officer (District Judge) to hear appeals from the decisions of the Adjudicating Officer to be guided by Principles of Natural Justice.

- (1) The Central Government or as the case may be, the State Government may, by notification, establish one or more tribunals to be known as the Food Safety Appellate Tribunal to hear appeals from the decisions of the Adjudicating Officer under section 68.
- (2) The Central Government or the State government, as the case may be, shall prescribe the matters and the areas in relation to which the Tribunal may exercise jurisdiction.
- (3) The tribunal shall consist of one person only (hereinafter referred to as the Presiding Officer of the Tribunal) to be appointed, by notification, by the Central Government or the State Government, as the case may be: Provided that no person shall be qualified for appointment as a Presiding Officer to the Tribunal unless he is or has been a District judge.

#### **(4) Procedure and powers of Tribunal-**

- i) The Tribunal shall not be bound by the procedure laid down by the Code of Civil Procedure, 1908 but shall be guided by the principles of natural justice and, subject to the other provisions of this Act and the rules made there under, the Tribunal shall have powers to regulate its own procedure including the place at which it shall have its sittings.
- ii) Every proceeding before the Tribunal shall be deemed to be a judicial proceeding within the meaning of sections 193 and 228, and for the purposes of section 196 of the Indian Penal Code, it shall be deemed to be a civil court for all the purposes of section 195 and Chapter XXVI of the Code of Criminal Procedure, 1973.
- iii) The appellant may either appear in person or authorize one or more legal practitioners or any of its officers to represent his case before the Tribunal.
- iv) The proceedings of the appellate shall be conducted in English or local language of the state.
- v) The provisions of the Limitation Act, 1963, shall, except as otherwise provided in this Act, apply to an appeal made to the Tribunal.
- vi) Any person aggrieved by any decision or order of the Tribunal may file an appeal to the High Court within 60 days from the date of communication of the decision or order of the Tribunal to him on any question of fact or law arising out of such order: Provided that the High Court may, if it is satisfied that the appellant was prevented by sufficient cause from filing the appeal within the said period, allow it to be filed within a further period not exceeding 60 days.

#### **Compounding of offences (Section 69)**

Power to compound offences- Designated Officer may be authorised by Commissioner to compound offences committed by petty manufacturers, hawkers,

itinerant vendors- compounding fee not more than Rs 1 lakh and offence for which punishment of imprisonment has been prescribed under this Act, shall not be compounded.

Compensation in case of injury or death of consumer (Section 65)

- (1) If any person whether by himself or any other person on his behalf, manufactures or distributes or sells or imports any article of food causing injury to the consumer or his death, it shall be lawful for the Adjudicating Officer or as the case may be, the court to direct him to pay compensation to the victim or the legal representative of the victim, a sum-
  - (a) Not less than 5 lakh rupees in case of death.
  - (b) Not exceeding three lakh rupees in case of grievous injury; and
  - (c) Not exceeding one lakh rupees, in all the cases of injury: Provided that the compensation shall be paid at the earliest and in no case later than six months from the date of occurrence of the incident: Provided further that in case of death, an interim relief shall be paid to the next of the kin within thirty days of the incident.
- (2) Where any person is held guilty of an offence leading to grievous injury or death, the Adjudicating Officer or the court may cause the name and place of residence of the person held guilty, the offence and the penalty imposed to be published at the offender's expense in such newspapers or in such other manner as the Adjudicating Officer or the court may direct and the expenses of such publication shall be deemed to be part of the cost attending the conviction and shall be recoverable in the same manner as a fine.

**(3) The Adjudicating Officer or the court may also**

- (a) Order for cancellation of license, re-call of food from market, forfeiture of establishment and property in case of grievous injury or death of consumer;**
- (b) Issue prohibition orders in other cases.**

**Nomination by a company (existing section under PFA)**

**Offences and liabilities of a company**

- (1) Where an offence under Section 48 of this Act has been committed by a company, every person who at the time of offence was committed was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company, shall be deemed to be guilty of the offense and shall be liable to be proceeded against and punished accordingly under Section 66 of the act.
- (2) Where a company has different establishments or branches or different units in any establishment or branch, such company shall inform the concerned licensing authority, the name and designation of the Head, or the person in-charge of such establishment or branch or unit nominated by the company as responsible for food safety, and such head or the person in-charge shall be responsible for all activities and compliances with this Act, rules and regulations. Such nomination in respect of the person in charge shall be made in prescribed format, signed by the proprietor or any signatory authorized by the Board of Directors of the company for the purpose.
- (3) Where
  - (a) A company having different establishments or branches or different units in any establishment or branch has not intimated name and designation of the head, or made any nomination under sub-rule (2) above for any or all of its establishments or branches, or

- (b) Determination of the Head, or the person in-charge or the person responsible for food safety in any establishment, branch or unit cannot be made for any reason whatsoever, or
- (c) The nomination under sub-rule (2) above is found to be not in accordance with the provisions of the Act and procedure laid down in these rules,

then every person who at the relevant time was in-charge of the affairs of the company, or responsible for the conduct of the affairs of the company as well as the company shall be deemed to be guilty of the offence for the purposes of section 66 of the Act.

### **Special courts and powers (Section 74-75)**

- (1) Notwithstanding anything contained in this Act or in the Code of Criminal Procedure, 1973, the Central Government or the State Government in their respective jurisdiction may, if consider expedient and necessary in the public interest, for the purposes of the trial offences relating to grievous injury or death of the consumer for which punishment of imprisonment for more than three years has been prescribed under this Act, constitute, by notification in the Official Gazette, as many Special Courts with the concurrence of the Chief Justice of the High Court as may be necessary for such area or areas and for exercising such jurisdiction, as many be specified in the notification.
- (2) A Special Court may, on its own motion, or on an application made by the Public Prosecutor and if it considers it expedient or desirable so to do, sit for any of its proceedings at any place other than its ordinary place of sitting.
- (3) The trial under this Act of any offence by a special Court shall have precedence over the trial of any other case against the accused in any other court (not being a Special Court) and shall be concluded in preference to the trial of such other case and accordingly the trial of such other case shall remain in abeyance.
- (4) For every Special Court, the Central Government or the State Government, as the case may be, shall appoint a person to be the Public Prosecutor and may appoint more than one person to be the Additional Public Prosecutors: Provided that the Central Government or the State Government, as the case may be, may appoint for any case or class or group of cases, a Special Public Prosecutor.
- (5) A person shall not be qualified to be appointed as a Public Prosecutor or an Additional Public Prosecutor or a Special Public Prosecutor under this section unless he has been in practice as an Advocate for not less than seven years or has held any post, for a period of not less than seven years, under the Union or a State, requiring special knowledge of law.
- (6) Power to transfer cases to regular courts – where, after taking cognizance of any offence, a Special Court is of the opinion that the offence is not triable by it, it shall, notwithstanding that it has no jurisdiction to try such offence, transfer the case for the trial of such offence to any court having jurisdiction under the Code of Criminal Procedure, 1973 and the court to which the case is transferred may proceed with the trial of the offence as if it had taken cognizance of the offence.

### **Time limit for prosecutions- no case to be tried after one year from the date of commission of offense**

### **Appeal (Section 76)**

- (1) Any person aggrieved by a decision or order of a Special Court may, on payment of such fee as may be prescribed by the Central Government and after depositing the amount, if any, imposed by way of penalty, compensation or damage under this Act, within forty-five days from the date on which the order was served, prefer an appeal to the High Court: Provided that the High Court may entertain any appeal after the

expiry of the said period of forty-five days, if it is satisfied that the appellant was prevented by sufficient cause for filing the appeal within the said period.

- (2) An appeal preferred under this section shall be disposed of by the High Court by a bench of not less than two judges.

### **Power of court to implead manufacturer (Section 78) Existing Provision in PFA**

Where at any time during the trial of any offence under this Act alleged to have been committed by any person, not being the importer, manufacturer, distributor, or dealer of any article of food, the court, is satisfied, on the evidence adduced before it, that such importer, manufacturer, distributor or dealer is also concerned with that offence, then the court may, notwithstanding anything contained in sub-section (3) of section 319 of the Code of Criminal Procedure, 1973, or in section 71 of this Act, proceed against him as through a prosecution has been instituted under this Act.

### **Highlights of Case laws in PFA**

1. The knowledge and awareness of the buyer are immaterial as the object and policy of the statute is to protect the public by prohibiting the sale in any circumstances of adulterated milk or milk which did not come up to the prescribed standard of purity.

In *M.V. Krishnan v. State of Kerala*, the prosecution related to butter milk and it was observed that a person selling butter milk cannot be convicted for an offence under section 16(1) (a) (i) and Sec. 7 of the Prevention of Food Adulteration Act, 1954, read with Rule 44 of the Prevention of Food Adulteration Rules, 1955, as no standard is prescribed for butter milk.

So far as the food adulteration Act and the rules there under are concerned, what is pure ghee and what is adulteration of ghee are matters of definition. When the rules say that any deficiency in the Reichert value below a particular stipulated figure means a sub-standard quality and such sub-standard quality is by definition an act of adulteration, it will not be open to the Court to embark on an academic investigation about the Reichert value and its bearing upon the quantum of fat in milk in different areas in this country.

2. The supreme court in *M.V. Joshi v. M.U. Shimpi* while dealing with an analogous case of adulteration of butter observes:  
“if the quality of purity of butter falls below the standard prescribed by the said rules or its constituents are in excess of the prescribed limits of variability, it shall be deemed to be adulterated within the meaning of Sec. 2 of the Act”.

The same reasoning will apply when the quality of ghee and its definitions for the purpose of adulteration are prescribed by the statute in relation to the result revealed in the Central Food Laboratory for the Reichert test.

3. **Clause (v):** The Apex Court in *State of Tamil Nadu V. R. Krishnamurthy* ruled that any article used for human consumption is food irrespective of purpose for which it is sold. According to definition of ‘food’ for the purposes of the Act, **any article used as food or drink for human consumption and any article which ordinarily enters into or is used in the composition or preparation of human food is ‘food’**. It is not necessary that it is intended for human consumption or for preparation of human food. It is also irrelevant that it is described or exhibited as intended for some other use. **It is enough if the article is generally or commonly used for human consumption or in the preparation of human food**. It is notorious that there are, unfortunately in our vast country, large segments of population, who living as they do, far beneath ordinary subsistence level, are ready to consume that which may otherwise be thought not fit for human consumption. In order to keep their body and soul together, they are often tempted to buy and use as food, articles which are adulterated and even unfit for human consumption but which are sold at



inviting prices, under the pretence or without pretence that they are intended to be used for purposes other than human consumption. It is to prevent the exploitation and self destruction of these poor ignorant and illiterate persons that the definition of food is couched in such terms as not to take into account whether an article is intended for human consumption, or not. In order to be 'food' for the purposes of this Act, an article need not be fit for human consumption; it need not be described or exhibited as intended for human consumption, it may be even otherwise described or exhibited, it need not even be necessarily intended for human consumption, it is enough if it is generally or commonly used for human consumption or in preparation of human food.

4. **Ice is not food: It is pertinent to note here that in the Appendix B of the Prevention of Food Adulteration Rules, 1955, no definition or standard of quality is prescribed for the Ice. However, at para A. 07. 04 and A.07.04.01 standards are prescribed for "Ice Lollies or Edible Ice" and "Ice Candy" respectively. It will be seen that under both the paragraphs, ice is considered as food only when it contains sugar, syrup, fruit, fruit juice with permitted flavours and colours. Ice in original form does not find place in the Appendix B. The omission is deliberate, keeping in view the definition of food given under Cl. (v) Sec. 2 of the Act, which excludes water. Needless to add, the water means water in every form i.e. liquid, solid or gas.**
5. **State vs Nanu Ram (2008 FAJ 429 (Raj)** —The State (HC) has preferred this criminal appeal against the judgment dated 2.9.1988 passed by the learned Chief Judicial Magistrate, Chittorgarh whereby the learned Chief Judicial Magistrate has acquitted the accused respondent Nanu Ram in the offence under Section 7 read with Section 16 of Prevention of Food Adulteration Act.

As per the prosecution story, a sample of milk was collected by the Food Inspector at 7.30 a.m. from the milk tank of accused being carried for sale. On examination of this sample, milk was found to be adulterated.

The Food Inspector filed a complaint against the accused respondent in the Court. After recording the evidence of the prosecution witnesses the lower Court did not find the accused respondent guilty and acquitted him of the aforesaid charge.

The Hon'ble HC found that the judgment of acquittal of the lower Court is well founded, sound and well merited. Apart the grounds of acquittal enumerated by the learned lower Court, it was found that the Chief Medical Health Officer, Pratapgarh issued two sanctions to prosecute the accused respondent in the Court. Both the sanctions were carrying serial No.143 but they were bearing different dates. One was found to have been issued on 16.2.1984 and the second issued prior to 29.12.1983. Further, the exhibit revealed that the sanction to prosecute the accused respondent was issued prior to 29.12.1983 and thereafter the relevant documents were sent to the Food Inspector to file a complaint in the Court of law. It speaks of a sample No.8/SI/83 but so far as the prosecution sanction Ex.P8 issued on 16.2.1984 is concerned, this document does not bear any sample and it does not disclose as to which is the sample taken by the Food Inspector for which the prosecution sanction was accorded and a complaint was directed to be filed. "These material variations with regard to the prosecution sanction had unequivocally and undisputedly caused a serious prejudice to the accused respondent and the accused respondent could have been acquitted on this ground alone". The order read "The learned lower Court is not found to have committed any error in arriving at conclusion to acquit him. I agree with the grounds of acquittal as enumerated and enunciated by the lower Court and in my opinion the judgment of the lower Court calls for no interference. In view of

the above, the State appeal preferred by the State deserves to be dismissed and is dismissed accordingly”.

6. **Gujarat high Court case on Section 378(1)** —case filed under Section 2(1a)(a)(m) and 16(1)(a) of PFA Act and under Prevention of Food Adulteration Rules, 1955—Rule 14. A sample of milk was found not to be in conformity with standards prescribed under the Act and Rules. Respondent acquitted by trial court. Appeal filed against acquittal on grounds of failure on part of prosecution in establishing beyond doubt, absolute compliance of provisions of Rule 14 of Rules—Categorical admission of Food Inspector in his deposition that bottles were obtained from local Health Authority, Nadiad, who in turn collected it from Gandhinagar and he had no personal knowledge about that being cleaned. Food Inspector also admitted that he had no knowledge regarding vessel, in which initially the sample food articles was collected, was cleaned or not. Deposition of complainant itself was sufficient to show that complainant was not sure of status of bottles wherein sample was collected. Failure on part of prosecution in proving due compliance with mandatory Rule 14 of rules vitiated prosecution case—Appeal dismissed.
7. **State vs D P Bhatia and Ors – Delhi High Court – under criminal procedure Code 1973 and PFA Act Section 2(1a) (a) (m), 7, 16(1). 2008 FAJ 546** - This petition by the State under Section 482 CrPC challenged the impugned order dated 9th March, 1995 passed by the learned Metropolitan Magistrate (‘MM’), Delhi holding that no offence was made out against the respondents under Section 2(1a) (a) (m) read with Section 7 and punishable under Section 16 (1) of the Prevention of Food Adulteration Act, 1954 (‘PFA Act’). The State also challenged an order dated 19th April, 2003 passed by the learned Additional Sessions Judge (‘ASJ’), New Delhi dismissing its Criminal Revision No.50 of 2000 against the aforementioned order dated 9th March, 1995 passed by the learned MM.

The controversy in the present matter concerns a sample of “breakfast sugar” collected from Hotel Oberoi Maidens, a unit of the East India Hotels Ltd. When one part of the sample was sent to Public Analyst, the report was that it was adulterated. It was stated that the sample did not conform to the standards of sugar since the sucrose content in it was less than the prescribed minimum limit of 98%. The learned MM discharged the accused after observing that breakfast sugar was distinct in quality, identity and price from the ordinary sugar and that since there was no prescribed standard under the PFA for breakfast sugar there was no offence committed.

In his order the learned ASJ noted that when the second part of the sample was sent to the Director, Central Food Laboratory (‘CFL’), Mysore at the instance of the respondent, the report of the CFL stated that there are no existing standards for breakfast sugar under the PFA. This fact is not disputed by the State.

Since two courts have concurrently held on facts that there were no standards for breakfast sugar under the PFA, this Court finds absolutely no ground for interference at the instance of the State in the present matter. The petition is dismissed with no order as to costs.

8. **Wheat flour kept in a dhaba for preparation of chapattis for sale – it is sufficient to hold that wheat flour is meant for sale within the meaning of Sec. 2 (xiii) of the Act** - it was submitted by the learned counsel for the petitioner that petitioner was running dhaba. Assuming that he was found in possession of wheat flour in his dhaba, that wheat flour was not meant for sale

as such. He was to prepare chapattis and sell them. Suffice it to say the sale of a constituent of a finished product in which the petitioner was dealing to the food Inspector would also amount to sale within the meaning of Sec. 2 (xiii) of the Prevention of Food Adulteration Act.

9. **Standards prescribed for various articles of food part of the statute – Court not empowered to vary or meddle with the standards:** A seller of an article of food is liable to be convicted if the article is found below the prescribed standard. Wherever the standards are fixed by the statute, it is not for the Courts to consider their reasonableness or correctness. It is not permissible for an accused to prove that though the standard prescribed is not attained the article of food is not adulterated.
10. **Conviction for selling adulterated milk – sample taken by a food inspector from an area beyond his jurisdiction – trial and proceedings vitiated – conviction not sustainable** – Section 9 of the Prevention of Food Adulteration Act lays down that the Central Government or the State Government may appoint such persons as it thinks fit, having the prescribed qualifications to be Food Inspector for such local areas as may be assigned by the Central Government or the State Government, as the case may be. Thus, the local area within which Food Inspector is authorized to act may be assigned by the Central Government or State Government. The power of the Central Government or State Government has not been delegated to the Chief Medical Officer. Bijnor to change the area or assign additional jurisdiction of the area to a Food Inspector for which he was not appointed as a Food Inspector.
11. **Offender cannot be simultaneously convicted for selling adulterated food and for selling same food without licence** –A conjoint reading of both sub-clauses (i) and (ii) of the Sec. 16 makes it clear that a vendor can be punished under the former sub-clause if he sells, stores or distributes food which is adulterated, misbranded or sale of which is prohibited and so far as the latter sub-clause is concerned he can be punished there under if he sells, stores or distributes food articles other than those mentioned in sub clause (i). Rule 50 of the rules prohibits manufacture, sale etc. of the prescribed food without a license so if a vendor sells any such food article without a license as required under the said rule, then he shall be punished under sub-clause (ii). An authority grants license for sale of 'food' as defined in Sec. 2(v) of the Prevention of Food Adulteration Act and not adulterated food. So if he deals in articles of food without a license and that article of food is found to be adulterated, then he cannot be held guilty and convicted under both the sub-clauses (i) and (ii) since as has been observed earlier, license is granted by the authority for sale of food and not adulterated food. When a person sells adulterated food, though he may not have a license, the proper procedure to deal with such an offence would be by resorting to sub-clause (i) and not sub-clause (ii).
12. **Ballabh v State of Uttar Pradesh - What Consumer wants is important**  
When a person is purchasing mustard oil the standards to which it should conform is the standard prescribed under Item A.17.06. In case the purchaser has not been supplied with the commodity which he was seeking to purchase, the question then arises as to whether the article of food will be deemed to be adulterated as defined in section 2(a) of the Act. Imported rapeseed oil and mustard oil are two distinct edible oils which are known as such in common parlance and also according to the different standards prescribed under the rules. In case the person asked for mustard oil, and is supplied with imported rapeseed oil, there cannot be any manner of doubt that the nature, substance or quality of the article which is demanded by the purchaser is not the same. The edible oil which is supplied to the purchaser is a different commodity altogether and hence shall be termed as adulterated as defined in Sec 2(a) of the Act.
13. **Sandep Kumar vs State of Haryana 1998 (2) EFR 116** - Even if for an article of food no standard with regard to quality or purity has been prescribed, yet that article of food will be considered as adulterated if it is injurious to health. In this

case the for Bundi and bedanna no standard has been prescribed. But for besan, which is the main essential ingredient standard has been laid down, Yet in the opinion of Punjab and Haryana High Court, Bundi or bedana has to satisfy that it was not injurious to health. In this the products were infested with fungus and hence were injurious to health.

14. **Patna Municipal Corporation v Dularchand Sao, AIR 1964.** In view of the definition of “food” as per Section 2(v), the Act is not concerned with the actual use to which the article in question may be put. To constitute food, for the purpose of the Act, it is enough that the article in question is usable as food or drink for human consumption. The word “used” in section 2 (v) obviously means that usable or capable of being used and not to be used or for the purpose of being used. By the word ordinary in section 2(v) it seems that the Legislature intended to lay down that when an article or substance is used as an ingredient in the preparation of food even by some inhabitants of this country, usually and not as something exceptional or out of the ordinary, it would come within the definition of “food” .

Now it is matter of common knowledge that coconut oil is used extensively in Kerala as a cooking medium and Malayalees wherever they may be, generally use coconut oil for that purpose. That being so, the fact that coconut oil is not used as edible oil in Andhra is beside the point and is irrelevant in determining whether it comes within the definition of food.

15. **Smt. A. Pavani v State of A.P (2006 FAJ 463):** sample of sealed packets of instant gulab jamun mix were taken from the accused, dealer. The samples were reported to be adulterated. The dealer was prosecuted, alongwith the distributor from whom the dealer had purchased the packets and the manufacturers. Now the distributor had had an invoice issued by the manufacturer for supply of packets in question and she had sold the same packets in the same form without manipulating them. section 19(2) of PFA Act, 1954 says that “ a vendor shall not be deemed to have committed an offence pertaining to the sale of any adulterated or misbranded article of food if he proves (a) that he purchased the article of food – (i) in a case where a license is prescribed for the sale thereof, from a duly licensed manufacturer, distributor or dealer; (ii) in any case, from any manufacturer, distributor or dealer, with a written warranty in the prescribed form, and (b) that the article of food while in his possession was properly stored and that he sold it in the same state as he purchased. by virtue of this section she was not liable to be prosecuted.

The important point being that where food article was sold by the distributor in sealed condition in which he had purchased it from manufacturer under a bill, he could not be prosecuted for such food articles if reported adulterated. The learned counsel for the petitioner has relied upon a decision of the SC in **P.Unnikrishnan v Food Inspector, Palghat municipality (AIR 1995 SC 1983)** and the decision of the Punjab high Court in **M/s Ram Dhan Rikhi Ram v State of Punjab (2001 (2) FAC 306 )**, where it was held that if the accused sold the article in the same form and manner and condition in which it was purchased by him, then he is entitled to be discharged. In view of the law laid down by the SC and the Punjab HC, the accused who have produced the bill to show that he purchased the food article from the manufacturer and sold it in the same condition was made not liable to be prosecuted and thus, the prosecution against her was quashed.

16. **Satya Narayan Agarwal v State of Assam (2007 FAJ 169):** the appellant was found guilty of offences punishable u/s 7 read with section 16(1) of PFA ACT, 1954, as the sample of chilli powder collected from him was found to be adulterated. He was sentenced to imprisonment for 6 months and to pay a fine of rs. 1,000 by the trial court. An appeal before the sessions judge and the learned single judge was dismissed. The counsel for appellant said that it is a case of misbranding and thus, minimum sentence is to be imposed. This contention was not accepted by the HC, as it said that it is not a case of

misbranding. It enhanced the fine to Rs. 5,000 and then permitted the appellant to move the state govt. u/s 433 of Cr.P.C.

17. **M.C Charlee v State by Food inspector (2007 FAJ 372):** the petitioner is an accused for an offence punishable u/s 7(i) and section 16(1)(a)(i) read with section 2(ia) and (m) of PFA Act, 1954. Section 7(i) says that no person shall himself or by any person on his behalf manufacture for sale, or store, sell or distribute any adulterated food. section 16(1)(a)(i) deals with penalties subject to the provisions as sub section (1A), if any person whether by himself or by any other person on his behalf imports into India, or manufactures for sale, or stores, sells or distributes any article of food which is adulterated within the meaning of sub clause (m) of clause (ia) of section 2 or misbranded within the meaning of clause (ix) of that section or the sale of which is prohibited under any provision of this act or any rule made thereunder or by an order of the Food (Health) Authority. the learned counsel for the petitioner submits that as per section 13(2) of the PFA Act, 1954, the petitioner has the inherent right to send the second sample to the CFL for analysis within a period of 10 days from the date of receipt of the report of the public analyst, whereas in this case the sample was taken on 7.1.2000 and the report was received on 27.1.2000. In the meantime the complaint was lodged on 3.4.2002 and notice given on 16.5.2002. A report has been received from the CFL to the effect that the sample is unfit for analysis and the counsel for petitioner pleads that under such circumstances the valid right of petitioner is defeated. For this point he relied on judgments of *Suresh V The State (2005 (1) C.T.C 645)* and *M. Chinnasamy and others v R. Satyanarayanan (2002 (1) LW (Crl.) 201)*. in view of the above said reasons the proceedings have been quashed and the petition allowed.

18. **Neel Kamal Narendra Mohan v State of Haryana (2007 FAJ 378):** the petitioner violated the provisions of rule 32 of the PFA Rules as the sweetened carbonated water was not labelled and the sample contained saccharine sodium. Rule 32 says that every pre packaged food is to carry a label. He was convicted by the chief Judicial Magistrate u/s 16(1)(a) and was sentenced to undergo simple imprisonment for one year and to pay a fine of Rs. 1,000.

The petitioner challenged this conviction by filing the appeal which was disposed by the additional sessions judge by maintaining the conviction and reducing the imprisonment to 9 months. The sample of the carbonated water was taken on 13.4.2002 and thereafter the petitioner faced agony of trial for another nine months. The petitioner was taken into custody on 6.7.2006 when the appeal was dismissed. The only fault committed was that the petitioner had not put labels on the bottles which contained sweetened carbonated water and accordingly, the ingredients were not made public. Though the act only provides for imprisonment of 6 months the petitioner is in the custody for the last more than two years, thus it would be appropriate to reduce the sentence of the petitioner to that already undergone by him. The counsel relied on judgments in *Sher Singh v State of U.T Chandigarh (2003 (2) RCR (Crl.) 826)* and *Sat Pal v State of Haryana (1999 (1) FAC 286)*. In view of the above, the present petition was disposed of by reducing the sentence of imprisonments from 9 months to the one already undergone by the petitioner.

19. **State of Punjab v Paramjit Singh and Ors ( 2008 FAJ 461 (P&H) Section 10(4) and 10(4)(a) –** Five trucks loaded with Gur/Jaggery were intercepted and the samples from each truck were found to be adulterated. The food inspectors and local health Authority moved an application before the judicial magistrate for disposing the recovered food items in accordance with law. Magistrate accepted application directing destruction of jiggery of all five trucks. The accused moved an application seeking release of the trucks , claiming that the same was not meant for human consumption and it was the raw material of the cattle feed and the sessions judge who accepted their application directed the release of the commodity.

The petitioner filed a Revision saying that Gur jaggery very much fell within the definition of food and the mere fact that the Public Analyst did not mention in the report that the item was unfit for human consumption would not affect the case of State. The proceeding u/s 10(4) and 10(4A) are clearly distinguishable from the procedure provided by section 11(4) and (5) of the act as the same applies when sections 10(4) and 10(4A) of the act do not apply and in case of perishable adulterated items the provisions of sections 10(4) and (4A) are applicable. The High Court in the said order observed that the divisional court had been wrong in observing that the report of public analyst does not mention that the jaggery was unfit for human consumption. If this jaggery was released it would play havoc to public health. The court practically gave a license to the accused to recycle and recirculate the adulterated food to public.

The judgement was very clear in observing that "It is a matter of common knowledge that jaggery is generally for human consumption and it even falls within the definition of food. In order to be food for the purposes of the Act, an article need not be 'fit' for human consumption. It need not be described or exhibited as intended for human consumption. It may even be otherwise described or exhibited. It is enough if it is generally or commonly used for human consumption or used in the preparation of human food. Where an article is generally or commonly not used for human consumption or in the preparation of human food but for some other purpose, notwithstanding that it may be capable of being used, on rare occasions, for human consumption or in the preparation of human food, it may be said, depending on the facts and circumstances of the case, that it is "not food". In such a case the question whether it is intended for human consumption or in the preparation of human food, may become material. **But where the article is one which is generally or commonly used for human consumption, there can be no question but the article is 'food'.**

20. **2006 FAJ 5) Magma (India) & Anr. v Union of India & Ors.** - Food samples were drawn by the commissioner of Customs from import consignments. The samples were sent to the Central Food Laboratory which in its report stated that they were adulterated. An application by petition was made for sending the second sample to the Central food Laboratory for retesting reanalysis. This request was turned down by CFL on ground that there was no provision under PFA Act for retesting the same sample. Counsel for the CFL have not been able to cite any provision of law which prohibits the carrying out of a second testing of a food sample especially where the authority who has forwarded the first sample requests to do so. Thus, petition allowed.
21. **Rajiv Kumar Gupta & ors. V State of Maharashtra (2006 FAJ 135)** The petitioners here are the directors of a company manufacturing Rajnigandha Pan masala. They were prosecuted along with company u/s 272, 273, 420 IPC and section 2(a)(h)(i) and (v) of PFA Act. The seized samples contained a banned substance, magnesium carbonate. Writ petition filed by the petitioners for quashment of FIR and proceedings under the IPC sections mentioned above. The court held that detailed investigation was needed prima facie for averments in complaint. As it was not correct for the police to proceed only in reference to the breaches of the provisions of PFA Act and not u/s 420 IPC, restricted prayer as sought for could not be granted at this stage. Positive assertion in newspapers that the pan masala did not contain magnesium carbonate was not without knowledge or permission of the directors. Proper investigation was in interest of public. There is no bar under PFA act and rules that guilty person could not be prosecuted for offence under IPC on same averments. Hence, no case for quashment and setting aside of FIR.
22. **State of Karnataka v Shetty Ice Cream Company, Kulai, Manglore and Others (2006 FAJ 235)** The accused were charged for offences u/s 7(1) read with 2(ia),(m), 16(1)(a)(i) of PFA Act, 1954. A3 was selling ice cream in a public place. The ice cream was manufactured by company of A1 and A2. Ice cream found to be adulterated and not in conformity with the prescribed standards.

But the evidence adduced by the prosecution did not prove that the ice cream was manufactured by company of A1 and A2, hence, their acquittal was held to be proper. Also the court observed that where people belonging to economically lower sections of society are consumers and aware of the fact that the ice cream sold is not of best quality but still choose to purchase it to relish it within their financial capacity, then the local manufacturers selling ice cream cannot be held guilty of an offence punishable under the act.

23. **Pepsi Case:** In 1998, a cockroach was found floating in the bottle of Pepsi. A complaint was filed against M/S Pepsi Food Ltd and a distributor and his retail outlet. They were guilty u/s 2(ia)(f) as the article was insect infested making it unfit for human consumption. The applicant approached the Delhi Consumer Commission after his complaint was dismissed by the District Forum, saying that the bill produced by him nowhere specifically mentions that the drink was Pepsi and it also did not carry the name of the person who had bought it. It further found fault in the complaint saying that the bill was of Rs. 80 and a Pepsi bottle cannot cost this much. The Commission differed from this view and said that the forum had failed to appreciate the fact that 4 bottles were purchased by the applicant. After the commission's judgment the applicant was awarded compensation of Rs. 1,000 as the petitioners were directed to pay the damages to him for the mental agony and shock that he had suffered.
24. **Cadbury India Ltd. Vs Niranjan :** the chocolate when opened was found to be infested with worms and fungus. The complainant approached the district forum for compensation. The petitioner contended that they always comply with the norms provided by the various legislations such as PFA act, Standards of Weights and Measures act etc. and if it is not kept in a cool place by the retailers or the shop keepers then the petitioner should not be blamed.

Further it was submitted that the chocolate was sent for analysis after the lapse of four months and till that it was in custody of the complainant only. Thus, the petitioner should not be held liable. It is for the manufacturer to see that unauthorized people do not carry out the business of goods of perishable nature. On the contrary, the petitioner had given an undertaking before the district forum that it would see to it that the goods are stored under hygienic conditions by providing visi- coolers and other storage devices to the retail outlets. It was pointed that maintenance of hygienic conditions is mainly the duty of the local health authority which issues license to the retailers. The counsel for the petitioner also said that due to high fat content in the chocolate it is not conducive to fungal growth and such occurrence can only be associated with bad storage conditions which are largely prevalent at small retail shops. To prevent this, the petitioner had been asked to intimate the consumers through their advertisements that they should not purchase such goods from the retail shops that doesn't have visi cooler or fridge. The petitioner was also asked to deposit Rs. 10,000 as directed by the state commission along with Rs. 5000 as costs to the respondents for coming here, with the District Forum.

25. **Ramesh Chandra Nair and State of Rajasthan (2008 FAJ 422) - Section 17 on Nomination** – Aerated water drink bottle sample (manufactured by M/s Ajmer Bottling Company Pvt Ltd) was found to be adulterated. Prosecution of the Manufacturing company, person from whom sample was drawn and petitioners who were promoters of the manufacturing company. Petition was for quashing proceedings.

The Chief medical officer of Ajmer, got the list of promoters of the company from the commercial taxes Officer, Ajmer and on finding the sample adulterated and launched prosecution against all the promoters which was heard by the Trial Court and framed the charges against the promoters. Thereafter the said order was challenged before the revisional court by the petitioners but was dismissed by the ASJ, District Ajmer. The submission was that CMO had not looked into the documents filed along with challan revealing that the accused petitioners had no concern with either manufacturing or for conducting the business of the

company. The learned judge in the final order observed that “on perusal of the complaint it is revealed that there is no assertion to the effect that the petitioners were in charge of and responsible to the company for the conduct of business..... Merely, by making avertainment in the title of the complaint, a presumption can not be raised that they are automatically in charge of and responsible for the conduct of the business.

In a similar case of *Sharda Prasad v State of Bihar*, it has been held by the Apex Court that where the allegations made in the complaint or in the charge sheet do not constitute any offence, the High Court is competent to exercise its inherent jurisdiction so as to quash the proceedings before the learned Magistrate.

26. **2008 FAJ 440 (P&H) – Criminal procedure Code 1973- Section 275- Rajinder Kumar v State of Haryana** on evidence in Prosecution for offence of sample chilli powder found adulterated.

This revision petition was directed against a judgement of 2007 rendered by Court of ASJ, Rohtak, vide which it dismissed the appeal of the revision petitioner against the judgement of conviction in 2005 and the order of sentence passed by CJM, convicting him for the offence punishable under Section 16 (1) (a) (i) of the PFA Act and sentenced him to undergo simple imprisonment for one year and to pay fine of Rs 1000 and in default of payment of the same, to undergo further simple imprisonment for a period of two months.

The counsel for the revised petitioner contended that the Court of CJM Rohtak, acted against the provisions of Section 275 of the Code of Criminal procedure, by not appending his signatures on the deposition of the Food inspector, recorded before framing of the charge, as also after framing the charge. A plain reading of the provision reveals that the evidence so taken down by the concerned Magistrate shall be signed by the magistrate and shall form part of the record. Only after the evidence, so taken down, by the Magistrate if signed by him, that it can form part of the evidence and not otherwise. It was the food inspector who was took sample of chilly powder, it was he who allegedly divided the sample into 3 parts, and put the same into glass bottles, and sent one portion of the sample to the Public Analyst, and launched prosecution against the accused. In the absence of his legally admissible evidence, on record, all these facts remain unproved.

**References:**

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2. Commentaries on Food Safety & Standards Act 2006 alongwith Prevention of Food Adulteration Act 1954 2<sup>nd</sup> edition – Law Publishers (India) Pvt. Ltd.



## **Procedure for launching prosecution (Section 42)**

- (1) The Food Safety Officer shall be responsible for inspection of food business, drawing samples and sending them to Food Analyst for analysis.
- (2) The Food Analyst after receiving the sample from the Food safety officer shall analyze the sample and send the analysis report mentioning method of sampling and analysis within **fourteen days to Designated officer with a copy to commissioner of Food Safety.**
- (3) The Designated officer after scrutiny of the report of the Food Analyst shall decide as to whether the contravention is punishable with imprisonment or fine only and in case of contravention punishable with imprisonment, he shall **send his recommendations within fourteen days to the Commissioner of Food Safety for sanctioning prosecution.**
- (4) The Commissioner of Food Safety shall, if he so deems fit, decide, within the period prescribed by the Central Government, as per the gravity of offence, whether the matter be referred to,- (a) court of ordinary jurisdiction in case of offences punishable with imprisonment for a term up to three years; or (b) a Special Court in case of offences punishable with imprisonment for a term exceeding three years where such Special Court is established and in case no Special Court is established, such cases shall be tried by a court of ordinary jurisdiction.
- (5) The Commissioner of Food Safety shall communicate his decision to the Designated Officer and the concerned Food Safety Officer who shall launch prosecution before courts of ordinary jurisdiction or Special Court, as the case may be; and such communication shall also be sent to the purchaser if the sample was taken under section 40.

### **Purchaser may have food analysed (Section 40)**

- (1) Purchaser of any article of food other than a Food Safety Officer shall have the right to analyze the food by a Food Analyst on payment of fees and receiving a report of this analysis from the analyst within a specified period as may be specified in the regulation.
- (2) In that case the purchaser shall inform the food business operator at the time of purchase of his intention to have such article analysed and if the report of the Food Analyst shows that the article of food is not in compliance with the Act or the rules or regulations made there under, the purchaser shall be entitled to get refund of the fees paid by him under this section.
- (3) In case the Food Analyst finds the sample in contraventions of the provisions of this Act and rules and regulations made there under, the Food Analyst shall forward the report to the Designated Officer to follow the procedure laid down in section 42 for prosecution.

#### **a. Offences and Penalties (section 48-67)**

##### **Only fine**

- Not confirming to the law – up to Rs. 5 lakhs (section 50)
- Sub standard food - up to Rs. 5 lakhs
- Misbranded - up to Rs. 3 lakhs
- Misleading ad - up to Rs. 10 lakhs
- Extraneous matter - up to Rs. 1 lakh
- Section 55: Fails to comply with the standards - Rs. 2 lakhs
- Unhygienic and unsanitary condition - Rs. 1 lakh
- Sale of adulterant – non injurious – 2 lakhs
- Sale of adulterant – injurious – 10 lakhs
- Imported food – over and above the regulation, restrictions and prohibitions under the Foreign Trade Act, 1992, all imported food products/ ingredients

shall be liable to prosecution and penalty as provided above for domestic products.

- For knowingly contravening the Prohibition Order shall be punishable with a fine up to a maximum of 3 lakh rupees.
- Imprisonment + fine
- Unsafe – non injurious – imprisonment up to 6 months and fine up to 1 lakh
- Unsafe – non grievous injury – imprisonment up to 1 year - Fine Rs.3 lakh and + compensation to the consumer up to 1 lakh
- Unsafe – grievous injury – imprisonment up to 6 years - Fine Rs.5 lakhs + compensation - up to 3 lakh
- Unsafe – leading to death – imprisonment not less than 7 years up to life – fine not less than Rs. 10 lakhs + compensation not less than 5 lakhs
- For knowingly contravening an emergency prohibition order shall be punishable with imprisonment for a term extended up to 2 years and extendable up to 2 lakhs of rupees

**Note: All the above provisions will be equally applicable for imported products**

Note: Misleading ad is equated with the most severe offence of selling adulterant or injury causing death and fine suggested of Rs. 10 lakhs. Misleading ad cannot be more serious an offence than selling unsafe, unhygienic food.

#### **Defences which may or may not be allowed (Section 80)**

##### **(A) Defence relating to publication of advertisements-**

- (1) In any proceeding for an offence under this Act in relation to the publication of an advertisement, it is a defence for a person to prove that the person carried on the business of publishing or arranging for the publication of advertisements and that the person published or arranged for the publication of advertisement in question to the ordinary course of that business.
- (2) Clause (1) does not apply if the person- (a) reasonably have **known that the publication of the advertisement was an offence**; or (b) had previously been **informed in writing by the relevant authority that publication of such an advertisement would constitute an offence**; or (c) if the food business operator or is otherwise engaged in the conduct of a food business for which the advertisements concerned were published.

##### **(B) Defence of due diligence-**

- (1) In any proceedings for an offence, it is a defence if it is proved that the person took all reasonable precautions and exercised all due diligence to prevent the commission of the offence by such person or by another person under the person's control.
- (2) Without limiting the ways in which a person may satisfy the requirements of clause (1) a person satisfies those requirements if it is proved-
  - (a) That the commission of the offence was due to-
    - (i) An act or default of another person; or
    - (ii) Reliance on information supplied by another person; and
  - (b) (i) the person carried out all such checks of the food concerned
  - (c) That the person did not import the food into the jurisdiction from another country; and
  - (d) In the case of an offence involving the sale of food, that-

- (i) The person sold the food in the same condition as and when the person purchased it; or
  - (ii) The person sold the food in a different condition but that the difference did not result in any contravention of this Act and
  - (e) That the person did not know and had no reason to suspect at the time of commission of the alleged offence that the person's act or omission would constitute an offence under the relevant section.
- (3) Another person in sub-clause (a) of clause (2), does not include a person who is-
- (a) An employee or agent of the defendant; or
  - (b) In the case of a defendant which is a company, a director, employee or the agent of that company.
- (4) Without limiting the ways in which a person may satisfy the requirements of clause (1) and item (i) of sub-clause (b) of clause (2), a person may satisfy those requirements by proving that-
- (a) In the case of an offence relating to a food safety programme as required to be prepared in accordance with the regulations, or
  - (b) The person complied with a scheme (for example, a quality assurance programme or an industry code of practice) that was designed and documented to manage food safety hazards based on the national or international standards, codes or guidelines designed for that purpose
- (C) **Defence in respect of handling food-** In proceedings for an offence under section 56, it is a defence if it is proved that the person destroyed or disposed of the food immediately after finding the food was handled in the manner that was likely to render it unsafe.
- (D) **Defence of mistaken and reasonable belief nit available-** In any proceedings for an offence under the provisions of this Act, it is no defence that that the defendant had a mistaken but reasonable belief as to the facts that constituted the offence.
- (E) **Defence of significance of the nature, substance or quality of food-** It shall be no defence in prosecution pertaining to the sale of any unsafe or misbranded article of food to allege merely that the food business operator was ignorant of the nature, substance or quality of the food sold by him or that the purchaser having purchased any article for analysis was not prejudiced by the sale.

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